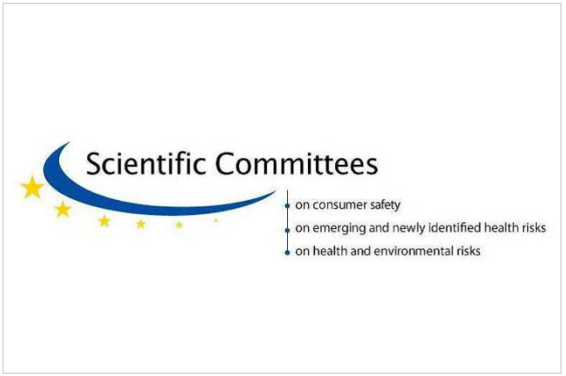
STANDARDIZATION COMMENTS ON SCENIHR DRAFT OPINION ON SUNBEDS.



Correlation of mandate questions, draft answers and standardization issues

Public hearing on the Preliminary Opinion 'Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes'.

Luxembourg, April 12th,2016

IEC TC61 / MT16 “Biological effects of optical radiation”

- **Since the 1980’s MT16 is a IEC standardization team in the technical committee for household appliances**
- **Based on the Dresden agreement there is no CENELEC body dealing with the same content**
- **Team contains and had contained:**
  - Radiation Protection Authorities (FIN, NOR, UK, FDA/USA)
  - Well known Photobiologists and Dermatologists (van de Leun, Cesarini, Fernandez, de Gruijl, Sliney)
  - Test laboratories (UL, TÜV)
  - Manufacturers (Philips, Hereaus, JK Holding, Cosmedico, Lighttech)

Our Mission:

Transfer the state-of-the-art scientific knowledge into safety requirements of UV appliances

We have followed the following values:

- **“A photon is a photon”**
- **A tan is a protective response of the human body for future exposures**
- **Photobiological effects either follow action spectra, have thresholds or have dose effects**
- **Sunbeds provide the same effects and risks as exposure to natural sunlight**
- **Sunbeds allow control of the UV exposure dose**
- **Risk factors can be addressed by clear and prominent displayed information to the user**
- **Let the user draw educated decisions**

We have introduce during the years:

- **Classification system for UV appliances**
  - based on what was on the market in 1980
  - Now used to address any risks due to spectral distribution
- **UV measurements**
  - Detailed procedure to find the point of maximum irradiance
- **Exposure schedule**
  - Controlled gradual increase of exposure doses always well below the erythemal threshold
- **Different weighting functions (erythema, NMSC)**
  - Non-Melanoma Skin Cancer action spectrum was THE indicator for long-term effects in the early 2000's, but has been withdrawn in the meantime
- **Irradiance limits**
  - Based on Bunsen-Roscoe-Law, as discussed in the SCCP report
  - 0.7 W/m2 erythemal weighted in 2005 (prior to SCCP, but never transferred to EU, due to the formal objection to the previous standard)
- **Lamp identification system X-Y-Code**
  - Easy identification system to check if the UV lamp fits to the appliance and does not exceed the original UV output

Warnings and instructions (I)

7 Marking and instructions

Appliances having **UV emitters** shall be marked with the substance of the following:

WARNING: Ultraviolet radiation can cause injury to eyes and skin, such as skin aging and eventually skin cancer. Read instructions carefully. Wear the protective goggles provided. Certain medicines and cosmetics may increase sensitivity.

NOTE 102 For appliances having **UV emitters** intended only for use in tanning salons, beauty parlours and similar premises, this warning may be given on a permanent label intended to be fixed on the wall adjacent to the UV appliance. The wording "Read instructions carefully" may be replaced by "Consult the attendant for further information".

Appliances having **UV emitters** with a luminance exceeding 100 000 cd/m² shall be marked with the substance of the following:

WARNING: Intense light. Do not stare at the emitter.

