



**Scientific Committee on Health, Environmental and Emerging Risks
SCHEER**

**Opinion on
Biological effects of UV-C radiation relevant to health
with particular reference to UV-C lamps**



The SCHEER adopted this Opinion at its plenary meeting on 2 February 2017

ABSTRACT

Following a request from the European Commission, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) reviewed recent evidence to assess health risks associated with UV-C radiation coming from lamps.

At the time of writing the Opinion, few studies were available on exposure to humans under normal conditions of use and there was insufficient data on long-term exposure to UV-C from lamps.

These studies report adverse effects to the eye and skin in humans, mainly from accidental acute exposure to high levels of UV radiation from UV-C lamps. Mechanistic studies suggest that there are wavelength-dependent exposure thresholds for UV-C regarding acute adverse effects to human eyes and skin, except for erythema. In contrast, the quantitative estimation of thresholds for long-term health effects could not be derived from currently available data. Due to the mode of action and induced DNA damage similarly to UV-B, UV-C is considered to be carcinogenic to humans. However, currently available data is insufficient for making a quantitative cancer risk assessment of exposure from UV-C lamps.

UV-C lamps emitting radiation at wavelengths shorter than 240 nm may produce ozone and need additional risk assessment concerning the exposure of the general public and workers from UV-C lamps to the associated production of ozone.

Keywords: UV radiation, UV-C lamps, ozone, risk assessment, cancer, skin, eye.

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All Declarations of Working Group members and supporting experts are available on the following webpage:

http://ec.europa.eu/health/scientific_committees/emerging/members_wg/index_en.htm

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SCHEER

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SUMMARY

Introduction

The European Commission requested the Scientific Committee to review recent evidence in order to better assess risks associated with UV-C radiation from lamps.

The part of the ultraviolet radiation (UVR) emitted in the wavelength range 280 nm–100 nm is called UV-C; this radiation is used in a growing number of applications, which include disinfection of water and air, food-industry processing, and air-conditioning. Although most appliances are sealed systems there is now increasing use of devices where consumers may be directly exposed to UV-C radiation. There have been several reports of adverse dermal or ocular effects from accidental exposure or through misuse of such appliances.

Legal background

The placing on the market of UV-C lamps is regulated by Directive 2014/35/EC¹, so-called Low Voltage Directive (LDV), on electrical equipment designed for use in defined voltage ranges². The overarching Directive 2001/95/EC³ on General Product Safety applies to UV-C lamps whenever the LVD is not applicable. It requires that products intended for consumers or likely to be used by them, including in the context of a service, must provide reasonably expectable safety throughout the lifetime of the product. Member States authorities responsible for the enforcement of these Directives have an obligation to carry out controls to ensure compliance by relevant economic operators.

European harmonised standards related to UV-C lamps are voluntary but, if published in the Official Journal of the European Union (OJEU), they provide presumption of conformity with the related essential requirements on safety in the relevant EU legislation. However, the applicable product standards do not yet fully address some specific safety risks of UV-C lamps. For example, standard EN 60335-2-109 for UV-C radiation water treatment appliances, which includes pond filters, excludes repair sets and replacement lamps from its scope.

To protect workers from acute health effects, limits of the exposure to UV-C radiation from devices are specified in Table 1.1 of Directive 2006/25/EC for artificial sources of non-coherent optical radiation.

Table 1.1 of Directive 2006/25/EC for artificial sources of non-coherent optical radiation

Wavelength, nm	Exposure Limit Value, ELV	Units	Part of the body	Hazard
180-400 (UVA, UVB and UVC)	H _{eff} = 30 Daily value 8 hours	[J m ⁻²]	eye cornea conjunctiva lens skin	photokeratitis conjunctivitis cataractogenesis erythema

¹Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits, OJ L 96, 29.03.2014, p. 357.

²Voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current

³Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety, OJ L 11, 15.01.2002

				elastosis skin cancer
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In particular for the UV-C range, the Exposure Limit Value (ELV) for the effective radiant exposure is 30 J/m².

As an unintentional side-effect or intentionally in combination with a dedicated ozone generator, UV-C lamps emitting wavelengths shorter than 240 nm may generate ozone which above certain limits may cause adverse health effects. Limits of ambient ozone levels are defined in the Directive 2008/50/EC⁴ to avoid, prevent or reduce harmful effects on human health and the environment. The Directive recommends not using ozone generators, which are air cleaners that intentionally produce ozone at home.

Exposure

There is a wide variety of UV-C lamps, working with different technologies and generating different irradiance levels and wavelengths. For most applications, the lamp is surrounded by an enclosure that prevents UVR exposure of the user in normal operation. For other applications, the UVR may be directly emitted to the environment. Most of the recently published data on exposure from UV-C lamps comes from reports on accidental exposure.

Human health effects

There are very few studies that have investigated potential adverse health effects in humans from sole exposure to artificial UV-C radiation.

Most studies of adverse effects are case reports that report dermal or ocular effects from accidental exposure to UV-C radiation from lamps through, for example, inappropriately replaced bulbs or accidental prolonged exposure that is much higher than the safe occupational exposure limit.

Depending on exposure characteristics and exposure patterns, UV-C radiation from lamps may cause adverse health effects to the eye and skin, particularly in photosensitive persons.

Since the skin is composed of different layers of varying depths with different physical and chemical properties, UVR exerts different biological effects on different kinds of cells in the skin. The minimal erythema dose (MED) is highly dependent on skin type. Dose-response curves of the induction of minimal erythema show that human skin is more sensitive to 254 nm (UV-C) than to 300 nm (UV-B) radiation. It has not yet clearly been demonstrated to what extent UV-C-induced erythema may be related to chronic and stochastic effects in the skin or/and to skin cancer development in humans.

The studies of accidental overexposure of the eye generally report that ocular symptoms usually subside within about a week. However, in severe exposure cases, ocular problems may remain for a much longer period. In contrast, most of the effects on the skin have been reported as being transient.

Cumulative exposures to intense UV radiation (which includes UV-C) during welding can lead to cataract formation, retinal damage and an increased risk of melanoma, but detailed discussion is beyond the scope of this Opinion.

⁴Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe, OJ L 152, 11.06.2008

Exposure to ozone such as unintentionally produced by the UV-C lamps emitting at wave lengths shorter than 240 nm may present an additional risk of a variety of symptoms and diseases associated with the respiratory tract, particularly in ozone-sensitive and vulnerable individuals.

Mechanistic studies

In vitro studies and human volunteer studies have reported that UV-C radiation induces similar effects at the molecular level as UV-B; in vitro experiments have demonstrated UV-induced DNA damage peaking in the UV-C range.

It has been shown that UV-C radiation reaches to the level of the upper layers of the epidermis in intact skin, but where the epidermis was thin, UV-C exposure resulted in cyclobutane pyrimidine dimers (CPD) formation at the basal layer of the epidermis. These effects have been reported at doses below the bacteriostatic effect threshold of UV-C radiation with a wavelength of 222 nm.

Overall Conclusion

There are few studies of exposure to humans under normal conditions of use and insufficient data on long-term exposure to UV-C from lamps⁵.

Adverse effects to the eye and skin in humans are reported mainly from accidental acute exposure to high levels of UV radiation from UV-C lamps. Although mechanistic studies suggest that there are wavelength-dependent exposure thresholds for UV-C regarding acute adverse effects to human eyes and skin, except for erythema, quantitative estimation of exposure thresholds for long-term health effects could not be derived from currently available data. Due to the mode of action and induced DNA damage similarly to UV-B, UV-C is considered to be carcinogenic to humans. However, currently available data are insufficient for making a quantitative cancer risk assessment of exposure from UV-C lamps.

UV-C lamps emitting radiation at wavelengths shorter than 240 nm need additional risk assessment of the associated production of ozone in the environment.

More data are needed on the exposure of general population and workers to UV-C radiation from lamps and the generated ozone.

⁵UV exposure including UVC from welding is not discussed in this Opinion because the exposure is not comparable with that of UV-C lamps.

1 MANDATE FROM THE EU COMMISSION SERVICES

1.1 Background

Introduction

UV-C radiation is now used in a large range of applications, including for disinfection in water, air and surface treatment, in food-industry processing and in air-conditioning. In these situations, the systems are usually designed and built in such a way that UV-C radiation cannot escape (employing protective housings) and therefore there are no direct UV-C hazards for users. Servicing, maintenance and repair personnel must be instructed accordingly in the handling and use of sources that emit UV-C radiation, and the employer is required to reduce risks from the UV-C source through preventative measures related to work equipment and procedures, as well as the provision of personal protective equipment (Directive 2006/25/EC).

Another requirement is that the UV-C radiation source automatically shuts down when the protective housing is opened during operation.

Market surveillance authorities from Member States have observed that there is increasing use of UV-C radiation in products for consumers and in appliances with which consumers come into contact. For example, UV-C radiation is used in electrical pond filters, in the brush attachments of electrical vacuum cleaners, in special lamps used for local disinfection, in aquariums and for surface disinfection.

These developments have led the European Commission to request the SCENIHR (currently SCHEER) to review recent evidence in order to have a better understanding of risks associated with UV-C radiation coming from lamps. It should be noted that mercury-based lamps for lighting such as energy-saving lamps or fluorescent lamps, which unintentionally emit UV-C radiation, are out of the scope of this mandate and are thus not assessed.

Scientific background

The relevant literature indicates that UV-C radiation can be hazardous for both the human eye and human skin. The risk depends on a range of factors, for example, radiation intensity and duration (energy), which needs consideration in risk assessment.

There have been reports that electrical discharge insect control systems, used for example in the hotel and catering sector, have caused skin burns to those who have been exposed to UV-C because of fitting the wrong lamps (UV-C instead of UV-A). Consumers are also often unable to recognise the risks and may not take adequate precautions against emitted UV-C radiation.

UV-C lamps can also be sold separately, for example, with a conventional socket (TL socket, PL socket or G23 socket) up to a rated power of 55 W. It is also possible that lamps of an even high power could be sold. Moreover, the replacement lamps fit into lamp sockets for ordinary lamps, such as desk lamps and other household lamps. Consequently, inadvertent and inappropriate use of UV-C lamps cannot be excluded.

Legal & Enforcement Background

At EU level, a legal framework exists that aims to address the risks posed by UV-C lamps themselves. The placing on the market of UV-C lamps is regulated by Directive 2014/35/EU⁶ (Low Voltage Directive (LVD)) on electrical equipment designed for use in specified voltage ranges⁷. This Directive falls under the responsibility of Directorate General for Growth. Directive 2001/95/EC⁸ on General Product Safety applies to UV-C lamps whenever the LVD is not applicable (e.g. UV-C lamps outside the voltage range of LVD), requiring that products intended for consumers or likely to be used by them, including in the context of a service, must provide reasonably expectable safety throughout the lifetime of the product. The General Product Safety Directive falls under the responsibility of Directorate General for Justice. Member States' authorities responsible for the enforcement of these Directives have an obligation to carry out controls to ensure compliance by relevant economic operators.

European harmonised standards related to UV-C lamps are voluntary but, if published in the Official Journal of the European Union (OJEU), they provide presumption of conformity with the related essential requirements on safety in the relevant EU legislation. However, the applicable product standards do not yet fully address some specific safety risks of UV-C lamps. For example, standard EN 60335-2-109 for UV-C radiation water treatment appliances, which includes pond filters, excludes repair sets and replacement lamps from its scope. Pond filters are designed in such a way that no UV-C radiation can escape from them if they have been properly installed. However, repair sets and replacement lamps, which can also be operated outside the pond filter and without any screening, are also available for such appliances. The repair sets are generally ready-wired for connection and can be operated in this state without any further safety precautions.

