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Comments, for the EU´s Scientific Committee on Consumer Products (SCCP) and it´s EC-secretariat, on the SCCP´s "Preliminary Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sun beds for cosmetic purposes".

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The prospect of EC-based recommendations for sun beds holds a lot of potential, but also certain risks. People in different countries of Europe live under different natural solar conditions and have acquired different susceptibilities to ultraviolet radiation. A European uniform recommendation or harmonized standard may give many benefits, but it should consider the differences of the countries, the susceptibility of their

populations and their consequential regulations on artificial sun tanning. Therefore it is important that any recommendations from the EC allow a fair amount of local adaptation of criteria. The Nordic countries, especially Norway, Finland, Iceland and Sweden, have fairly powerful legal tools for regulating sunbeds based on the EN 60-335-2-27. We are concerned that European harmonization, if based on a general acceptance of commercial sun beds twice as erythemally effective as the tropical sun and the level allowed so far in several countries, may lead to more lenient regulation and advice than have been adopted in the Nordic countries at the present and that the health risk for our population will increase.

With the document "UV-Radiation of Sun beds - Common public health advice from Nordic radiation protection and health authorities" published February 28, 2005, the Director Generals of the radiation protection and health authorities of the Nordic countries (Denmark, Finland, Iceland, Norway and Sweden) asked the Commission to initiate recommendations for the most significant UV-protection guidelines for sunbeds, and proposed that such recommendations should be based on advice given in the Nordic document.

The Nordic authorities advise in general against the use of sun beds for tanning. Young persons (below 18 years) and UV-sensitive people (skin type I-II) are strongly advised not to use sun beds. Specific advice, if sun beds are used, is the necessity to keep the annual UV-dose low. Furthermore the erythemally effective irradiance of a sun bed for tanning must from a Nordic perspective not exceed the irradiance of the tropical sun and the spectral distribution of the radiation should not differ too much from the that of the sun.

General comments:

We think the SCCP preliminary opinion document is well referenced in scientific matters and we agree with it´s Overall Conclusion.

Specific comments:

However we disagree on some crucial details and offer the following comments and conclusions with regard to:

1. a) Maximum irradiance level, b) minimum timer setting, c) skin type exposure schemes and d) annual UV-dose

a) *UV irradiance levels higher than the tropical sun from artificial tanning devices are not, under any circumstances, justifiable for the sole purpose of quick cosmetic tanning and will only increase the risk of skin damage as a consequence of small errors or misjudgements which are human or technical in origin. The erythemally effective irradiance of tropical regions is typically 0,3 W/m^2 and is of the order of 12 in terms of the global solar UV index.*

b) *The erythemally effective dose of the first tanning session must never exceed 100 J/m^2 (= 1 SED) to safeguard against any possible over-sensitivities. One SED over*

the SCCP´s five-minute minimum timer setting leads to a maximum allowed erythemal irradiance level (0,33 W/m^2) equivalent to a tropical sun.

c) *Dose considerations should focus on melanocompetent individuals in terms of how little UV is needed to tan rather than how much the skin tolerates before burning. This should be skin type specific, which will demand the studios to be attended.*

d) *As a precaution, it is wise to minimize annual UV-doses as much as possible. It is important to try to change attitudes to tanning in order to limit all unnecessary UV exposure.*

2. Need for spectral composition information

It is necessary to retain a mandatory UV-type classification system using short and longwave UV bands and to label tanning appliances accordingly to inform of their different spectral and UV-power levels. So far the UV-types have worked well to meet conflicting interests of the industry and national health authorities.

3. Stochastic dose, exposed skin area and dose in a population

Taking the exposed skin area into account for a population UV-dose could make sunbeds rival the sun.

4. Updates on some matters concerning the standards

Changes of the IEC-standard IEC60335-2-27 influences the corresponding EN-standard EN60335-2-27. Several developments already finalised in the IEC-standard are not reflected by the SCCP-document, e.g. change of action spectrum. and maximum limit for total effective irradiance.

