



# The European Commission's non-food Scientific Committees



**DG SANTE – Country Knowledge and Scientific Committee  
Unit**



# **SCENIHR Opinion: Biological effects of UV radiation relevant to health with particular references to sunbeds for cosmetic purposes**

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# Health effects of UV radiation from sunbeds: Background to the Mandate

- Commission became aware of growing concern expressed by medical and scientific experts regarding high risk of developing skin cancer and other skin-related diseases from frequent sunbed use.
- IARC classification of UV radiation from sunbeds and sunlamps as Group 1 (definite human carcinogen)
- European Code against Cancer: recommendation of the revised Code relates to UV radiation and clearly suggests not using sunbeds at all
- Scientific Committee on Consumer Products (SCCP) provided an opinion for the EU in 2006



# Legal and Enforcement Background

- *Health & safety hazards of sunbed use determined by:*
  - the safety of the sunbed itself and compliance with existing applicable legislation and manufacturing standards
  - the use (or misuse) of the product by the consumer
- *EU legal framework aims to minimise risks of sunbeds themselves regarding intensity of UK radiation omitted, voltage, product safety etc.*
- *More recently some EU countries have adopted national legislation including ban below age limit of 18 years*



# Terms of Reference

1. Does new (last decade) scientific and medical evidence significantly impact on the conclusion of the previous SCCP Opinion of 2006 with regard to the general health and safety implications relating to the exposure of people to UV radiation (UVR)?

If **Yes**: what are the key elements to be considered and how is the health of users of tanning devices for cosmetic purposes (sunbeds) likely to be affected (both positively e.g. Vitamin D regulation and negatively, e.g. skin cancers and ocular melanoma).



## Terms of Reference

2. *Does SCENIHR uphold the SCCP (2006) assessment that the limit value of the Erythemally-weighted irradiance of 0.3 W/m<sup>2</sup> (equivalent to UV 12 index) ensures sufficient levels of protection for the health and safety of users? If not:*
  - Is it sufficient just to provide this information to users?or
  - Specify limit values above which adverse health effects can occur.
3. *What wavelength range for total Erythemally-weighted irradiance (e.g. <0.003 W/m<sup>2</sup>) should be set to minimise risk of developing skin cancer due sunbed use*



# Exposure

- *Large variation in UV output in different machines*
  - Tendency for higher UVA in more recent machines
  - UV emission of modern tanning appliance can be equivalent to midday topical sun (UVI 12)
- *EU surveys of Member States show:*
  - Consumer guidance in tanning studios not regularly given
  - Labelling of sunbeds fails to comply at least 20% of the time
  - Violation of the maximum UVA levels of sunbeds varies between 10-90% between Member States
- *Prevalence of sunbed use also varies:*
  - by EU state – higher in N European Caucasians
  - Age/sex – young/middle-aged women
  - Over 30% 'ever used' sunbed, approx. 20% adolescents



## Health Effects: Non-cancer

- Although UVB emitted from sunbeds can induce vitamin D production, there is evidence that excess exposure leads to photodegradation of Pre-Vitamin D3 in the skin
- UVA/B has immunosuppression effect (skin+systemic)
- UVA/B exposure enhances skin aging, and damages collagen and elastin
- Some people have UV exposure seeking behaviour (addictive?) – perceived positive influence on mood





## Health Effects: cancer

- Consistent evidence of significantly increased risk associated with sunbed use for Cutaneous malignant melanoma and squamous cell carcinoma:
  - Adjustment for individual susceptibility and sun exposure
  - Risk increases with increasing sessions/frequency
  - Risk increased with first exposure at younger age
- Similar but weaker findings for Basal cell carcinoma
- Generally no association with other cancers or all cancers taken together
- Increased ocular cancer risk with sunbed use



## Mechanistic studies

- UV-radiation (UVC, UVB and UVA) of solar origin as well as from tanning devices is a full carcinogen (involved in initiation, promotion and progression of skin cancer) and known as carcinogenic to humans (Group 1, IARC)
- In-vitro studies as well as in-vivo studies (animal, humans) have shown that UVA and UVB are involved in human skin photocarcinogenesis
- UVB and UVA signature mutation patterns could be identified (UVA and UVB equally involved in damage and mutation induction)
- UV-signature mutations have been found in wide range of genes (including driver genes for MM, and NMSC) involved in photocarcinogenesis
- Epigenetic changes can be introduced via UVA and UVB



## Risk attributable to sunbed exposure

- *Estimates of melanoma attributable to radiation from sunbeds in Europe (EC15 + EFTA3):*
  - Melanoma Incidence (new registrations)
    - ☐ ≈ 3500 (5.4%) (≈ 2350 (6.9%) women)
  - Melanoma deaths
    - ☐ approx 500 women, 300 men



## Terms of Reference

1. Does new (last decade) scientific and medical evidence significantly impact on the conclusion of the previous SCCP Opinion of 2006 with regard to the general health and safety implications relating to the exposure of people to UV radiation (UVR)?