To protect workers from acute health effects, limits of the exposure to UV-C radiation from devices are specified in Directive 2006/25/EC.

As an unintended side effect or intended in combination with a dedicated ozone generator, some UV-C lamps may also generate ozone, which above certain thresholds may cause adverse health effects. Limits of ambient ozone levels are regulated by the directive 2008/50/EC; Ozone generators, which are air cleaners that intentionally produce ozone, are not recommended for home use.

Regulations and standards

To protect humans from acute health effects, limits of the exposure to UV-C radiation from devices are set in ISO 15858 (2016). They are in compliance with the recommendation of the National Institute of Occupational Safety and Health (NIOSH,

⁶Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits, OJ L 96, 29.03.2014, p. 357.

⁷Voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current

⁸Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety, OJ L 11, 15.01.2002

1992⁹). Exposure during an 8-hour work day should not exceed 60 J/m² at 254 nm. The limit of the unweighted spectral irradiance at 254 nm is dependent on exposure time and shown in Figure 1. The recommended maximum exposure levels in ISO 15858 (2016) do not protect photosensitive persons. It needs to be noted that these limits do not account for existing UV-C sources emitting radiation at other wavelengths either.

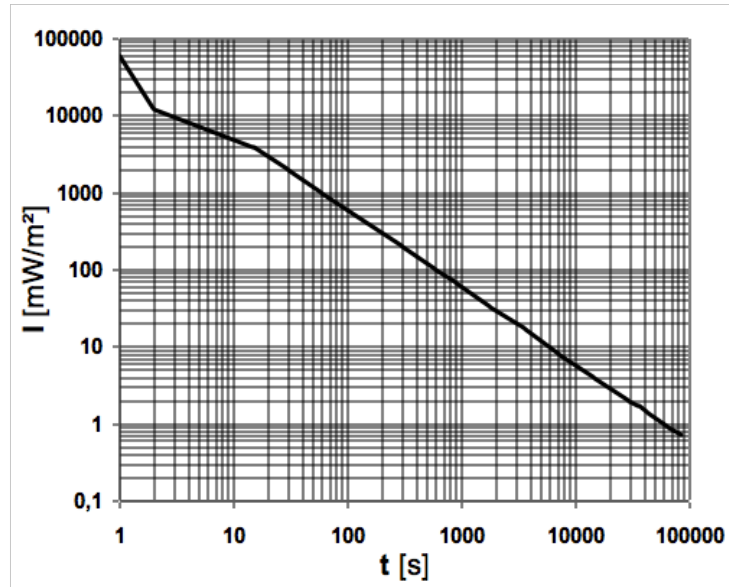


Figure 1: Recommended limits of the spectral irradiance I at 254 nm in dependence on exposure time t (ISO 15858) to reach the limit of 60 J/m² under constant continuous exposure during time.

To protect workers from acute UVR health effects based on a UVR exposure of 8 hours per day, European Directive 2006/25/EC¹⁰ limits UVR in the wavelength range 180 – 400 nm and hence also covers the relevant UV-C range including the second UV-C mercury emission line at 185 nm. The recommended protection levels of ICNIRP (2004) are also intended for workers based on an exposure of 8 hours per day, but it is mentioned that this also applies to the general population (photosensitive individuals excluded). The recommended levels for protection of skin and eyes are as follows:

$$E_{eff} = \sum E_{\lambda} S(\lambda) \cdot \Delta\lambda \leq 30 \text{ J/m}^2 \text{ (180-400 nm, spectrally weighted)}$$

where $S(\lambda)$ is spectral weighting taking into account the wavelength dependence of the health effects of UVR on eye and skin. For comparison, for UV-A the 8-hour exposure is limited to $\leq 10^4 \text{ J/m}^2$.

It should be noted that Exposure Limit Values (ELVs) are not set in the wavelength range between 100 nm and 180 nm, because in most cases the absorption of short wavelength radiation in air is considered to be sufficient to protect the skin. There are, however, optical sources of incoherent UV radiation with wavelengths shorter than 180 nm (e.g. excimer lamps) which are used so close (few centimetres) to the human skin that air absorption might be insufficient as a protective measure. Therefore, the Working Group

⁹ NIOSH: 1992: Criteria for a recommended standard: Occupational exposure to ultraviolet radiation. Publication 73-11009, Washington D.C.

¹⁰ EU 2006/25/EC (+EU 2007/30/EC+EC1137/2008+EU 2013/64/EU): European directive on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation)

Non-Ionizing Radiation (Arbeitskreis Nichtionisierende Strahlung, AKNIR) of the German-Swiss Fachverband für Strahlenschutz has proposed an extension of the existing limits to the wavelength range between 100 nm and 180 nm (Berlien *et al.*, 2016).

Limits of ambient ozone levels are defined in Directive 2008/50/EC to avoid, prevent or reduce harmful effects on human health and the environment as a whole. Ozone generators, which are air cleaners that intentionally produce ozone, are not recommended for home use. The European standard ambient air level for ozone¹¹ is 120 µg/m³, maximum daily 8 hours mean (target value entered into force on 1 January 2010); permitted exceedances each year: 25 days averaged over 3 years.

1.2 Terms of Reference

In view of the incidents¹² due to the UV-C lamps, the SCENIHR (currently SCHEER) is asked to assess the safety risks associated with the use of UV-C lamps and to provide an answer to the following questions:

1. What are the potential effects on human eyes and skin if these organs are exposed to UV-C radiation of varying wavelength, intensity and duration?
2. Is there a wavelength-dependent safety threshold with regard to UV-C intensity and/or energy (dose) that could prevent adverse health effects to the human eyes and/or skin?
3. Are there other safety aspects that should be considered together with/instead of any possible wavelength-dependent safety threshold?

¹¹<http://ec.europa.eu/environment/air/quality/standards.htm>

¹²Some Member States have indicated accidents due to UVC lamps, e.g. in Spain 2 insect killers installed in a public restaurant in a sports centre provoked an outbreak of an actinic conjunctivitis due to UVC lamps in the insect killers.

2 OPINION

The SCHEER replies to the answers of the terms of reference.

Q1. What are the potential effects on human eyes and skin if these organs are exposed to UV-C radiation of varying wavelength, intensity and duration?

Epidemiological data

There are few studies of UV-C exposure to humans from lamps under normal conditions of use; most data on both exposure and adverse health effects comes from reports on accidental misuse of UV-C lamps. UV-C radiation from lamps may cause different adverse health effects in the eyes and the skin, depending on exposure characteristics and exposure patterns. UV-C radiation can damage the superficial tissues of the eye. The studies of accidental exposure of the eye to values higher than the limits generally report that ocular symptoms usually subside within about a week. However, at high exposure, ocular problems may remain for much longer.¹³ The acute effects on skin, such as erythema, have been reported as being transient.

Mechanistic data

Information about the mode of action regarding DNA damage by UV-C radiation is well documented and is available from in vitro studies and human volunteer studies. UV-C is mainly absorbed by the horny layer of human epidermis. Histopathological and genetic investigations show alterations such as cyclobutane pyrimidine dimers (CPD) formation and gene modulations induced by UV-C. UV-C exposure was shown to result in basal CPD formation where the epidermis was thinned, i.e. in deeper skin parts than the usual horny layer. These changes have been reported to occur at a dose lower than the threshold for bactericidal effects of UV-C¹⁴.

The dose response curve for UV-C erythema in human skin is significantly less steep than for UV-B. Since the slope of the dose-response curve at UV-C wavelengths is much shallower than at UV-B wavelengths, it suggests that considerable uncertainty is possible in the estimation of the minimal erythema dose (MED) at these shorter wavelengths depending on the exact degree of erythema observed.

The mechanisms for DNA damage at molecular level from UV-C exposure are comparable to those known for UV-B. The mode of action of UV-C radiation is similar to UV-B radiation and therefore UV-C is capable of inducing skin cancer. Due to the mode of action and induced DNA damage similarly to UV-B, UV-C is considered to be carcinogenic to humans. However, currently available data does not allow quantitative cancer risk assessment of exposure from UV-C lamps.

Q2. Is there a wavelength-dependent safety threshold with regard to UV-C intensity and/or energy (dose) that could prevent adverse health effects to human eyes and/or skin?

Adverse effects to the eye and skin in humans are reported mainly from accidental exposure to UV-C radiation from UV-C lamps. There are wavelength-dependent exposure

¹³Although cumulative exposures to acute intense UV radiation (including some UV-C) during welding can lead to cataract formation, exposure to UVR from welding is outside the scope of the Opinion.

¹⁴For examples of various germicidal doses look at <http://www.americanairandwater.com/uv-facts/uv-dosage.htm> .

thresholds as reported in the Directive in the UV-C range for acute adverse effects to human eyes and skin. Induced DNA damage is similar to UV-B, therefore UV-C is considered to be carcinogenic to humans. Due to the mode of action, no limit value of either irradiance or dose (irradiance multiplied by time of exposure) exists to ensure protection from long-term effects to eyes and skin.

Q3. Are there other safety aspects that should be considered together with/ instead of any possible wavelength-dependent safety threshold?

Ozone may be produced from UV-C lamps emitting UV-C at wavelengths shorter than 240 nm. Exposure to ozone, above threshold levels, presents a risk of a variety of symptoms and diseases associated with the respiratory tract, particularly in sensitive individuals.

UV-C lamps capable of producing ozone in the environment need critical assessment.¹⁵

3 MINORITY OPINION

No minority Opinion.

¹⁵Other unintended side-effects, such as safety-relevant material degradation, are outside the scope of this Opinion.

4 DATA AND METHODOLOGY

The general approach by the Scientific Committee to health risk assessment is to evaluate all available evidence from human and mechanistic studies regarding effects to exposure to the agent of concern and then to weigh together this evidence across the relevant areas to generate a combined assessment. The overall quality of the studies is taken into account, as well as the relevance of the studies for the issue in question.

This combined assessment addresses the question whether there is a causal relationship between exposure to UV-C lamp radiation and adverse health effects. The answer to this question is not necessarily a definitive 'yes' or 'no', but may express the existing evidence for potential hazards.

In this current Opinion, the health risks associated with the exposure to radiation from UV-C lamps have been assessed by reviewing the literature on epidemiological studies, experimental studies in humans, experimental studies in animals and mechanistic in vitro studies. Information has primarily been obtained from papers and reports published in international peer reviewed scientific journals in the English language. Additional sources of information have also been considered, including web-based information retrieval and other documents in the public domain e.g. from governmental bodies and authorities, non-governmental organisations (NGOs) and safety data sheets (SDS) from industry.

The literature review carried out is explained in Annex I, including the search key words used.

Throughout the Opinion, consistency and adherence to the International System of Units (SI) regarding the use of terms and units has been used.

5 DEFINITION AND USE OF UV-C DEVICES

5.1 Definition of UVR and physical properties

Ultraviolet radiation (UVR) is electromagnetic radiation characterised by its spectrum that is the distribution of radiation intensity over its wavelength (or frequency). UVR is within a wavelength range of 400 nm to 100 nm (respectively with frequency between 750 THz and 3 PHz).