5. Applicability of the overall conclusion

We think the SCCP´s overall conclusion raises questions of sunbeds justifiability and if sunbed products do fit within the basic safety considerations of the LVD and the family of safety EN-standards.

Rationale for our specific comments are given in Appendix 1.

Background, illustrations and graphic description of the UV-types are given in an Addendum of section 2 of the Appendix.

APPENDIX 1

Rationale for our specific comments (numbered in the same order):

1. Maximum irradiance level, minimum timer setting, skin type exposure schemes and annual UV-dose.

The level of sunbed irradiance is perhaps the most controversial issue, and in practice the vital part of the SCCP-document. However, the SCCP-recommendation of a maximum level, equivalent to roughly twice the erythemally effective irradiance of a tropical sun, is based on judgement rather than science or technical considerations. From a Nordic perspective we think it would be a mistake to accept a max-level twice the tropical sun.

The advice of the Nordic authorities state that it is prudent "to keep the intensity and spectral distribution of artificial UV reasonably close to levels of solar UV-exposures." It is also stated that sunbeds must not be too powerful to minimize "risk of skin damage as a consequence of small errors or misjudgements which are human or technical in origin." The latter statement as well as sunsimilarity regarding UVB/UVA ratio is in agreement with arguments of the SCCP. However, the judgements differ as to what might be a reasonable maximum level as well as how to define sunsimilarity (see also 2).

Crucial in the SCCP-document is the recommendation (p 21, 26) for a minimum timer setting of 5 minutes for a tanning session and the max dose of 1 MED for a sun-sensitive normal skin (type I-II) recommended in that time. This implies a maximum of 0,7 W/m^2 erythemally weighted irradiance (i.e. 1 MED = 210 J/m^2), i.e. a max level of UV-index 28, or more than twice the erythemal strength of the tropical sun.

There are compelling arguments against such a high irradiance level (0,7 W/m^2).

1st:
IEC and CENELEC has so far in its sunbed standard recommended that the erythemally effective dose of the first tanning session must never exceed 100 J/m^2 = 1 SED to safeguard against any possible over-sensitivities and photosensitivity caused by commonly used pharmaceuticals e.g. some contraceptives. The IEC first session max dose (100 J/m^2) over the SCCP´s five-minute minimum timer setting leads to a max allowed erythemal irradiance level (0,33 W/m^2) equivalent to a tropical sun. This would be in agreement with "UV-type 3" and present regulations in several countries.

2nd:
There also are technical reasons for a longer minimum timer setting of a regular tanning session. Most tanning appliances need five minutes to stabilize their UV-emission during warm-up after start. Some slowly increase the output to a stable condition. Others during their first minutes have an emission-peak that exceeds later stable conditions more or less. In some cases output emission more than doubles during the first minutes (Holtschmidt, Quintern 1999). It depends on changing optical properties of lamps and filters, but also on cooling etc. However, dosage schemes and recommended exposure times are based on measurements during stable conditions.

3rd
Exposure schedules of tanning appliances and annual dose recommendations should focus on how little UV that is needed to acquire a desired tan for those persons with skin types who tolerate UVR well, rather than how much persons with sensitive skin types need to get a tan. The Nordic advice document recommends to keep the annual UV dose as low as possible.

The overall conclusion of the SCCP, WHO, etc - as well as of the Nordic authorities - is that persons with skin types I-II should not use sunbeds! For "melanocompromised" persons (with skin type I-II) the erythemal dose (MED) and the dose needed to initiate tanning is almost the same (Parrish et al 1982, Park et al 1984). That leaves us with the rest, i.e. "melanocompetent" persons who have "higher" skin types (e.g. III-IV). The MED for these persons are higher than for the skin types I-II. However, they tan with less! (Parrish 1982, Park et al 1984). They don´t need a MED to tan - neither the MED of skin types I-II during the first session nor the higher MED of their own skin types (III-IV) during any subsequent session! This is more pronounced with longer wavelengths which result in immediate pigment darkening rather than delayed pigmentation. For broadband UVA the pigmenting dose is approximately one quarter of the erythemogenic dose in skin type III-IV individuals (Park et al 1984).