Warnings and instructions (II)

BS EN 60335-2-27:2013

60335-2-27 © IEC:2009(E) – 11 –

The instructions for appliances having **UV emitters** shall include the substance of the following:

– a statement that UV appliances are not to be used by

- persons under the age of 18 years;
- persons who tend to freckle;
- persons with a natural red hair colour;
- persons having abnormal discoloured patches on the skin;
- 〚C〉 persons having more than 16 moles (2 mm or more in diameter) on the body; 〈C〛
- persons having asymmetrical irregularly shaped moles larger than 5 mm in diameter with variable pigmentation and irregular borders; in case of doubt, seek medical advice;
- persons suffering from sunburn;

Warnings and instructions (III)

BS EN 60335-2-27:2013
60335-2-27 © IEC:2009(E) – 11 –

The instructions for appliances having **UV emitters** shall include the substance of the following:

– a statement that UV appliances are not to be used by

- **persons not able to tan at all or not able to tan without burning when exposed to the sun;**
- **persons that burn easily when exposed to the sun;**
- **persons having a history of frequent severe sunburn during childhood;**
- persons suffering from or previously suffering from skin cancer or predisposed to skin cancer;
- persons having a first-degree relative with a history of melanoma.
- persons under a doctors care for diseases that involve photosensitivity;
- persons receiving photosensitising medications.

Warnings and instructions (IV)

- a statement that if unexpected side effects, such as itching, occur within 48 h of the first session of using a UV appliance, medical advice should be sought prior to further UV exposure;
- a statement that exposures should not exceed the minimal amount of UV radiation exposure required to cause perceptible reddening of the skin (a person's minimal erythemal dose (MED);
- a statement that if skin reddening (erythema) is visible approximately 16 h – 24 h after any exposure, further exposure should cease. After one week, exposures may be restarted from the beginning of the schedule of exposure;
- information concerning the intended exposure distance (unless this is controlled by the construction of the UV appliance);
- recommended schedule of exposure specifying duration and intervals (based on the **UV emitter** characteristics, distances and skin sensitivity), see Annex DD;
- 〚C〉 recommended schedule of exposure specifying duration and intervals (based on the **UV emitter** characteristics, distances and skin sensitivity), see Annex DD and Annex ZB; 〈C〛

Warnings and instructions (V)

The instructions for appliances having **UV emitters** shall contain the substance of the following information and precautions:

– ultraviolet radiation from the sun or from UV appliances can cause skin or eye damage that may be irreversible. These biological effects depend upon the quality and quantity of the radiation as well as the skin sensitivity of the individual;

– the skin may develop sunburn after overexposure. Excessively repeated exposures to ultraviolet radiation from the sun or from UV appliances may lead to premature ageing of the skin as well as increased risk of development of skin tumours. These risks increase with increasing cumulative UV exposure. Exposure at an early age increases the risk of skin damage later in life;

– the unprotected eye may develop surface inflammation and in some cases damage may occur to the retina after excessive exposure. Cataracts may develop after many repeated exposures;

– in cases of pronounced individual sensitivity or allergic reaction to ultraviolet radiation, medical advice is recommended before starting exposure;

– the type reference of the protective goggles to be used

Warnings and instructions (VI)

– the following precautions must be taken:

- always use the protective goggles provided. Contact lenses and sun glasses are not a substitute for goggles;
- remove cosmetics well in advance of exposure and do not use any sunscreens or products that accelerate tanning;
- certain medical conditions or side effects of certain medicines may be aggravated by ultraviolet exposure. In case of doubt, seek medical advice;
- allow at least 48 h between the first two exposures;
- do not sunbathe and use the appliance on the same day;
- follow the recommendations concerning exposure durations, exposure intervals and distances from the lamp;
- seek medical advice if persistent lumps or sores appear on the skin or if there are changes in pigmented moles;
- protect sensitive skin parts such as scars, tattoos and genitals from exposure.

Warnings and instructions (VII)

- **What are the consequences of this warnings and instructions?**

- **Why does the draft not assess the warnings and instructions, while they are very relevant for the use of the sunbeds?**

- **Is there any risk not already expressed in the product standard?**

Review new science of the past decade relating to the exposure of people to UV radiation.