If **Yes**: what are the key elements to be considered and how is the health of users of tanning devices for cosmetic purposes (sunbeds) likely to be affected (both positively e.g. Vitamin D regulation and negatively, e.g. skin cancers and ocular melanoma).



## Response to Reference Term 1

- I. No difference in biological (and general health) effects induced by UV-radiation from the sun or tanning devices imitating the natural spectrum.
- II. UV-radiation from the sun and from tanning devices is classified by IARC (2009) as carcinogenic to humans (class 1, IARC).
- III. Increasing evidence that UVA (main spectral component in usual tanning devices) is at least as mutagenic as UVB.
- IV. UV radiation introduces specific mutations in human genes which drive induction and development of skin cancer.



## Response to Reference Term 1 ctd

- V. UV-radiation also causes epigenetic alterations, which act in concert with genetic lesions to lead to skin cancer.
- VI. Evidence that UV-radiation is a main risk factor for ocular melanoma
- VII. Although the UVB radiation emitted from sunbeds can induce vitamin D production the consensus is that tanning devices are not needed to enhance vitamin D status.  
Short (minutes to half of an hour) daily exposures to solar UV of unprotected (e.g. no sunscreens applied) face and hands have been shown to build up and restore sufficient levels of vitamin D.



## Response to Reference Term 1 ctd

- VIII. Immune-suppressing effects of UVB and more recent evidence for immune suppressive effect of UVA in the wavelength range from 350 – 390 nm
- IX. Exposure to UVA and UVB contribute to photoaging
- X. Consistent evidence of significantly increased risk (adjusted for confounding factors) associated with sunbed use from cutaneous melanoma and squamous cell carcinoma and to a lesser extent for basal cell carcinoma.
- XI. Dose-response with increasing number of sessions and increasing frequency of use for melanoma and SCC
- XII. Increased risk with sunbed use at early ages
- XIII. Estimated 5.4% of incident melanoma cases in Europe may be related to sunbed use



## Terms of Reference

2. *Does SCENIHR uphold the SCCP (2006) assessment that the limit value of the Erythemally-weighted irradiance of 0.3 W/m<sup>2</sup> (equivalent to UV 12 index) ensures sufficient levels of protection for the health and safety of users?*

Due to:

- I. the carcinogenic effects of sunbed UV exposure,
- II. the nature of skin cancer induction
- III. no known threshold levels of UV-irradiance and UV-dose

No limit value of either irradiance or dose (irradiance x time of exposure) can be given to ensure protection for the health and safety of the users of tanning devices.



## Terms of Reference

3. *What wavelength range for total Erythemally-weighted irradiance (e.g.  $<0.003 \text{ W/m}^2 \approx 1\%$  maximal irradiance in a tanning device;  $0.3 \text{ W/m}^2$ ) should be set to minimise risk of developing skin cancer due sunbed use*
  - I. International agreement: contribution of UVC (100-280 nm) should be less than  $0.003 \text{ W/m}^2$  in a tanning device.
  - II. DNA molecules in cells absorb UV-radiation with maximal efficacy at wavelength of 254 nm which leads to high rates of mutagenicity and cell death.
  - III. Reducing the UVC irradiance level to below  $0.003 \text{ W/m}^2 \neq$  “safe” irradiation from a sunbed; with almost complete absence of UVC, there is still the carcinogenic effect of UVB and UVA
  - IV. Since there is no threshold for adverse long-term health effects, there is therefore also no safe limit for any irradiance over the entire spectral range of UV radiation.



# SCENIHR Overall Conclusions

- UV is a complete carcinogen; UV acts as
  - An initiator, through genotoxicity
  - A promoter, through immunosuppression
- Strong, consistent evidence that UV radiation from use of sunbeds causes
  - Skin melanoma
  - Squamous cell carcinoma
  - Basal cell carcinoma (less evidence)
- Moderate evidence that sunbed use may also cause ocular melanoma
- SCENIHR concurs that there is no need to use sunbeds to induce Vitamin D



# SCENIHR Summary Conclusion

Due to the evidence of:

- Carcinogenic effects from sunbed exposure,
- Nature of skin cancer induction
- No indication of a threshold effect

there is therefore also no safe limit for any irradiance over the entire spectral range of UV radiation.



**Thank you for listening**