Presently a UV-expert group of the International Electrotechnical Commission (IEC, TC61, MT16) is revising principles of tanning exposure schemes which are to be required for appliances complying with future editions of IEC´s sunbed standard IEC60335-2-27. The revised schemes are to be based on "how little UV that is needed" to tan, rather than "how much UV that is tolerated" before burning.

2. Spectral composition

The SCCP reports no need to specify separate wavelength bands for irradiance or dose and advocates total erythemally weighted UVR as a more appropriate way to speak of tanning devices. This contrasts with the view of the Nordic authorities which state that "the spectral distribution of the radiation should not differ too much from the tropical sun" and that the "irradiance and spectral distribution should be in accordance with UV type 3 appliances specified in the current standard EN 60335-2-27".

The erythema action spectrum is not necessarily relevant for photobiological effects other than erythema.

Spectral characteristics, dosages and power levels of sunbed products vary significantly. As the relative importance of short and long UVR wavelengths for melanoma skin cancer and immunosupression is still unknown, it is necessary to retain a UV-type classification system using short and longwave UV bands and to label tanning appliances accordingly to inform of their different spectral and UV-power levels. As stated in the SCCP document one approach is to strive for sunsimilarity and keep limits for long and short wavelengths not too different from tropical sun. In a Nordic initiative criteria for sunsimilarity have been proposed (Wester et al. 2001).

Addendum:

Until the late 1960´ies sunlamps were small inexpensive mostly facial devices with mercury-quartz medium-pressure gas discharge bulbs emitting mainly UVB-radiation, but often also UVC. In the 40´ies and 50´ies sunlamps sometimes had been recommended for health reasons to expose certain groups at risk for vitamin D deficiency (school children, miners). However greater variety of available foods, more varied diets and foods fortified with vitamin D made such applications superfluous. Instead sunlamps were used for tanning. In the 60´ies and 70´ies, panels with multiple mercury-quartz lamps appeared on the market for home use as "solariums" (Fig.1, "#4"). Exposure distances were critical, and so were exposure times which were short, a few minutes up to a maximum of 10-15. Acute skin burns were common due to misjudged exposure time or –distance, world-wide wherever sunlamps were used. E.g. every year in the US an estimated 10 000 people burned themselves severely enough under sunlamps to require emergency hospital treatment (FDA 1976). Both erythema and tanning was induced by UVB – already at that time considered a carcinogen in sunlight, in contrast to UVA that was thought to be harmless. The US was the first country to regulate sunlamps to some extent by requiring timers and by limiting a UVC/UVB ratio.

Tanning by UVA was not well known or feasible. However new photobiological research resulted in new types of tanning machines which emitted mainly UVA - and with intensities previously not achievable.

In fair-skinned Caucasians who tan poorly (skin types I and II), doses of UVA which result in tanning are similar to those resulting in erythema. In contrast, individuals who are more competent tanners (skin types III and IV) develop pigmentation from suberythemogenic doses of UVA. The pigmenting dose of broadband UVA is approximately one quarter of the erythemogenic dose of UVA in such individuals (Park et al 1984).

Sun beds with mainly UVA-emitting low-pressure fluorescent tube lamps appeared on the market in the late 1970´ies (Fig. 1, "#3"). These had a UVB-content around 1 % - less than in the sun. However the total UV-irradiance could be 3-4 times the solar UV. Therefore UVB-levels were comparable to summer sun. However the UVA fluorescent tube solariums were at their time of introduction thought to be a safer way of tanning than with the quartz lamps.