- **Following to the SCCP report in 2006 the standard on sunbeds has been immediately updated by an Adhoc WG of CENELEC to EN60335-2-27:2007 with:**
  - A reduction of erythemal irradiance to 0.3 W/m^2
  - An statement that persons under the age of 18 should not use UV appliances
  - A different limit for UVC of 0,003 W/m^2 unweighted irradiance below 280 nm (just above measurement noise)
  - A minimum tanning time of 10 minutes
  - A statement “As any exposure to UV radiation increases the risk of skin cancer, there is no safe value of maximal yearly dose, but it is recommended not to exceed 15 kJ/m2, weighted according to the erythemal action spectrum“
  - Rephrasing of other statements for persons who should not use UV appliances
    - persons suffering from sunburn
    - persons not able to tan at all or not able to tan without burning when exposed to the sun
    - persons that get burn easily when exposed to the sun
    - persons who tend to freckle
    - persons having more than 20 moles of any size on the body;
    - persons having atypical moles (atypical moles are defined as asymmetrical moles larger than 5 millimeters in diameter with variable pigmentation and irregular borders; in case of doubt, seek medical advice);
    - persons suffering from or previously suffering from skin cancer or predisposed to skin cancer
    - persons with family history of melanoma;
- **Why didn’t the draft assess the effects of these changes?**

UV limits of the world

Region	Max. Erythemal Irradiance [W/m²]	UVC limit [W/m²]	Max. Erythemal Dose [J/m²]	Annual Erythemal Dose [kJ/m²]
USA / FDA (current)	∞	0.3% of UVB	459 (recalc from CDRH spectra)	∞
USA / FDA (proposal)	∞	0.03 (200-290nm)	500-600	15
AUSTRALIA / NSZ	0.9	0.003	800	15
IEC	0.7	0.003	600	15
EN	0.3	0.003	600	15

The European Union already has the strictest limits on UV irradiance in the world.

Review new science of the past decade relating to the exposure of people to UV radiation. Is there new evidence?

- **Why are US or Australian studies used for an European evaluation?**
  - Both countries have very different regulations for sunbeds with much higher UV irradiance.
  - Both countries have a huge difference about the adaption of the population to their ambient UV environment

- **Why are studies used which did not subtract use of sunbeds by skin type I (always burn, never tan, excluded from sunbed use)?**

- **Why are studies used that have already been looked at by SCCP in 2006 and are based on much older appliances with different UV output?**
  - New UV appliances have been similar to natural sun since 1990, but with higher irradiance
  - Newest UV appliances are limited to 0.3 W/m^2 since July 2007

- **Why does the draft do not differentiate between pre-1990, 1990-2007 and post 2007 sunbeds used by the consumers?**

What are the key elements to consider?
How is the health of sunbed users likely to be positively or negatively affected?

- **The draft states:**

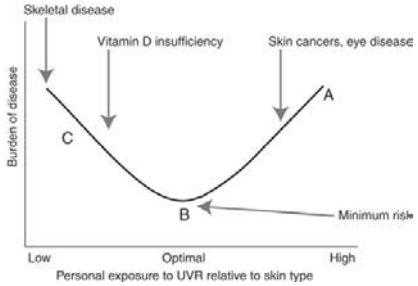
  „There is **no difference** in the **biological (and general health) effects** induced by UV radiation in respect to their origin, the natural **solar UV or artificial UV** from e.g. tanning devices.“

- **Why then didn’t the draft take into account the 2006 WHO report on health effects of UV radiation?**

  WHO: Global burden of disease from solar ultraviolet radiation, No. 13, 2006

- **When the mandate is asking for all key elements, isn’t it ultimately asking for the point of minimal risk (B)?**

Figure 2.1 Schematic diagram of the relation between ultraviolet radiation (UVR) exposure and the burden of disease



Points A and C represent inappropriate UVR exposure. Fair-skinned populations in Australia with high outdoor UVR exposure typify point A. Point C represents people with insufficient UVR exposure, whose dietary vitamin D intake will also be important in determining their vitamin D status. Point B represents optimal UVR exposure: a person with careful titration of correct UVR dose for skin type.

Lucas, RM and Ponsonby, AL. Ultraviolet radiation and health: friend and foe. MJA 177:594-598

- **Why does the draft only describes the skin cancer effect on the right side?**

What are the key elements to consider?
How is the health of sunbed users likely to be positively or negatively affected?