Table 1: Definition of different spectral regions of electromagnetic radiation¹⁶

Region	Wavelength (nanometers, (nm))	Frequency (Hz)
Radio waves	10^{13} - 10^9	3×10^4 - 3×10^{11}
Microwaves	10^9 - 10^6	3×10^8 - 3×10^{11}
Infrared radiation	10^6 - 780	3×10^{11} - 3.8×10^{14}
Visible light	780 - 400	3.8×10^{14} - 7.5×10^{14}
Ultraviolet radiation	400 - 100	7.5×10^{14} - 3×10^{15}
X-rays	< 10	> 3×10^{16}

Wavelengths of UVR are shorter than those of visible light but longer than X-rays, i.e. UVR wavelengths are in the region 400-100 nm (Table 1). UVR is found in sunlight and can be produced by electric arcs, sunbeds and some technical devices such as water and air disinfectors. To account for different physical and biological effects, the UVR wavelength range is subdivided into three main ranges A, B and C. The following ISO-21348 definitions are used in this Opinion:

UV-A (400 nm – 315 nm)

UV-B (315 nm – 280 nm)

UV-C (280 nm – 100 nm)

The UV-C range is frequently subdivided into:

far UV (FUV) (280 nm – 200 nm),

vacuum UV (VUV) (200 nm – 100 nm)

Sunlight is absorbed as it propagates through the earth's atmosphere. As a result, radiation with wavelengths below 280 nm (UV-C) is filtered out by the stratospheric ozone layer and the UV radiation that reaches the earth's surface is largely composed of UV-A and UV-B. 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 the day; atmospheric ozone and cloudiness¹⁷.

¹⁶There are also other definitions for wavelength ranges.

¹⁷http://earthobservatory.nasa.gov/Features/UVB/uvb_radiation3.php,
http://www.who.int/uv/uv_and_health/en/

5.2 UV-C lamps technology

5.2.1 Mercury-containing lamps

The lamps of this technology are called *mercury* or *amalgam lamps*, because they contain tiny solid quantities of either pure mercury or an amalgam, i.e., an alloy of mercury with another element, typically indium and gallium (although bismuth may also be used). The aim of this additive is to control mercury vapour pressure. Together with mercury vapour, a starter gas, usually argon, is contained in the lamp. There are two categories of lamps in this technology, based on the pressure at which mercury vapour is kept:

- low-pressure lamps, which work with approximately 1 Pa, and
- medium- or high-pressure lamps, for which the pressure is higher than 100 kPa.

The low-pressure mercury lamps generate UV radiation in a narrower spectrum (with peaks at 185 nm and 254 nm, the two mercury resonance lines) compared to the high-pressure lamps, which are also called high intensity discharge (HID) lamps and generate high levels of UV radiation in a broad-spectral range.

Low-pressure mercury lamps used for UV-C generation are similar to fluorescent lamps, which are also low-pressure mercury discharge lamps. Common ballasts and pin types for UV and fluorescent lamps permit the use of the same fixtures. Although this may be very convenient in many cases, it may comprise a hazard in others, especially when replacing a lamp with the wrong type. The main difference between mercury/amalgam and fluorescent lamps is their envelope coating. Their operation is common with the ballast providing the necessary voltage across the electrodes of the lamp to initiate a current, which heats up mercury vapour, thus stimulating electronic transitions that result in emission in the UV and visible spectrum. However, in the fluorescent lamps the glass wall is coated with phosphors which absorb UV radiation and re-emit radiation in the range of visible light.

The phosphor coating is missing in the UV-C lamps: the glass used, typically quartz, is transparent to all UV wavelengths and permits the radiation of the two mercury peaks at UV-C to be emitted. However, it is possible to use another type of glass, i.e. soft glass (sodium-barium glass), which absorbs the 185 nm peak and transmits only the 254 nm radiation peak. The UV-C radiation near 185 nm can produce ozone; therefore, it is also quite common to categorise low-pressure mercury lamps with this criterion into:

- ozone-free lamps, with a peak wavelength of 254 nm (high efficiency) only, and
- ozone-generating lamps, with a peak wavelength at 185 nm (low efficiency),

However, there are also ozone generators used in conjunction with UV-C lamps¹⁸.

The most common type of mercury lamp is a hot cathode lamp, although lamps with cold cathodes also exist. The cathodes are usually coated with electron emissive material which erodes when the lamp is first used and continues to evaporate during lamp use. The lifetime of a hot cathode lamp is determined by the rate of loss of this electron-emissive coating. The lamp reaches the end of its lifetime when the coating is completely removed from at least one of the electrodes, so that a current cannot be established.

¹⁸ http://www.ozonegenerator.com/ozone_generators/ozone_generators.php

5.2.2 Excimer technology

UV-C lamps operating with the excimer technology are mercury-free. The word excimer originates from the expression 'excited dimer', which is a short-lived dimeric or heterodimeric molecule formed from two species, at least one of which has a completely filled electron valence shell - for example, noble gases. In this case, formation of molecules is possible only if the noble gas atom is in an excited state. Excimers are often diatomic and are composed of two atoms or molecules that would not bond if both were in the ground state. The lifetime of an excimer is very short, in the order of nanoseconds. Such excimers can form in a dielectric barrier discharge, i.e., an electrical discharge between two electrodes separated by an insulating dielectric barrier. Such a discharge can be achieved with high AC voltage electric fields, ranging from lower RF to microwave frequencies. The dielectric barrier can be formed, for example, by a quartz glass body filled with xenon (Xe) gas, giving rise to Xe₂ excimers. The electrodes are placed on the surface of the glass body to prevent short-circuiting from the plasma gas created.

In UV-C lamps, the excimers produced are heterodimeric (exciplex technology), depending on the type of rare gas and halogen used inside the dielectric barrier. For example, the KrCl* excimer lamps radiate at 222 nm and XeBr* emit at 282 nm. Excimer lamps are 'instant-on' (there is no need to warm up) but have low efficiency.

Lasers are another light source based on the exciplex technology at the UV-C spectrum, which, like the ArF*, emit a wavelength of 193 nm and a KrF* at 248 nm. They are used in high-resolution photolithography for producing semiconductor integrated circuits, industrial micromachining, and for eye surgery and scientific research.

5.2.3 UV-C Light emitting diodes (UV-C LEDs)

A light-emitting diode (LED) is a compact light source consisting of compound semiconductor materials like gallium arsenide (GaAs), gallium phosphide (GaP), indium phosphide (InP) and aluminum nitride (AlN), which also emit in the UV part of the electromagnetic spectrum. Doping can shift the emitted spectral lines into the UV-C region. For instance, AlGaIn LED lamps emit in the wavelength range of 247 – 280 nm; AlBN LED lamps emit at 214 nm.

UV-C-LEDs are operated with low DC voltages. They are environmentally friendly, but they are not yet as highly effective as mercury lamps.

5.2.4 Pulsed UV lamps

Pulsed UV lamps may be subtypes of flashtubes (or flashlamps) or light-emitting diodes (LEDs).

Flashtubes are electric arc lamps designed to produce extremely intense, incoherent, full-spectrum white light for very short durations. Flashtubes are made of lengthy glass tubing (envelope) with electrodes at either end and are filled with a gas that, when triggered by a high voltage pulse, ionises and produces radiation. The pulse of Xenon and Krypton flashlamps lasts from μ s to ms with high-intensity spectral peaks which, depending on the lamp type, lie in the range of ultraviolet to infrared. They are capable of operating at high repetition rates (>120 Hz) and can have peak wavelengths in the

UV-C range (220-275 nm) for synthetic quartz enclosures (quartz is transparent down to 160 nm).

5.2.5 Deuterium lamps

Molecular deuterium arc lamps are sources which have advantageous properties as a radiometric standard (also in the UV-C range) and are quite convenient to use. The discharge created between the filament (cathode) and the anode excites the molecular deuterium contained within the bulb to a higher energy state. The deuterium then emits radiation in a continuous spectrum as it transitions back to its initial state, unlike the process of atomic emission where electrons are excited and then emit radiation at specific wavelengths. This lamp has considerable UV radiant power, is light and compact, low-powered, and has a maximum radiant power of 190 nm (Klose *et al.*, 1987).

5.3 UV-C lamps applications

There is a wide variety of UV-C lamps, working with different technologies and generating variable irradiance levels and peak wavelengths. The choice¹⁹ of a lamp for a specific application depends on the optimisation of cost, spectrum requirements and operating conditions. For some applications, the lamp is inserted in a closed system with no UVR exposure of the user in normal condition for other applications; the radiation is directly emitted to the environment.

Low-pressure mercury lamps are often used for water treatment at small- or medium-flow rates for disinfection and/or oxidation processes; such applications include a wide range of water types (drinking and domestic water, ground water, industrial and waste water, ultrapure water and public pool water). Soft glass lamps are mainly used for drinking water disinfection systems and domestic water treatment systems (aquaria, fishponds, private pools, etc.), transilluminators and sterilising equipment because of their small flow rates and low cost. HID lamps of increased UV-flux are also used for water treatment, usually with the exception of residential drinking water systems.

Air treatment may include disinfecting and oxidising processes. In air conditioning, low pressure mercury lamps are used to disinfect the cooling coils or the air stream directly. Fixed installations of low-pressure mercury lamps are used for air disinfection in sensitive areas within hospitals (e.g. operating theatres), laboratories (e.g. thin-layer chromatography (TLC) viewing cabinets, cadmium/mercury lamps, phospholuminescence equipment, clean rooms, storage rooms) and in heavily frequented areas, such as airports, cinemas, homeless shelters, etc. Air oxidation via UV is used for odour removal (in sewage plants, rest rooms, hotels, restaurants, catering, senior citizen homes, food processing, caravan trailers, cars, etc. and industrial exhausts). Ozone-generating, low-pressure mercury lamps are used at temperatures below 40°C, whereas amalgam lamps can be used at higher air temperatures up to 120°C. The so-called "disinfection wands" or "sanitizing wands" for surface disinfection are offered as hand-held consumer products for disinfecting, e.g., toilet seats, clothes or computer keyboards. The distance to skin and eyes by hand held consumer products is much shorter than to UV-C lamps that are

¹⁹The choice should be meaningful because the level of disinfection is not always proportional to the product of irradiation intensity (E) and exposure time (t). Proportionality may not be valid for a wide range of E and t. For a long period of time (t) at low irradiation intensity (E), the microorganism will be able to reproduce themselves with a high rate at the beginning, resulting in lower disinfection level.

fixed at the ceiling. Disinfection efficiency as well as human exposure from these lamps is ill-defined.

Germicidal UV-C food irradiation uses short wave UV-C light to kill germs on packaging materials, working surfaces and food (e.g. potatoes, onions and garlic from sprouting grains, dried fruit, vegetables or nuts), slow the process of ripening and aging, prolong shelf life and freshness for dairy and bread products, prevent food-borne illness (meat, poultry and seafood), in order to reduce the number of microorganisms in spices and herbs. The studies on carrots (Mercier *et al.*, 1993), grapes (Nigro *et al.*, 1998), sweet potatoes (Stevens *et al.*, 1999) and spinach leaves (Artés-Hernández *et al.*, 2009; Escalona *et al.*, 2010), show that UV-C treatment reduce product deterioration and prolong storage life, alone or in combination with ozone (Selma *et al.*, 2008).