Also high-intensity tanning appliances with UVA-emission from filtered high pressure metal halide gas discharge lamps appeared. Such whole-body canopies, consuming more than ten kW of electric power, can emit pure UVA-1 radiation (340 – 400 nm) twenty times more intense than in sunlight (Fig.1, "#1"). One such tanning session would give an almost immediate tan by "immediate pigment darkening" (IPD). The high UVA-intensities, however, raised questions about risks due to possible over-sensitivities – especially from cosmetics and medicines.

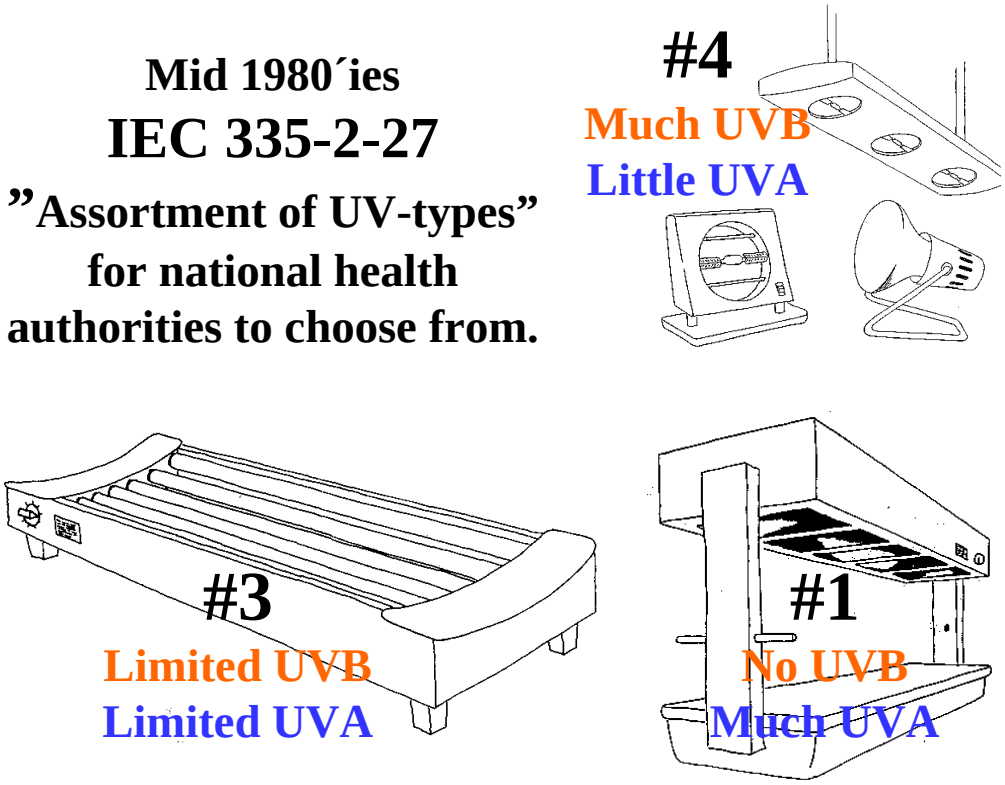

Figure 1. *Different kinds of tanning appliances.*

In Scandinavia quartz sunlamps as well as high intensity UVA appliances were banned 1982-83. Regulations favored the UVA-fluorescent tube type sun beds as these deviated least from the sun as compared to the other types.

As countries introduced regulations or recommendations for certain tanning devices, and as these regulations could vary, IEC-standardisation initiatives in the mid 1980´ies categorized tanning appliances into an assortment of “UV-types” with defined spectral- and power level characteristics (Fig.2). The purpose of the categorization system was to meet the interests of both the industry, that wanted to manufacture products within the frames of one universal standard, and of national health authorities, which wanted to regulate, require licenses for, or exclude the use of some UV-types, thought to be specifically hazardous, in tanning studios. So far the UV-types have worked well to meet conflicting interests of the industry and national health authorities. Possibly a future categorization system needs a higher degree of flexibility to meet both varying new authority demands and industry interests of a uniform standard that within one frame offers different options with specified requirements.