- **The draft states:**

  „During the last decade there is, furthermore, increasing evidence that **UVA (the main spectral component in usual tanning devices)** is at least as mutagenic as UVB.“

- **Why are the spectral components compared to the reference sun?**
  - Reference sun (30°northern latitude, June 21st, 12 a.m., clear sky): UVB / UVA = 4,1%
  - Usual tanning device: UVB / UVA = 0,9%

- **Natural sun varies a lot with latitude, time of the day, ozone and clouds:**
  - Luxembourg (50°northern latitude, June 21st, 12 a.m., clear sky): UVB / UVA = 3,5%
  - Luxembourg (50°northern latitude, June 21st, 3 p.m., clear sky): UVB / UVA = 3,0%
  - Luxembourg (50°northern latitude, August 21st, 4 p.m., clear sky): UVB / UVA = 2,1%
  - Luxembourg (50°northern latitude, August 21st, 4 p.m., light cloudy sky): UVB / UVA = 0,9%
  - Oslo (60°northern latitude, June 21st, 12 a.m., clear sky): UVB / UVA = 3,0%
  - Oslo (60°northern latitude, June 21st, 16 p.m., clear sky): UVB / UVA = 1,8%
  - Oslo (60°northern latitude, August 21st, 16 a.m., clear sky): UVB / UVA = 0,2%

- **Why is the UVA component of sunbeds stressed in the draft, when it is similar to natural European sun?**

Specify the limit values which adverse health effects can occur and reassess the limits set by SCCP in 2006.

- **Unfortunately the draft does not mention the limits from the standard correctly**

  - EN60335-2-27:2007 has adopted all requirements from SCCP and regained presumption of conformity with the European directives
  - The draft shows **classification limits for UV types** which do **not correspond to the standard**
  - The draft **shows IEC limit**s of household appliances and commercial appliances, which are not valid in Europe, **as European limits**
  - **No information or warning** directed to the user as introduced or updated following the SCCP report is **mentioned in the draft**

Specify the limit values which adverse health effects can occur and reassess the limits set by SCCP in 2006.

- **0.3 W/m^2, the maximum erythemal irradiance of European sunbeds has been set by SCCP in correspondence to Mediterranean sun on June 21st at noon**
  - Mediterranean sun (erythemal UVB = 0.18 W/m^2 and erythemal UVA = 0.12 W/m^2)
  - Not justified by Bunsen-Roscoe-Law (see SCCP draft)
  - But as a **precaution measure**:
    This is an irradiance people might know from their **lifetime experience**

- **Why does the draft not include any discussion or reassessment of this value?**

Specify the limit values which adverse health effects can occur and reassess the limits set by SCCP in 2006.

- **0.003W/m^2, limit for physical UVC has been set by CENELEC corresponding to the measurement accuracy of spectro-radiometers**
  - Sunbeds do not emit UVC since the 1990's
  - Nevertheless SCCP recommended correctly that sunbeds should not emit UVC
    - Who knows what UV emitting technology will be available in the future?
  - Therefore the CENELEC Adhoc WG has set a limit just above the noise level of typical laboratory measurement equipment (double monochromator)

- **Any discussion of changing this value is highly academic and has absolutely no impact on reality**

- **Why does the draft not reassess this value?**

Define the wavelength range for which the irradiance should be negligible to minimise the risk of developing skin cancer.

- **No such information in the draft**

- **Instead the draft states:**
  - “...there is ... no safe limit for any irradiance over the entire spectral range of UV radiation.”

- **Why does the draft not include any discussion or reassessment of the wavelengths?**

SCENIHR should rework the document completely.

- **To included current scientific knowledge**
  - Based on European population
  - Based on European sunbeds implemented into the market after 2007
- **To represent the WHO knowledge of a “U”-shaped disease burden**
  - Representing a photobiology view instead of a solely dermatology view
  - Identify the UV exposure for minimal risk
- **To answer the questions of the mandate**

LVD WG should not request any change in the product standard.

- **There should be scientific proof that the current product standard lacks any safety measure in:**
  - Radiation limits, thresholds, doses or wavelength areas
  - Information to the users
- **Member states should implement and enforce the current standard requirements for all sunbeds used in the market place**
- **EN 16489 should be implemented and enforced by all member states**
  - Part 1: Requirements for the provision of training
  - Part 2: Required qualification and competence of the indoor UV exposure consultant
  - Part 3: Requirements for the provision of services
- **The later two would really increase the consumer protection by providing them the best possible information to draw educated decisions for their skin**

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