UV-C lamps emitting radiation above 200 nm can be tested for compliance with IEC 62471 (2006). This standard gives guidance for evaluating the photobiological safety of lamps and lamp systems including luminaries. It defines exposure limits, measurement techniques and the classification scheme for the evaluation and control of photobiological hazards from all electrically powered incoherent broadband sources of optical radiation, including LEDs (but excluding lasers), in the wavelength range from 200 nm through 3000 nm. However, in Europe the limiting values are already covered by the Artificial Optical Radiation Directive (Directive 2006/25/EC). Thus, the limits of the directive have to be applied instead of those mentioned in Clause 4 of IEC 62471 (2006).

5.4 UV lamps maintenance²⁰

UV lamps are housed within lamp sleeves. Their role is to keep the lamp at optimal operating temperature and to protect it from breaking. Lamp sleeves are usually tubes of quartz or vitreous silica. The sleeves must be long enough to include the lamp and its associated electrical connections. Sleeve walls are typically 2 to 3 mm thick.

Lamp sleeves can fracture and foul. Fractures can occur from internal stress and external mechanical forces (such as resonant vibration or impact by objects). Microscopic fractures may also occur if lamp sleeves are not handled properly when removed for manual cleaning. When the sleeves are replaced, the manufacturer's procedure should be closely followed, because the lamp sleeve can crack and break from overtightening of the compression nuts that hold it in place. If the sleeve fractures while in service, the lamp becomes vulnerable to breakage. Lamp breakage is undesirable, due to the potential for mercury release (depending on the lamp technology, section 5.2).

In addition to internal and external fouling when various substances come in contact with the surface of the sleeve, exposure of quartz contaminated with metal cations can cause solarisation as lamp sleeves age. Both fouling and solarisation can decrease the UV transmittance of the sleeve, which may appear as changes in the lamp spectra or changes in dose calculation (Jin *et al.*, 2007; Schmalwieser *et al.*, 2014). Sleeves should be replaced every 3 to 5 years or when damage, cracks or excessive fouling diminishes UV intensity to the minimum-validated intensity level, whichever occurs first.

²⁰This subsection is based on the guidance provided in EPA (2003) and EPA (2006)

However, aging affects not only lamp sleeves, but the lamps themselves (Jin *et al.*, 2007; Schmalwieser *et al.*, 2014). Lamp degradation occurs with both low- and medium-pressure lamps and is a function of the number of hours in operation, number of on/off cycles, power applied per unit (lamp) length and heat transfer from lamps. The reduction in output occurs at all wavelengths across the germicidal range. UV with wavelengths in the range 260-265 nm is the most effective for sterilization and disinfection since it corresponds to a maximum in the DNA absorption spectrum (WHO, 1994). Any deposits on the inner or outer surfaces of the lamp envelope and metallic impurities within the envelope can absorb UV radiation and cause premature lamp aging. Electrode sputtering during start-up can also coat the inside surface of the lamp envelope with tungsten as the lamp ages. The tungsten coating is black, non-uniform, concentrated close to the electrode and can absorb UV radiation. If the lamps are not sufficiently cooled during operation, electrode material in medium-pressure lamps may evaporate and condense on the inside of the envelope. Electrode sputtering can also be reduced by designing lamps that pre-heat the electrode before applying the start voltage, that are driven by a sinusoidal current waveform, or have higher argon (inert gas) content.

6 EXPOSURE

The Exposure Limit Value (ELV) for workers is set for 8 hours exposure duration for 180-400 nm (UV-A, and UV-B, and UV-C) to $H_{\text{eff}}=30 \text{ J/m}^2$ (H_{eff} is effective radiant exposure, i.e. radiant exposure spectrally weighted by $S(\lambda)$, expressed in joules per square metre, Directive 2006/25/EC). These ELVs may be lower if someone is photosensitised, e.g. by pathology, medication or diet.

6.1 Water disinfection

Since the beginning of the 20th century, UV irradiation of water has been used as a means of disinfection (Henry *et al.*, 1910). This was possible because of the new technologies using low-pressure mercury vapour lamps and quartz tubes around these lamps. This technology is now widely used in drinking water plants for water disinfection, especially because of its activity against chlorine-resistant parasites like *Cryptosporidium* and *Giardia*.

Different UV-C devices are used today (low-pressure, medium-pressure mercury) and these are protected by a quartz tube (doped or not) inserted into a metallic reactor permitting the irradiation of water as a small flowing layer around the quartz tube (a minimum of 400 J/m^2 is necessary for obtaining a 3-log reduction with a contact time of 1-15 sec). The reactor is always closed, except during the maintenance phases where the lamps are turned off, thus there is no possible exposure of the workers inside the water treatment plants.

Some small devices for UV water disinfection are sold for the general public but, excepting cases of accidental irradiation linked to misuse, there should be no UV-C exposure to users. However, data on UV-C exposure of users of water disinfection systems is lacking.

6.2 Air disinfection and insect killers

Information on the exposures experienced from the use of UV-C lamps for air disinfection is available from some of the case reports reviewed in this section in relation to the adverse health effects that occurred.

Accidental high exposure to UV-C irradiation experienced by 26 medical students from germicidal (UV-C) lamps was calculated to be approximately 70 J/m^2 absorbed energy (Trevisan *et al.*, 2006). The actual radiation emitted by the lamps was estimated to be 1.4 W/m^2 (the radiometric measurements confirmed this, because the effective irradiance measured from the height of the autopsy table to about 1 m under the UV-C lamp varied from 0.5 to 2.5 W/m^2) but, more likely, the effective energy absorbed, according to skin phototype and symptoms, was between 5 and 10 J/m^2 .

An electric insect killer (bug zapper) is a device that attracts and kills flying insects that are attracted by light. A light source attracts insects to an electrical grid, which electrocutes the insects. The device is housed in a protective cage of plastic or grounded metal bars to prevent people or animals from touching the high-voltage grid. A light source is fitted inside, often a fluorescent lamp designed to emit violet and ultraviolet light, which is visible to insects and attracts them. Usually these devices do not emit UV-C but in some cases they do. A report of accidental radiation effects includes exposure

measurement data from electric fly killers (Forsyth *et al.*, 1991). The effective irradiance ranged from 0.3 to 4.6 mW/m². UV-A radiation was found to be within the current occupational limits but both UV-B and UV-C levels exceeded the 8-hour maximum occupational exposure. 10 of the 16 tubes were non-standard and were designed to emit UV-C for germicidal purposes.

Measurements of one UV-C tube mistakenly fitted in an electric fly killer were made at a distance of 30 cm using a Bentham DM150 double grating spectroradiometer (Oliver *et al.*, 2005). The tube was found to emit strongly in the UV-C region; total irradiance from the tube (200–600 nm) was found to be 4.6 W/m². Erythral weighting of the UV-C tube spectra revealed that the erythral effective irradiance was 4.5 W/m². The authors note that midday southern European summer sun has an erythemally effective irradiance of 0.27 W/m².

Zaffina *et al.* (2012) reported on the overexposure of two health care workers (nurses) from a germicidal lamp. In particular, for UV-C radiation the maximum exposure measured at the eyes and skin after the accident was 3.36 W/m² (which resulted in an absorbed dose of 5822 J/m², in skin). It was calculated that this exposure must have resulted in an overexposure of the skin and the eyes by 194 and 126 times respectively compared to the daily 8-hour limit in Directive 2006/25 /EC.

In a case report of adverse eye symptoms in Botswana, the lamp of concern was secured to the ceiling (at 3 m) and provided direct irradiation of the area below; no louvres or reflectors were in place (Talbot *et al.*, 2002). Twenty-five centimetres from the UV germicidal lamp, UV irradiation levels ranged from 1.79 to 1.82 W/m². The resulting permissible exposure time was therefore estimated as 34 to 33 seconds. At eye level (about 1.7 m) underneath the lamp, UV irradiation ranged from 0.573 to 0.899 W/m², which corresponded to a permissible exposure time of 105 to 67 seconds. At seated level at one workstation, UV irradiation ranged from 0.20 to 0.222 W/m² (6 to 5 minutes). At the other workstation, UV irradiation ranged from 0.343 to 0.499 W/m² (3 to 2 minutes).

However, reports on the use of UV-C radiation for air disinfection without any reported adverse health effect were also found in the literature reviewed. First *et al.* (2005) have reported measurements of UV-C radiation exposure for 19 different scenarios of subjects in four environments (hospital, homeless shelter, university, school). The subjects carried the dosimeter at the height of the chest. The radiation peak was essentially at 254 nm, since the authors reported that systems were low pressure mercury lamps. The measured doses exhibited a large variation from 0.2 to 200 mJ/m² with the maximum eye-level irradiance ranging between 0.2 and 12 mW/m². The authors concluded that an eye-level irradiance up to 4 mW/m² could have been used to increase the efficiency of disinfection lamps without causing overexposure.

6.3 Summary on exposure

Most of the recently published data on exposure from UV-C lamps comes from reports involving accidental misuse of the lamps, e.g. incorrect lamps being fitted into electrical equipment such as insect killers. Current product standards do not require that UV-C (germicidal) lamps have different fittings than other lamps. Evidence from case reports suggests that the risk of accidental exposure would be considerably reduced if product

standards were changed to make it impossible to accidentally use an UV-C lamp instead of another lamp. Some of the studies compare the exposures observed with limits applicable at the time of the incident. Many find exceedances, with varying results between UV-A, UV-B and UV-C, e.g. UV-A radiation being found to be within current occupational limits but both UV-B and UV-C levels exceeding the 8-hour maximum occupational exposure. It has to be noted that the effective irradiance reported in the different studies ranged from 0.3 mW/m² to 4.6 W/m². The variation in exposures with distance from the source is also highlighted in some studies.

It should also be noted that in one study in which measurements of UV-C were made in some premises, the disinfection systems had been installed and operating for more than 15 years, without any side effects for the workers in these environments.

7 ASSESSMENT

7.1 Human health effects

UV-C is highly absorbed by chromophores in the outer layer of the epidermis. As an example, only 5% of incident 254 nm UV-C reaches the top viable cell layer, compared to 50% of 365 nm UV-A and 15% of 297 nm UV-B (Bruls *et al.*, 1984). In contrast, the cornea has no such outer layer. Consequently, the cells of the cornea are at higher risk of injury from exposure to UV irradiation. Thus when fixtures of UV-C lamps are improperly installed or when accidental high-intensity exposure occurs to room occupants, UV-C can result in photodermatitis and, more commonly, in photokeratitis and photoconjunctivitis (Nardell *et al.*, 2008; Verma *et al.*, 2007).

The following sections review literature on dermal and ocular effects from UV-C exposure from lamps. They derive from studies with humans, i.e. case reports and observational, volunteer or other epidemiological studies that did not aim at investigating the mechanism of interaction of UV-C radiation and biological tissue.

In addition, because UV-C radiation exposure may be experienced during welding operations, a short overview of the adverse health effects from welding is given in section 7.1.2. It should be noted that the exposures from welding are usually in combination with UV-A and UV-B exposure and occur repeatedly at high levels for a short duration; these are thus not directly comparable with the exposures from UV-C lamps.

As the UV-C lamps emitting radiation with wavelengths shorter than 240 nm produce ozone, a brief review of the adverse health effect of ozone is given in section 7.1.4.

7.1.1 Skin and ocular effects from exposure to UV-C lamps

There are very few recent studies that investigate potential adverse health effects in humans from exposure to UV radiation from UV-C lamps. Most are case reports of dermal or ocular effects from accidental exposure. There are a few papers reporting small volunteer studies on skin tolerability.