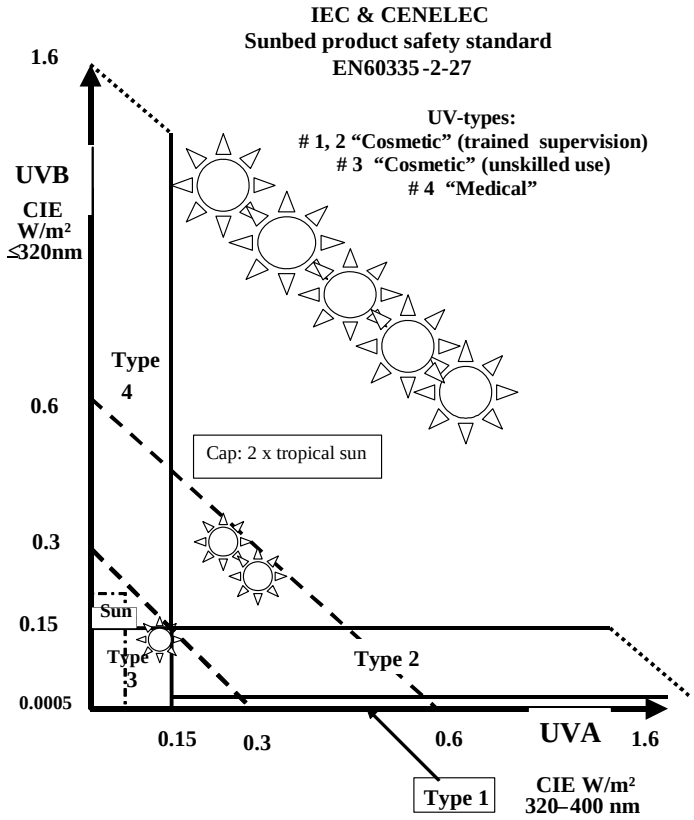

Figure 2. *Graphic representation of the distribution of short- and longwave UV-radiation for the four UV-types of the sunbed standard EN60335-2-27:1997.*

<u>Detailed explanations of Figure 2</u>: Only radiation values within the square of solid lines marked "Type 3" (lower left corner) are allowed for commercial sunbeds in the Nordic countries Sweden, Norway, Finland and Iceland. The alone sunsymbol represents maximal total biologically effective UV-radiation of both UVA and UVB-emissions of a UV-type 3 sunbed that is equivalent to the erythemally effective irradiance level of the equatorial sun (UV-index 12). France has the same limits (UV-type 3), but with an added requirement to safeguard against too high UVB-content. Spain has, regardless of spectral distribution, a total limit of erythemal effective irradiance equivalent to the tropical sun (lower inclined dashed line). The small dotted-dashed rectangle at the lower left corner represents the actual distribution of UV-radiation in sunlight. The EN-standard of 1997 intended UV-type 4 appliances to be used "following medical advice". (Very UVB-strong devices specially made for home-treatment of psoriasis also are type 4.)
IEC presently designates UV-type 3 sunbeds as "Household appliances" and all other types as "Commercial" with a defined cap for sunbed irradiance levels 2x the tropical sun.
New versions of the IEC-standard and probably also of the EN-standard will use a CIE non-melanoma skin cancer action spectrum for categorization instead of the CIE erythema action spectrum (CIE 2005). Limit values in the IEC-standard have been recalculated to minimize practical consequences of that change.

There is another implication of the specific preliminary SCCP-opinion that spectral composition of the radiation weighted with the erythema action spectrum does not need to be taken into account. (The wavelength dependent factors of relative spectral efficiency ranging from 1,0 to 0,00012 of the CIE reference action spectrum for erythema are listed in Appendix of the SCCP-document.)

