

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

Request for a scientific opinion: Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes

1. Background

In recent years, the Commission has become aware of growing concerns expressed by various medical and scientific experts who have concluded that people who use sunbeds frequently have a higher risk of developing skin cancer and other skin-related diseases. In our mission to protect the health and safety of users of such devices, we would like to have a better understanding of risks associated with UV radiation in general and with sunbeds in particular.

A. Scientific Background

The fourth edition of the European Code against Cancer¹ was recently presented to the public and is the result of a project co-financed by the European Union and coordinated by the International Agency for Research on Cancer, a specialized cancer agency of the World Health Organization. The code informs people about actions they can take to reduce the risk of cancer. One of the twelve recommendations of the revised Code relates to UV radiation and clearly suggests not using sunbeds at all. This recommendation is based on evidence from epidemiological studies, established causal mechanisms, the increasing skin cancer burden in the mostly fair-skinned European populations, and the modifiability of the risk factor by individual action, acknowledging also the beneficial effects of sunlight such as vitamin D production. Further detailed information is presented in the **Scientific Justification which underpins The European Code against Cancer** (to be disclosed to the general public by the end of 2014).

B. Legal & Enforcement Background

The health and safety hazards associated with the use of sunbeds are determined by two key elements: a) the safety of the sunbed itself (and its compliance with existing applicable legislation and manufacturing standards), and b) the way in which the product is used (or misused) by the consumer – this depends greatly on the knowledge of the consumer and on the information and advice given to the user by the tanning service operator².

At EU level, a legal framework exists that aims at minimising the risks posed by sunbeds themselves, e.g. as regards the intensity of the UV radiation emitted. The placing on the market of sunbeds is regulated by Directive 2006/95/EC³ on electrical equipment designed for use in certain voltage limits.. If they consist of linked parts or components at least one of which moves, their placing on the market and/or putting into service is regulated by Directive 2006/42/EC⁴. It is noted that for electrical hazards, the safety objectives of the Low Voltage Directive are applicable also to machinery. These two Directives, which fall under the responsibility of Directorate General for Enterprise and Industry, are

¹ <http://cancer-code-europe.iarc.fr/index.php/en/>

² The requirements for information to be provided to consumers are different, depending on national legislation in each Member State.

³ Directive 2006/95/EC on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits, OJ L 374, 27.12.2006, p. 10. As of 20 April 2016, it will be replaced by Directive 2014/35/EU (OJ L 96, 29.03.2014, p. 357).

⁴ Directive 2006/42/EC on machinery and amending Directive 95/16/EC (recast), OJ L157, 09/06/2006, p. 24.

full harmonisation Directives and aim at ensuring that equipment, if within their scope and complies with the legal requirements, both provides a high level of protection and moves freely in the European Union. Lastly Directive 2001/95/EC⁵ on General Product Safety applies, whenever the Low Voltage Directive and the Machinery Directive are not applicable, requiring that products intended for consumers or likely to be used by them, including in the context of a service, must be safe (throughout the lifetime of the product). The General Product Safety Directive falls under the responsibility of Directorate General for Health and Consumers. Member States authorities responsible for the enforcement of these Directives have the obligation to carry out controls to ensure compliance by relevant economic operators.

The relevant European standard EN 60335-2-27:2010⁶, which is a voluntary harmonised standard under Directive 2006/95/EC, but if it is applied it provides a presumption of conformity with the safety objectives, takes into account the recommendations of the 2006 Opinion of the Scientific Committee for Consumer Products on biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes⁷.

In recent years some Member States have adopted national legislation regulating the tanning services (including for example a minimum age set at 18 years, the need for proper health and safety information, stricter hygiene conditions, the need for properly trained staff, etc.). These measures, when properly enforced, can ensure that tanning studios act more responsibly and that there is a better level of protection for consumers who choose to use these devices.

In 2008-2009, ten market surveillance authorities from ten European Union Member States have participated in a cross border action to enforce the safety requirements for sunbeds and sunbed services⁸. During the action, tanning salons and similar facilities were inspected, as well as the sunbeds offered there for use to the general public. The overall conclusions from the results of the inspections in this action on sunbeds is that Consumer guidance in tanning studios is not regularly given and, where it is claimed to be given this is often not verifiable. Moreover, the labelling of the sunbeds fails to comply in at least 20% of the cases. In addition, how often the maximum values for sunbeds are violated varies between the Member States. In several Member States the percentage may be above 90%, while in others the percentage of sunbeds not complying is estimated to be between 10% - 20%.

⁵ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety, OJ No L 11 of 15 January 2002

⁶ EN 60335-2-27:2010: Household and similar electrical appliances - Safety - Part 2-27: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation (IEC 60335-2-27:2002, modified + A1:2004, modified + A2:2007, modified)

⁷ http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_031b.pdf

⁸ http://europa.eu/rapid/press-release_MEMO-10-37_en.htm?locale=en

2. Terms of reference

In view of new medical evidence and the development of science and technology over the past decade, including the Scientific Justification which underpins The European Code against Cancer and in particular the recommendation on UV radiation, the SCENHIR is asked to reassess the safety risks associated with the use of sunbeds and to provide an answer to the following questions:

- 1. Does new scientific and medical evidence (collected over the past decade) have a significant 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 and ocular melanoma).*
- 2. Does SCENIHR uphold the assessment of the SCCP that the limit value of the Erythemally-weighted irradiance of 0.3 W/m^2 (equivalent to an UV index of 12) ensures sufficient levels of protection for the health and safety of users? If this is not the case, please specify if it is sufficient to give specific information. If it is not sufficient to provide information, please specify the limit values above which adverse health effects can occur.*
- 3. What should be the wavelength range for which the total Erythemally-weighted irradiance should be negligible (e.g. under 0.003 W/ m^2) to minimise the risks of developing skin cancer due to the use of sunbeds?*

Deadline: December 2015