Case reports

There were a handful of reports on the adverse health effects of UV-C radiation before the 1990s, for example, a report of acute sunburn due to accidental UV-C irradiation in the butcher's department of a meat-processing firm (Forsyth *et al.*, 1991). Fifteen employees complained of sunburn and gritty eyes; symptoms improved on holidays and recurred on return to work.

Two health-care workers in a hospital pharmacy received accidental overexposure to UV-C radiation produced by a germicidal lamp which was accidentally turned on instead of the supplied fluorescent neon light (Zaffina *et al.*, 2012). The absorbed dose in the skin had reached 5,822 J/m². A few hours after the exposure, the two subjects reported symptoms of ocular itching and conjunctival injection, along with facial erythema; they were both wearing gloves so their hands were not affected. After 30 days, the ocular signs of actinic keratitis associated with conjunctival injection, disorders of accommodation and blurred vision were still present. The dermatology specialist check, performed about 60 days after the accident, showed first-degree erythema (skin

dyschromia and desquamation) in both operators. The publication reported that both continued having significant clinical signs for over 2 years.

In another hospital setting in Botswana, two nurses and one housekeeper complained of eye discomfort, 'like sand in the eyes', after working in an administrative office. The following day, one employee noted facial skin peeling (Talbot *et al.*, 2002). All symptoms resolved over 2–4 days without sequelae. Six weeks later, the syndrome recurred for all three employees. A workplace investigation revealed that the office had been converted from a hospital sputum induction room and that an unshielded 36 W UV lamp was still installed and operational. The on/off switch for the UV lamp was immediately adjacent to the fluorescent bulb on/off switch and did not have a locking mechanism. In the office, UV measurements at eye level and looking directly at the UV lamp ranged from a low of 0.2 W/m² when seated to a high of 0.49 W/m² when standing. The US National Institute for Occupational Safety and Health recommends that exposure to UV-C (254 nm) be less than 60 J/m² over a daily 8-hour period for unprotected skin or eyes. These radiant exposure levels result in allowable exposure times of 300 and 120 seconds, respectively.

A 90-minute accidental exposure to similar levels of UV-C radiation as reported by Zaffina *et al.* (2012) was experienced by 26 medical school students from germicidal lamps that were lit due to a malfunctioning of the timer system (Trevisan *et al.*, 2006). Several hours after irradiation exposure, all subjects reported the onset of ocular symptoms, subsequently diagnosed as photokeratitis, and skin damage to the face, scalp and neck. While the ocular symptoms lasted 2-4 days, skin erythema was followed by deep skin exfoliation, in all but one subject. The ocular and skin effects produced by such a high irradiation appeared reversible within a short time – several days. It should be noted that in order to keep the dose below 60 J/m², as recommended by the ACGIH, the duration of continuous exposure to the 254 nm UV-C radiation should not exceed 21.4 s.

In another example of misuse of UV-C exposure, two electric fly killers positioned on the ceiling and sidewalls of a hotel kitchen were found to be incorrectly fitted with UV-C tubes (Oliver *et al.*, 2005). Eight cooks reported having painful red skin on their face, eyelids and the side and front of their neck as well as burning, gritty eyes, and a clinical examination diagnosed conjunctivitis and sunburn-like erythema.

In contrast to the above reports, the study by First *et al.* (2005) described in section 6.2 points out that the disinfection systems had been installed and operating for more than 15 years, without any side effects for the workers in these environments. Similar results were reported by Nardell *et al.* (2008) in their homeless shelter study where irradiance at eye level reached values as high as 13 mW/m². The authors interviewed 3,611 subjects for eye and skin complaints and concluded that there was a 6% incidence rate of some type of related symptom. However, an analysis of the interviews showed that there was not a statistically significant correlation between the symptoms and the activity of the disinfection lamps.

Volunteer studies

Results for the gene expression, which are part of these studies, are reported in section 7.2.

The buttock skin of humans (n = 16) was irradiated with 5-fold MED of UV-C and the time course of hyperalgesia (increased sensitivity to pain) and axon reflex erythema

(redness of the skin) was monitored (Weinkauff *et al.*, 2012). Skin biopsies were assessed for gene expression levels (reported in section 7.2). No side effects of the irradiation such as blisters, infection or scarring were observed. In addition, a lasting pigmentation as regularly reported after a 3-fold minimum erythema dose (MED) UV-B irradiation was not observed upon UV-C exposure. Among the individuals, no correlation between the individual UV-C irradiation dose required for the 5-fold MED and the mechanical or thermal hyperalgesia was found. Hyperalgesia due to mechanical stimuli delivered at an impact velocity of 12 m/s and heat (48°C) stimuli was significant at 6 hours ($p < 0.05$ and $p < 0.01$) and 24 hours ($p < 0.005$ and $p < 0.01$) after irradiation. Axon reflex erythema upon mechanical and thermal stimuli significantly increased 3 hours after irradiation and was particularly strong 6 hours after irradiation.

A 'Sterilray' disinfectant source (222 nm) conventionally used to sterilise equipment and work surfaces was assessed for tolerability in four healthy volunteers with phototype I and II skin (Woods *et al.*, 2015). The MED was determined using an escalating dosage study methodology. Biopsies of irradiated sites (on the back) were stained for cyclobutane pyrimidine dimers (CPD) and the degree of CPD was compared with that in biopsies from unexposed skin and from areas exposed to UV-B (280–315 nm) radiation (section 7.2). Calibrated spectral measurements revealed emission at a peak wavelength of 222 nm with 97% emission at wavelengths less than 250 nm. For UV-C, the MED values in the four volunteers tested were either 400 J/m² or 500 J/m², i.e. at doses below the threshold of bacteriostatic effects; the source was capable of inducing both erythema and CPD formation in human skin.

7.1.2 Studies of welders

Occupational exposure to artificial UV radiation, including UV-C, during welding is common in the construction industry and in many manufacturing industries. However, a comprehensive examination of UVR exposure from welding is outside of the scope of this Opinion.

Electric welding arcs emit radiation within a radius of several meters, thus people working nearby, not just welders themselves, can suffer from overexposure. Gas welding and cutting torches also produce UV radiation but at a much lower level; this process mainly consists of exposure to infrared radiation. Arc welding processing scatters bright light with UVR emission over the full UV spectrum (UV-A, UV-B, and UV-C). The worst case of irradiance measurement from 50 cm arc welding reported by Peng *et al.* (2007) showed a broad UVR spectrum with 33% UV-C, 19% UV-B, and 48% UV-A distributions. As the distance increased, the percentage of UV-A increased while the percentages of both UV-B and UV-C radiation decreased.

Ocular hazards in welders

Ocular hazards experienced by welders include photophthalmia (welder's flash), keratoconjunctivitis and cataracts caused by UVR emitted from welding arcs. The condition of 'arc-eye', a sensation of sand in the eyes, is a result from excessive eye exposure to UV welding due to the damage to eye lens (Dixon and Dixon, 2004; Magnavita 2002). Photokeratoconjunctivitis cases from work-related welding processes have been observed in occupational ophthalmological emergencies in Taiwan (Yen *et al.* 2004).

An increased risk of eye melanoma associated with welding has also been observed (reviewed in IARC 2012; HSE 2012). Studies which related specifically to working as a

welder or sheet metal worker (as opposed to working in proximity to welding) found a strong association between increased risk and increased duration of welding (years welding or lifetime hours welding) (Holly *et al.*, 1996; Guénel *et al.*, 2001; Vajdic *et al.*, 2004). A meta-analysis included 5 studies and found a statistically significant meta-OR of 2.05 (95%CI=1.20-3.51) (Shah *et al.*, 2005). There was significant heterogeneity between studies due to two that included iris melanomas, as well as choroids and ciliary body melanomas, reporting higher ORs. The authors concluded that welding was a significant risk factor for the development of uveal melanoma, but due to the relatively small number of studies available, potentially under-powering the analysis, the results should be interpreted with caution.

Section 7.1.2 briefly reviews literature on skin and ocular effects from welding. It should be noted, however, that these studies do not specifically evaluate the risk from exposure to the UV-C from welding.

Skin effects in welders

There have been several case reports of welders experiencing skin effects following welding (Bruze *et al.*, 1994; Donoghue and Sinclair, 1999; Roelandts and Huys, 1993). A 1-year history of recurrent, severe facial dermatitis, mainly involving the right side of the face, neck and right ear was described in a patient employed in a steel fabrication plant where a considerable part of the workload was the welding of steel bars and plates (Shehade *et al.*, 1987). A 71-year-old woman experienced numerous squamous cell carcinomas (SCCs) on her hands after she had frequently experienced 'sunburn' on her hands after assisting her son with his welding business (Dixon 2007). A 32-year-old welder showed atopic dermatitis repeatedly upon occupational exposure to UV-C, which subsided only after the patient was removed from the welding site (Elsner and Hassam, 1996).

A case-control study compared acute and chronic photo-damage and the incidence of malignant skin disorders between a group of welders, a group of other trades exposed to welding operations and a non-exposed group (Emmett *et al.*, 1981). There were no significant differences among the groups in regard to the prevalence of various dermatoses, skin tumours, changes in visual acuity, clinical ocular abnormalities or the prevalence of actinic elastosis. The degree of elastosis was significantly associated with type of complexion, original hair colour, eye colour, childhood freckling, poor ability to tan and ease of sun burning. However, cutaneous erythema and cutaneous scars were more frequent in welders. In addition, a large number of the examined welders showed UV-related acute erythema with blistering in the area of the neck, nose, the rest of the face, arms, chest and throat.

7.1.3 Health and wellbeing

A pilot study tested whether installation and operation of germicidal UV-C lamps in central ventilation systems would be feasible, without adverse effects, undetected by building occupants and effective in eliminating microbial contamination (Menzies *et al.*, 1999). Germicidal UV lamps were installed in the ventilation systems serving three floors of an office building and were turned on and off during a total of four alternating 3-week periods. Workers reported their environmental satisfaction, symptoms and absences due to sickness, without knowledge of whether the lamps were on or off. The indoor

environment was measured in detail including airborne and surface bacteria and fungi. The intensity (irradiance) of UV radiation, measured at the cooling coils of the lights, exceeded 5.5 mW/m². Airborne bacteria and fungi were not significantly different, whether the UV-C lights were on or off, but were virtually eliminated from the surfaces of the ventilation system after the UV-C lamps were operated for 3 weeks. Of the other environmental variables measured, only total airborne particulates were significantly different under the two experimental conditions — higher with UV lamps on than off. Of 113 eligible workers, 104 (87%) participated; their environmental satisfaction ratings were the same, whether or not UV-C lamps were on. With UV-C lamps on, headaches, difficulties concentrating and eye irritation occurred less often, whereas skin rash or irritation was more common. Overall, the average number of work-related symptoms reported was similar whether or not the UV lamps were on or off. Overall it was concluded that UV lamps can be installed and working in central heating, ventilation and air conditioning systems of office buildings without workers noticing any difference and without resulting in any adverse effects.