The low UVA weighting factors may lead to absurd consequences - although seemingly hypothetical – if applied for tanning with sunbeds which emit a narrow UVA spectrum rather than a broad spectrum of UVR. I.e. when a sunbed functions with extremely longwave UVA-radiation and has an effective irradiance higher than the tropical sun´s. Theoretically it would be acceptable to design a tanning apparatus with monochromatic UVA-irradiance that may emit intolerably high levels of radiation. For the monochromatic wavelength of 400 nm it takes a real (unweighted) irradiance level of almost 6 kW/m^2 to achieve an erythemally effective irradiance of 0,7 W/m^2. In comparison, solar global irradiance, summed over all optical wavelength bands (UV+Visible+IR), only amounts to a little more than a tenth of that intensity at the surface of the earth. In five minutes such a monster solarium would deliver an uncomfortably high radiation load of 1,8 MJ/m^2 to one´s skin - and perhaps even might have the capacity to incinerate people into ashes rather than tan them!

3. Stochastic dose, exposed skin area and dose in a population

Exposed skin area should be taken into account for any stochastic dose considerations – especially when comparing sunbed exposures with exposures from the sun or from other possible UV-sources.

Modern “clam-type” tanning beds and canopies generally expose more of one´s skin area to UV-radiation than it would be in most outdoor situations, therefore increasing the health risk (WHO 2004, Wester et al. 1999). It has been estimated that taking the skin area into account ups the sunbed exposures by a factor 2-10 in such comparisons. For a population UV-dose this could make the sunbeds rival the sun (Wester et al 1999).

Proportionality of skin area exposure and total number of DNA-damages has been demonstrated. Exposing one´s skin in clam-type tanning appliances simultaneously to both the canopy and the bed instead of only to one of these parts, doubles one´s skin DNA damages. This has been found from measuring the rest products of the damaged DNA found in urine after the exposure and using UV-dosimetry techniques based on thymine-dimer measurements (Kotova et al 2005).

These facts might help explain the epidemiologic findings that sun bed use increases the squamous cell carcinoma risk and is likely to increase the risk of malignant melanoma.

4. Updates on some matters concerning the standards:

Changes of the IEC-standard IEC60335-2-27 influences the corresponding EN-standard EN60335-2-27. Several developments already finalised in the IEC-standard are not reflected by the SCCP-document, e.g. change of action spectrum etc.

a) In the SCCP-document (page 26, question 5) it is said that "This weighting should be done with the human erythema action spectrum, which is similar to the tanning action spectrum". In the IEC standard the erythema action spectrum is used only for acute effects (to determine first tanning session) and in future in lamp coding. For long term effects (annual dose and UV type classification) and in lamp coding the non-melanoma skin cancer action spectrum is used.

A recent amendment to the IEC-standard (A1:2004) has replaced the CIE erythema action spectrum with the CIE´s non-melanoma skin cancer action spectrum split into two wavelength bands for calculation of acceptable annual dose and for categorization purposes. The erythema action spectrum remains for calculation of 1st exposure and for exposure schedules.

b) The 5-nm wavelength step in the SCCP´s Appendix A is not OK. The present IEC- and EN-standard require spectral measurements in 1 nm increments by means of a spectroradiometer having a bandwidth not exceeding 2.5 nm. Further revisions of the required measurement procedures are being considered for future editions of the IEC-standard by the IEC TC61 UV-expert group MT16.

5. Applicability of the overall conclusion

The overall conclusion of the SCCP is that artificial tanning equipment is likely to increase the risk of all kinds of skin cancers including malignant melanoma if such equipment is used to achieve or maintain a tan for cosmetic reasons. A logical consequence is that the use of cosmetic sunbeds should be discouraged.

The physical agent of artificial tanning equipment is ultraviolet radiation. A basic and internationally accepted principle in the field of radiation protection is that any practice involving radiation must be justifiable (ICRP 1991). Clearly, the justification of sunbeds for sole cosmetic purposes is questionable.

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