Another field trial (double-blind, placebo-controlled) was carried out to evaluate whether the use of upper-room (i.e. mounted high on the wall or on the ceiling) UV-C germicidal irradiation could prevent transmission of tuberculosis at 14 homeless shelters in six U.S. cities from 1997 to 2004 (Nardell *et al.*, 2008). As part of this trial, the safety of room occupants was evaluated through administering questionnaires regarding eye and skin irritation to a total of 3,611 staff and homeless study subjects. Approximately every 12 months, the head of the data safety and monitoring committee randomly assigned each shelter to either a placebo or active UV status. Overall there were 3611 questionnaires administered, with 223 (6%) reports of eye or skin symptoms. Of the 223 complaints, 95 occurred in the active UV periods and 92 during the placebo period; in the 36 remaining cases it was unclear in which period they occurred. There was no statistically significant difference in the number of reports of symptoms between the active and placebo periods. One definite occurrence of UV-related keratoconjunctivitis occurred, resulting from a placement of a bunk bed in a dormitory where a single bed had been used when the UV fixtures were first installed. The authors concluded that effective use of upper-room UV germicidal irradiation can be achieved without an apparent increase in the incidence of the most common side effects of accidental UV overexposure.

7.1.4 Health effects of ozone

Ozone is a highly reactive substance and adverse health effects are usually found at the sites of initial contact especially the respiratory tract (nose, throat and airways), the lungs, and at higher concentrations, the eyes. The principal health effects are produced by irritation of and damage to the small airways of the lung. However, people's sensitivity to ozone exposure varies considerably (Lippmann, 1989). Studies of the adverse health effects of ozone include volunteer studies, studies of 'natural exposure' of ozone in ambient air and hospital-based studies to investigate longer-term chronic effects. Symptoms from short-term transient exposures include coughing and wheezing, pain when taking a deep breath and breathing difficulties during exercise or outdoor activities.

Volunteer studies have shown reductions in lung function following ozone exposure in healthy children and adults and also in asthmatics. Studies of ozone exposure as a component of ambient air pollution have identified associations with respiratory mortality

(both short-term and long-term exposure); short-term exposure has also been shown to be associated with respiratory symptoms, asthma and COPD (EPA, 2014).

Population groups at risk include children and adults who are active outdoors, outdoor workers, people with respiratory diseases such as asthma or emphysema and people with unusual susceptibility to ozone.

The EPA advises that the UV-C lamps that emit ozone should not be used in closed premises without ventilation (EPA, 2013).

7.1.5 Summary on health effects in humans

There are very few studies that investigate potential adverse health effects in humans from exposure to UV radiation from UV-C lamps when used as intended. Most are case reports that report dermal or ocular effects from accidental exposure through, for example, use of inappropriate bulbs or accidental prolonged exposure. UV-C radiation can damage the superficial tissues of the eye. However, in general it is reported that while eye exposure to UV-C from lamps may cause extreme discomfort, the symptoms subside within about a week. However, one study reported that, following UV-C lamp exposure which caused more immediate first-degree erythema and ocular problems, ocular problems remained for up to 2 years after exposure. In contrast, most of the effects on the skin have been reported as being of short duration.

One of the volunteer studies found no lasting pigmentation after irradiation with 5-fold MED of UV-C and no side effects of the irradiation such as blisters, infection or scarring were observed. The other volunteer study found that 222 nm UV-C radiation at low doses (below the bacteriostatic effect threshold) was capable of inducing both erythema and CPD formation in human skin.

Two intervention trials found no difference in eye or skin irritation between periods when germicidal UV lamps were switched on and periods when they were off, nor any difference in symptoms of health and well-being, such as headache and difficulty concentrating.

Exposure to ozone may cause a variety of symptoms and diseases associated with the respiratory tract, particularly in sensitive individuals.

Ocular adverse effects experienced by welders include 'arc-eye' (a sensation like sand in the eyes), photophthalmia (welder's flash), keratoconjunctivitis, cataracts caused by the wide spectrum of UVR (including UV-C) emitted from welding arcs and an increased risk from ocular melanoma. UV-related acute erythema with blistering has also been reported in welders.

7.2 Biological effects

7.2.1 Biological effects of UV radiation

General overview

As UV-C from solar radiation is effectively filtered by the atmosphere, in particular the ozone layer, there is normally negligible exposure to this type of radiation on the earth's surface. However, artificial UV-C radiation is now used in a large range of applications.

The penetration of UV radiation in the eye and the skin tissues largely depends on the wavelength. Since the spectrum of UV-C lamps may also contain some UV-B, biological effects of both UV-C and UV-B radiation are discussed together in this chapter.

UV radiation can damage the eyes (Bova *et al.*, 2001). One of the most common ocular conditions associated with UV-A and UV-B exposure is cataract development. A crystalline lens is made up of proteins. These proteins can be altered or denatured by exposure to UV radiation. In fact, all three layers of the lens — nucleus, cortex and capsule — can have alterations in their protein structures. Figure 2 shows that UV radiation with wavelengths longer than 315 nm penetrates up to the lens, with the UV-C wavelengths being absorbed at the surface of the cornea - both the corneal epithelium and endothelium (which cannot regenerate) are vulnerable to UV radiation. Mallet and Rochette (2013) have shown *ex vivo* that UV-B- and UV-C-induced CPDs are concentrated in the corneal epithelium and do not penetrate deeply beyond this corneal layer.

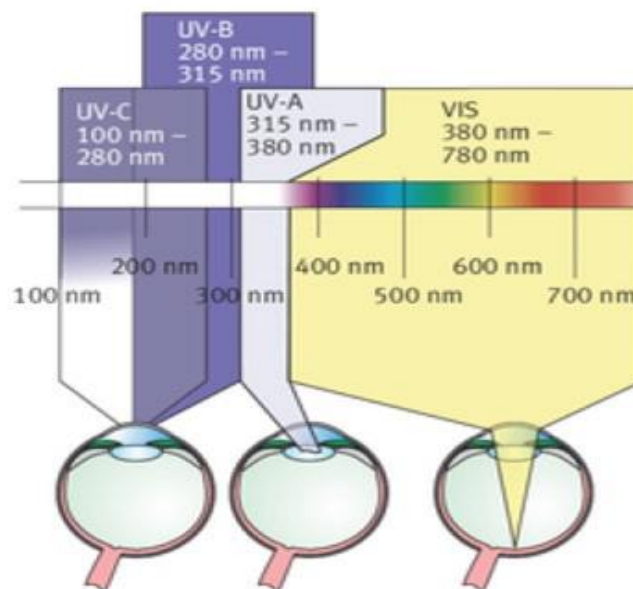


Figure 2: Variation of penetration depth in the eye with UV radiation wavelength.

(Source: LASERVISION GmbH & Co. KG. Safety Guidance, The Use of Lasers in the Workplace
http://www.laser2000.co.uk/safety_guidance.php)

It has been shown by Meinhardt *et al.* (2008) that the penetration depth of UV radiation into the skin depends on the body site and the skin phototype. Usually UV-C does not penetrate deeper than the horny layer in the intact skin as illustrated in Figure 3. It should be noted that skin thickness exhibits a large variation both interpersonally as well as intrapersonally, and varies with age.

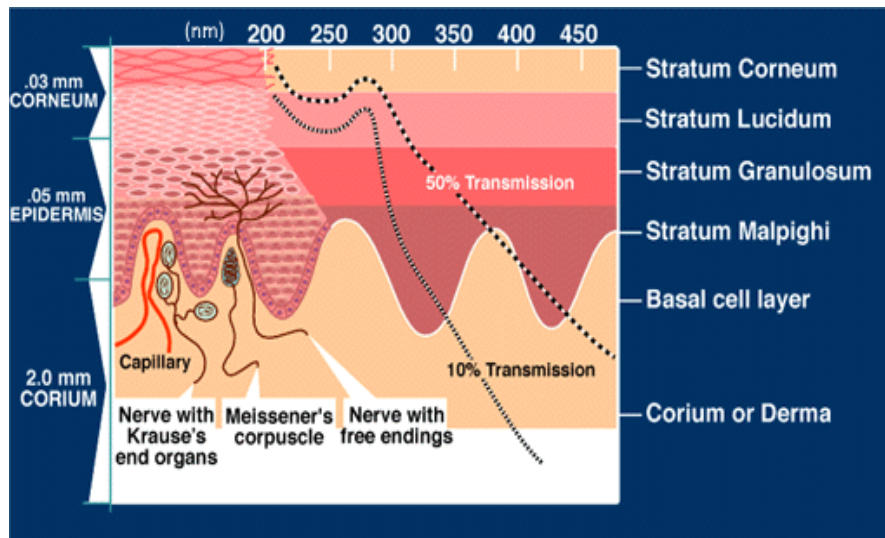


Figure 3: Variation of penetration depth in a standard skin with wavelength.

(Source: Bezzant JL, Penetration of human skin by ultraviolet light, M.D. http://library.med.utah.edu/kw/derm/pages/meet_2.htm)

It is clearly shown by the isoparametric transmission contours that less than 10% of the radiation at UV-C wavelengths reaches depths below the upper two skin layers, whereas 10 to 50% of radiation at UV-A wavelengths reaches the basal cell layer and the corium.

The harmful effects from exposure to UV radiation include acute (deterministic) effects on the human skin, like photodermatosis, photosensitisation and erythema (inflammation/sunburn) as well as chronic and stochastic effects like premature ageing of the skin, suppression of the immune system and skin cancer. UV-A radiation effects are not considered here (for details see the SCENIHR Preliminary Opinion on sunbeds).

Artificial UV-C is also known to induce erythema in human skin. For erythema that is just perceptible to the eye, the dose is approximately one-thousand-fold higher for 360 nm radiation (UV-A) than for 300 nm (UV-B) or 254 nm (UV-C) radiation (Diffey and Farr, 1991). The development of measurement techniques to quantify UVR erythema has permitted the response of normal skin to UVR of different wavelengths to be defined in terms of its dose-response relationship, rather than the conventional and limited visual threshold assessment of minimal erythema. This has facilitated investigation of the biochemical processes of ultraviolet erythema in normal skin (Diffey *et al.*, 1984). The time course of ultraviolet erythema was measured at exposure to six different doses of UV-C and UV-B radiation in each of eight adult subjects (Farr *et al.*, 1988). The intensity of erythema was measured by reflectance spectrophotometry at 4, 8, 24, 36, and 48 hours after irradiation. In five subjects, there was no significant difference between the form of the UV-B and UV-C erythema time course. A significant difference was observed in three subjects, but this was random rather than systematic between subjects.

The dose-response curve for UV-C (253.7 nm) erythema in human skin has been shown to be significantly less steep than for UV-B (300 nm) (Farr and Diffey, 1985; Diffey and Farr, 1991). The degree of erythema increases more rapidly with equal increments of dose above the MED for irradiation with UV-A or UV-B than for UV-C radiation. The significant difference in slope of the dose-response curve at these two wavelengths (254 nm and 300 nm) means that, when compared in this fashion at doses greater than the MED, UV-B erythema will always be of much greater intensity.

Diffey and Farr (1991) also point out that the criterion used to judge the erythema could be a major factor in the reported variability of erythema sensitivity to wavelengths of 280 nm or less. Since the slope of the dose-response curve at 254 and 280 nm is much shallower than at 300, 313 or 365 nm, they suggest that appreciable uncertainty is possible in the estimation of the MED at these shorter wavelengths depending on the exact degree of erythema observed. They show that this means that although the skin is more sensitive to 254 than 300 nm radiation in terms of minimal erythema, the reverse is the case for moderate or severe erythema.

IARC classified UV radiation as carcinogenic to humans (Group 1 carcinogen) (IARC, 1992; IARC, 2012). The group 1 classification for UV-C was based on experimental evidence in mice causing squamous cell carcinoma of the skin and mechanistic considerations that UV-C is carcinogenic in human cells (IARC, 2012). This is also in line with the International Commission on Illumination (CIE) which mentions that "from basic biophysical principles, UV-C radiation is carcinogenic" (CIE, 2010). The main source for UV-induced skin cancer is DNA damage. In addition, suppression of the immune system resulting from exposure to UV radiation is considered to be an important contributor to the development of non-melanoma skin cancers.

Animal studies

Yel *et al.* (2014) investigated the ultrastructural effects of UV-C radiation on the stratum corneum of mole rats. The control group did not receive any radiation while the animals of the treated groups were irradiated with UV radiation (254 nm) for 14, 28, or 60 days, corresponding to 52, 112 and 168 h. The total dose was reported to be 2,822.4 J/m², 5,644.8 J/m² or 8,647.2 J/m², respectively.

Skin samples were prepared and analysed by transmission electron microscopy. Depending on dose and exposure period, ultrastructural changes occurred in mole rats' skin. An increase in the keratohyalin and the formation of vacuoles in the cytoplasm were among the remarkable changes induced by UV-C. It was found that the transformation of granular cells into horny cells was not completed in the stratum corneum. Pathological aggregations of tonofilaments were formed in the desmosomes. Lacunae formations and unkeratinised cytoplasmic residues were observed within the horny cells.

Human studies

In the study of 4 volunteers using a 'Sterilray' disinfectant source (Woods *et al.*, 2015), described in detail in 7.1.1, the histopathology results showed evidence of CPD formation after irradiation with 'Sterilray' UV-C at 222 nm. In two volunteers with epithelial thinning over the suprapapillary plates, UV-C exposure resulted in basal CPD formation where the epidermis was thinned.

These events occur at 'Sterilray' dosage levels below the threshold for bacteriostatic/cidal effects. The authors concluded that in hand skin, if UV-C exposure was employed to reduce microsurface organisms, potentially mutagenic damage to the basal layer keratinocytes would occur during use of this disinfection source, particularly within the thinned suprapapillary plates. There might be some filtering out of the damaging effects of UV-C by the thicker corneal layer on palmar skin, but DNA damage might still occur at other less cornified sites such as the dorsal hands and wrists.

In the study of volunteers irradiated in the buttocks (Weinkauf *et al.*, 2012), described in section 7.1.1, skin biopsies were assessed for expression patterns of 31 gene levels by RT-PCR analysis. Twenty-three of those genes could be reliably quantified. A modulated gene expression pattern was found in the irradiated skin for e.g. bradykinin receptor 1, chemokine ligand CCL-2, COX-2, NGF and its high affinity receptor TrkA. Analysing the individual pain responses upon heat and mechanical stimuli with the individual mRNA expression patterns, a correlation between COX-2 and PGES levels at 6 h and heat evoked erythema was found, and in addition the possible role of Nav1.7 (gene SCN9A) in mechanical hyperalgesia was identified.

Some of the reported gene modulations are already known to occur in human skin after UV-B radiation: (1) Bradykinin receptor 1 is correlated with an increased sensitivity in human sunburn as an increased B1 and B2 receptor-mediated hypersensitivity, and additionally, enhanced local vasodilatation upon B1-receptor activation has been previously described in UV-B irradiated human skin. (2) Following UV-C exposure, COX-2 was upregulated and this is in-line with the well-known anti-inflammatory and analgesic effect of COX-2 inhibitors in human sunburn. (3) The strong increase of the chemokine (C-C motif) ligand 2 (CCL-2) in UV-C skin is in accordance with recent findings exploring the cytokine profile after UV-B irradiation in human skin.

Mechanistic studies

Based on human mechanistic studies and studies in experimental animals, it can be anticipated that UV-C is a human carcinogen. Conjugated organic structures (from biological targets) include nitrogen-containing ring structures such as pyridines, pyrimidines, flavins and the aromatic amino acids (Jagger, 1967). These structures could act as chromophors, being composed of bases, sugars and phosphates. The sugars and phosphate groups do not absorb wavelengths above 210nm, but conjugated bases have peak absorption of ultraviolet light energy at 260nm; pyrimidines are 10 times more sensitive to UV₂₅₄ than purines. Conjugated bonds hold two electron pairs, and when a photon of UV-C radiation energy strikes an electron, it is induced to rise to an excited (higher energy) level. This disruption of stable electrons can affect the entire organic structure, leading to an unstable conformation.

UV-C induces gene mutation, cytogenetic damage and other forms of DNA damage. Some studies of human tissue demonstrated that exposure to UV-C causes DNA damage, via direct excitation of DNA bases, through oxygen-independent reactions, leading in principal to dimeric pyrimidine photo-lesions and with relatively minor yields to DNA photoproducts that include the thymine-adenine photo-adducts, the "cytosine photohydrates" (Herrlich *et al.*, 1994) and a few purine decomposition products (Cadet *et al.*, 1992). This structure requires more energy but is formed when UV₂₅₄ irradiation of cytosine yields 6-hydroxy-5,6-dihydrocytosine (O'Donnell *et al.*, 1994).

Even if there are no epidemiologic studies adequate for evaluation of UV-C carcinogenicity in humans, the exposure of experimental animals to high doses of radiation from devices emitting primarily UV-C caused skin tumours in rats (keratoacanthoma-like skin tumours) and mice (squamous cell carcinoma and fibrosarcoma) (IARC, 1992; IARC, 2012; ICNIRP, 2004).

7.2.2 Summary on biological effects

UV-C is mostly absorbed in the horny layer of human epidermis. Both histopathological and genetic investigations show alterations like CPD formation and gene modulations induced by UV-C. UV-C exposure resulted in basal CPD formation where the epidermis was thinned even at low doses below the threshold of bacteriostatic effects.

UV-C from solar radiation is effectively filtered by the ozone layer and there is normally negligible exposure to UV-C from the sun on the earth's surface. Artificial UV-C radiation has been shown to induce erythema in human skin. The time course of UV-induced erythema appears not to be significantly different between UV-C and UV-B radiation. However, the dose response curve for UV-C erythema in human skin is less steep than for UV-B. As the mechanisms for DNA damage at molecular level are comparable to those known for UV-B, UV-C is considered carcinogenic.

8 RECOMMENDATIONS FOR FURTHER WORK

Data is needed on medium- and long-term health effects from exposure to UV-C from lamps to both workers and the general public, under normal use conditions. Little is known about exposures from private use of UV-C lamps.

Exposure data is also scarce for the use of UV-C irradiation in disinfection of water. Moreover, UV-C sterilisation is increasingly used in medical facilities, for example in operating theatres. In such cases the potential material degradation due to the UVC exposure should be further studied, before such practices are established. The SCHEER recommends further research in this area.

Although mechanistic studies suggest that there are wavelength-dependent exposure thresholds for UV-C regarding acute adverse effects to human eyes and skin, except for erythema, quantitative estimation of these thresholds could not be derived from currently available exposure data. In addition, there are no quantitative data on dose-response of stochastic effects such as skin cancer or ocular cancer, neither with regard to UV-C intensity or irradiance nor with regard to cumulated absorbed radiation energy. Therefore, more research is needed on these issues.

9 CONSIDERATION OF THE RESPONSES RECEIVED DURING THE CONSULTATION PROCESS

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 (providing 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.

Some commentators recommended editorial changes to make the Opinion compatible with international guidelines and standards. Other commentators suggested that a better explanation be given of the legislative framework of this Opinion, namely concerning the Artificial Light Directive. Moreover, several technical suggestions were proposed (e.g., inclusion of other technologies of UV-C lamps and technical standards with which they are tested for conformity). All these suggestions were accepted and the Opinion was changed accordingly. However the two most prominent changes were the inclusion of the CIE 187:2010 document ("UV-C: Photocarcinogenesis risks from germicidal lamps") and the rewording of the response to the second question of the mandate for the sake of clarity. It was made clear that all exposure guidelines reflect wavelength-dependent thresholds for acute effects but that there can be no threshold for long-term stochastic effects, like cancer. Moreover, there are no data for other long-term effects or for low-chronic exposure.

The text of the comments received and the response provided by the SCHEER is available at:

http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consultation_02_en

10 ABBREVIATIONS

ACGIH	American Conference of Governmental Industrial Hygienists
AlN	Aluminum nitride
BCC	Basal cell carcinoma
CIE	International Commission on Illumination
COPD	Chronic obstructive pulmonary disease
CPDs	Cyclobutane-pyrimidine dimers
ELV	Exposure Limit Value
EM	Electromagnetic radiation
EPA	United States Environmental Protection Agency
FUV	Far UV
GaAs	Gallium arsenide
GaP	Gallium phosphide
HID	High intensity discharge
IARC	International Agency for Research on Cancer
ICNIRP	International Commission on Non-Ionizing Radiation Protection
IEC	International Electrotechnical Commission
InP	Indium phosphide
ISO	International Organization for Standardization
LED	Light emitting diode
LVD	Low Voltage Directive
MED	Minimal erythema dose
MPE	Maximum Permissible Exposure
NIOSH	National Institute of Occupational Safety and Health
OJEU	Official Journal of the European Union
SCC	Squamous cell carcinoma
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SI	International System of Units

UVR	Ultraviolet radiation
VUV	Vacuum UV

REFERENCES

- Artés-Hernández F, Escalona VH, Robles PA, Martínez-Hernández GB, Artés F. (2009) Effect of UV-C radiation on quality of minimally processed spinach leaves. *J Sci Food Agr* 89(3):414-421
- Berlien H-P Brose M, Franek J, Graf M-J, Halbritter W, Janßen W, Ott G, Reidenbach H-D, Romanus E, Schmitz B, Siekmann H, Udovicic L, Weiskopf D. (2016) Statement on ICNIRP guidelines on limits of exposure to incoherent optical radiation. *baua: Fokus, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Dortmund.* doi: 10.21934/baua:focus20160509
- Bova LM, Sweeney MH, Jamie JF, Truscott RJ. (2001) Major changes in human ocular UV protection with age. *Invest Ophthalmol Vis Sci* 42(1):200-205
- Bruls WA, Slaper H, van der Leun JC, Berrens L. (1984) Transmission of human epidermis and stratum corneum as a function of thickness in the ultraviolet and visible wavelengths. *Photochem Photobiol* 40(4):485-494
- Bruze M, Hindsen M, Trulsson L. (1994) Dermatitis with an unusual explanation in a welder. *Acta Derm Venereol* 74(5):380-382
- Cadet J, Anselmino C, Douki T, Voituriez L. (1992) New trends in photobiology: Photochemistry of nucleic acids in cells. *J Photochem Photobiol B: Biology* 15(4):277-298
- Diffey BL, Farr PM, Ive FA. (1984) The establishment and clinical value of a dermatological photobiology service in a district general hospital. *Br J Dermatol* 110(2):187-189
- Diffey B, Farr P. (1991) Quantitative aspects of ultraviolet erythema. *Clin Phys Physiol Meas* 12(4):311-325
- Dixon AJ, Dixon BF. (2004) Ultraviolet radiation from welding and possible risk of skin and ocular malignancy. *Med J Aust* 181(3):155-157
- Dixon A. (2007) Arc welding and the risk of cancer. *Aust Fam Physician* 36(4):255-256
- Donoghue AM, Sinclair MJ. (1999) Basal cell carcinoma after frequent episodes of cutaneous erythema and peeling induced by welding. *Occup Environ Med* 56(9):646
- Elsner P, Hassam S. (1996) Occupational UVC-induced exacerbation of atopic dermatitis in a welder. *Contact Dermat* 35(3):180-181
- Emmett EA, Buncher CR, Suskind, RB, Rowe KW. (1981) Skin and eye diseases among Arc Welders and those exposed to welding operations. *J Occup Med* 23(2):85-90
- Environmental Protection Agency, EPA (2003) Ultraviolet disinfection guidance manual (EPA 815-D-03-007), Draft, June 2003

Environmental Protection Agency, EPA (2006) Ultraviolet disinfection guidance manual for the final long term 2 enhanced surface water treatment rule (EPA 815-R-06-007), November 2006

Environmental Protection Agency, EPA (2014) Health risk and exposure assessment for ozone. Final report (EPA-452/R-14-004a), August 2014

Escalona VH, Aguayo E, Martínez-Hernández GB, Artés F. (2010) UVC doses to reduce pathogen and spoilage bacterial growth in vitro and in baby spinach. *Postharvest Biol Technol* 56(3):223-231

Farr PM, Diffey BL. (1985) The erythema response of human skin to ultraviolet radiation. *Br J Dermatol* 113(1):65-76

Farr P, Besag J, Diffey B. (1988) The time course of UVB and UVC erythema. *J Invest Dermatol* 91(5):454-457

First MW, Weker RA, Yasui S, Nardell EA. (2005) Monitoring human exposures to upper-room germicidal ultraviolet irradiation. *J Occup Environ Hyg* 2(5):285-292

Forsyth A, Ide CW, Moseley H. (1991) Acute sunburn due to accidental radiation with UVC. *Contact Dermatitis* 24(2):141-142

Guénel P, Laforest L, Cyr D, Févotte J, Sabroe S, Dufour C, Lutz JM, Lynge E. (2001) Occupational risk factors, ultraviolet radiation, and ocular melanoma: a case-control study in France. *Cancer Causes Control* 12(5):451-459

Health and Safety Executive, HSE (2012) The burden of occupational cancer in Great Britain: Technical report: melanoma.

Henry V, Helbronner A, Recklinghausen M. (1910) Nouvelles recherches sur la stérilisation de grandes quantités d'eau par les rayons ultraviolets. *Comptes Rendus Académie des Sciences* 151:677-680

Herrlich P, Sachsenmaier C, Radler-Pohl A, Gebel S, Blattner C, Rahmsdorf HJ. (1994) The mammalian UV response: mechanism of DNA damage induced gene expression. *Adv Enzyme Regul* 34:381-395

Holly EA, Aston DA, Ahn DK, Smith AH. (1996) Intraocular melanoma linked to occupations and chemical exposures. *Epidemiology* 7(1):55-61

International Agency for Research on Cancer, IARC (1992) Volume 55: Solar and ultraviolet radiation. In *IARC Monographs on the evaluation of carcinogenic risk of chemicals to man*

International Agency for Research on Cancer, IARC (2012) Volume 100D: Radiation. In *IARC Monographs on the evaluation of carcinogenic risk to humans*

International Electrotechnical Commission, IEC 62471 (2006) Photobiological safety of lamps and lamp systems

International Commission on Illumination, CIE (2010) UV-C Photocarcinogenesis risks from germicidal lamps.

International Commission on Non-Ionizing Radiation Protection, ICNIRP (2004) Guidelines on limits of exposure to ultraviolet radiation of wavelength between 180 nm and 400 nm (incoherent optical radiation). *Health Physics* 87(2):171-186

International Organization for Standardization, ISO 15858 (2016) UV-C Devices - Safety information - Permissible human exposure

Jagger J. (1967) *Introduction to Research in Ultraviolet Photobiology*. Prentice-Hall, Inc., Englewood Cliffs, New Jersey

Jin S, Sharpless C, Linden K, Kelly R, Ferran B. (2007) Aging evaluation of medium-pressure mercury lamps under typical operating conditions for drinking water disinfection applications. *Proceedings of the Water Environment Federation, Disinfection 2007*, 276-292(17)

Klose JZ, Bridges JM, Ott WR. (1987) NBS measurement services: Radiometric standards in the vacuum ultraviolet. Center for Radiation Research, National Measurement Laboratory, National Bureau of Standards, Gaithersburg (MD)

Lippmann M. (1989) Health effects of ozone: a critical review. *J Air Waste Management Assoc* 39(5):672-695

Magnavita N. (2002). Photoreinitis: an underestimated occupational injury? *Occup Med* 52(4):223-225

Mallet JD, Rochette PJ. (2013). Wavelength-dependent ultraviolet induction of cyclobutane pyrimidine dimers in the human cornea; *Photochem Photobiol Sci* 12(8):1310-1318

Meinhardt M, Krebs R, Anders A, Heinrich U, Tronnier H. (2008) Wavelength-dependent penetration depths of ultraviolet radiation in human skin. *J Biomed Opt* 13(4):044030

Menzies D, Pasztor J, Rand T, Bourbeau J. (1999) Germicidal Ultraviolet Irradiation in Air Conditioning Systems: Effect on Office Worker Health and Wellbeing: A Pilot Study. *Occup Environ Med* 56(6):397-402

Mercier J, Arul J, Ponnampalamm R, Boulet M. (1993) Induction of 6-methoxymellein and resistance to storage pathogens in carrot slices by UV-C. *J Phytopathol* 137:44-54.

Nardell EA, Bucher SJ, Brickner PW, Wang C, Vincent RL, Becan-McBride K, James MA, Michael M, Wright JD. (2008) Safety of Upper-Room Ultraviolet Germicidal Air Disinfection for Room Occupants: Results from the Tuberculosis Ultraviolet Shelter Study. *Public Health Reports* 123(1):52-60

Nigro F, Ippolito A, Lima G. (1998) Use of UV-C light to reduce Botrytis storage rot of table grapes. *Postharvest Biol Technol* 13(3):171-181

O'Donnell R, Boorstein ERJ, Cunningham RP, Teebor GW. (1994) Effect of pH and temperature on the stability of UV-induced repairable pyrimidine hydrates in DNA. *Biochem* 33:9875-9880

Oliver H, Moseley H, Ferguson J, Forsyth A. (2005) Clustered outbreak of skin and eye complaints among catering staff. *Occup Med* 55(2):149-153

Peng CY, Liu HH, Chang CP, Shieh JY, Lan CH. (2007) Evaluation and monitoring of UVR in shield metal arc welding processing. *Health Phys* 93(2):101-108

Roelandts R, Huys I. (1993) Broad-band and persistent photosensitivity following accidental ultraviolet C overexposure. *Photodermatol Photoimmunol Photomed* 9(4):144-146

Schmalwieser AW, Wright H, Cabaj A, Heath M, Mackay E, Schauburger G. (2014) Aging of low-pressure amalgam lamps and UV dose delivery. *J Environ Eng Sci* 9(2):113-124

Selma MV, Allende A, López-Gálvez F, Conesa MA, and Gil MI. (2008) Disinfection potential of ozone, ultraviolet-C and their combination in wash water for the fresh-cut vegetable industry. *Food Microbiol* 25(6):809-814

Shah CP, Weis E, Lajous M, Shields JA, Shields CL. (2005) Intermittent and chronic ultraviolet light exposure and uveal melanoma: a meta-analysis. *Ophthalmology* 112(9):1599-1607

Shehade SA, Roberts PJ, Diffey BL, Foulds IS. (1987) Photodermatitis due to spot welding. *Br J Dermatol* 117(1):117-119

Stevens C, Khan VA, Lu JY, Wilson CL, Chalutz E, Droby S, Kabwe MK, Haung Z, Adeyeye O, Pusey LP, Tang AYA. (1999) Induced resistance of sweet potato to *Fusarium* root rot by UV-C hormesis. *Crop Protection* 18(7):463-470

Talbot EA, Jensen P, Moffat HJ, Wells CD. (2002) Occupational risk from ultraviolet germicidal irradiation (UVGI) lamps. *Int J Tuberc Lung Dis* 6(8):738-741

Trevisan A, Piovesan S, Leonardi A, Bertocco M, Nicolosi P, Pelizzo MG, Angelini A. (2006) Unusual high exposure to ultraviolet-C radiation. *Photochem Photobiol* 82(4):1077-1079

Vajdic CM, Kricker A, Giblin M, McKenzie J, Aitken JF, Giles GG, Armstrong BK. (2004) Artificial ultraviolet radiation and ocular melanoma in Australia. *Int J Cancer* 112(5):896-900

Verma AS, Dwarika D, Bhola RM, Emamali S. (2007) Photokeratitis following the manipulation of aquaria disinfection lamps. *Emerg Med J* 24(3):232

Weinkauff B, Rukwied R, Quiding H, Dahllund L, Johansson P, Schmelz M. (2012) Local gene expression changes after UV-irradiation of human skin. *PLoS ONE* 7(6):e39411. doi:10.1371/journal.pone.0039411

Woods JA, Evans A, Forbes PD, Coates PJ, Gardner J, Valentine RM, Ibbotson SH, Ferguson J, Fricker C, Moseley H. (2015) The effect of 222-nm UVC phototesting on healthy volunteer skin: a pilot study. *Photodermatol Photoimmunol Photomed* 31(3):159-166

World Health Organization, WHO (1994) Environmental Health Criteria (EHC) 160: Ultraviolet radiation

Yel M, Güven T, Türker H. (2014) Effects of ultraviolet radiation on the stratum corneum of skin in mole rats. *J Rad Res Appl Sci* 7(4):506-511

Zaffina S, Camisa V, Lembo M, Vinci MR, Tucci MG, Borra M, Napolitano A, Cannatà V. (2012) Accidental exposure to UV radiation produced by germicidal lamp: case report and risk assessment. *Photochem Photobiol*, 88(4):1001-1004

ANNEX 1

Literature review on the biological effects of UV-C radiation relevant to health with particular reference to UV-C lamps

The purpose of the literature review was to assess the scientific literature papers to permit the assessment of the scientific evidence concerning the biological effects of UVR relevant to human health with particular reference to UV-C radiation and lamps.

Method

PubMed was used as the main database for searching. Since no MeSH heading includes the term 'UVC', the terms used in the searches are given in the table below (Table A.1), together with their results. The searches covered the period until 31 March 2016. Some of the publications included in the list of references have appeared in the results of more than one search terms combinations (lines in Table A.1).

The majority of the studies identified did not pertain to the work towards the current Opinion, i.e., they could not be used for risk assessment of UV-C lamps. The most common subjects of research were the disinfecting properties of UV-C radiation, its use in clinical practice and protective measures to reduce damage during exposure to it. Some studies were not used for risk assessment because it was not possible to differentiate between exposures to distinct ranges (UV-A, UV-B, UV-C) of the UV spectrum or they were lacking the corresponding dosimetry.

The studies on welders/welding were not systematically reviewed or considered, for the reasons mentioned in section 7.1.2. The same holds for the occupational risks of exposure to ozone.

Table A.1. Literature search terms and results (PubMed)

Search term	Total number of studies	Human studies	Number of references included
UVC radiation	1137	587	11
UVC light	1079	553	11
UVC exposure	421	211	8
UVC exposure occupational	14	13	4
UVC DNA damage	466	275	1
UVC skin	256	178	6
UVC skin cancer	114	84	1
UVC eye	27	14	3
UVC eye cancer	3	3	1
UVC risk	79	57	2
UVC risk occupational	5	5	1