

Appendix: European and international positions regarding artificial sources of UV radiation

Establishment of a standard for appliances designed specifically for tanning purposes

Appliances designed specifically for tanning purposes are defined in the international standard prepared by the International Electrotechnical Commission (IEC 60 335-2-27). This standard was first established in 1985 (IEC, 1987) and slightly modified in 1989 (2nd edition; IEC, 1989), in 1995 (3rd edition; IEC, 1995) and in 2002 (4th edition; IEC, 2003). The USA follow the recommendations of the Food and Drug Administration (US FDA, 1985), which were recently updated (Lim *et al.*, 2004; US FDA, 2004).

According to the 3rd edition of the IEC standard, appliances emitting UV radiation must belong to one of the types described below:

- Type UV-1 appliance: appliance with a UV source such that the biological effect is triggered by radiation wavelengths >320nm, and which is characterized by relatively high irradiance efficiency in the range 320–400nm.
- Type UV-2 appliance: appliance with a UV source such that the biological effect is triggered by radiation wavelengths above or below 320nm, and which is characterized by relatively high irradiance efficiency in the range 320–400nm.
- Type UV-3 appliance: appliance with a UV source such that the biological effect is

triggered by radiation wavelengths above or below 320nm and which is characterized by restricted irradiance over the entire range of UV radiation.

- Type UV-4 appliance: appliance with a UV source such that the biological effect is triggered primarily by radiation wavelengths <320nm.

Table I shows the physical characteristics of the appliances.

According to the standard, "the appliances must not be toxic or represent similar hazard. The appliances emitting UV radiation must not emit radiation in dangerous amounts and their irradiance efficiency must be within the values specified in Table [I]". In addition, the standard states that the verification of conformity must be performed by 1) determining the ageing of the appliance before measurement and 2) respecting a distance of 0.3m.

The guidelines recommend that the exposure time for the first session on untanned skin should correspond to an effective dose not exceeding 100 J/m²; this is approximately equivalent to 1 MED for subjects with sun-reactive skin type I. The annual exposure should not exceed an effective dose of 25 kJ/m² (IEC, 1989).

Although these guidelines form the basis of several national standards on the use of tanning appliances, it should be noted that variations exist; for example, in the Netherlands, Norway

Table I. Type of UV appliances according to their irradiance efficiency

Type of UV appliance	Irradiance efficiency in W/m	
	250 nm < λ < 320 nm	320 nm < λ < 400 nm
1	< 0.0005	≥ 0.15
2	0.0005 to 0.15	≥ 0.15
3	< 0.15	< 0.15
4	≥ 0.15	< 0.15

λ , radiation wavelength

and Sweden, certain UV appliances are not permitted. Regulations concerning the use of tanning appliances are in force in only a few countries, but many others have published advice on their use, including information on adverse effects, as well as guidelines on manufacturing standards.

In 2004, amendment 1 (2004-2007) to the 4th edition of the standard (2002-2009) added type-5 appliances to the standard: appliance with a UV source such that the biological effect is triggered by radiation wavelengths above or below 320nm and which is characterized by a relatively high irradiance efficiency over the entire range of UV radiation.

The second amendment is currently being voted internationally. This amendment would suppress the current classes and distinguish only two classes: appliances for sale to the general public (formerly type-3 appliances) and appliances for professionals making UV available to the public.

National and international scientific policies

Several international authorities have adopted a defined position regarding specifically the use of UV-emitting appliances for tanning purposes. These positions are almost invariably accompanied by recommendations targeted at the safety of customers.

ICNIRP

The International Commission on Non-Ionizing Radiation Protection (ICNIRP) is an independent group of experts convened to evaluate available data on the effects of non-ionizing radiation to humans. ICNIRP proposes exposure limits to UV radiation for the general population and in occupational settings for the eye and for the skin, for an 8-hour exposure period (ICNIRP, 2004).

In its statement relating to UV-emitting appliances for tanning purposes, ICNIRP, after considering the effects of UV radiation on the skin and the different types of existing appliances, concluded that use of UV-emitting appliances for tanning and other non-medical purposes should be discouraged. High-risk individuals must be particularly warned against

the use of tanning appliances. These include:

- individuals with skin phototypes I and II;
- children and adolescents under the age of 18 years;
- individuals with a large number of naevi;
- individuals with a tendency to have freckles;
- individuals who had frequent sunburns during childhood;
- individuals with pre-malignant and malignant skin tumours;
- individuals with actinic skin ageing;
- individuals who have applied cosmetics on their skin; and
- individuals who are taking medication must seek advice from their doctor to determine whether their medication renders them more sensitive to UV.

If, in spite of the above-mentioned recommendations, individuals decide to use tanning appliances, a number of measures must be implemented to minimize the risk. These measures apply specifically to skin phototype I and II, children, individuals with increased sensitivity due to the use of medication or cosmetics, or individuals with a skin cancer-related pathology.

World Health Organization (WHO)

In 2003, WHO published a document entitled: "Artificial tanning sunbeds: risks and guidances" in the framework of the INTERSUN program (WHO, 2003). This document is based on recommendations cited by other organisations such as ICNIRP, EUROSkin and the National Radiological Protection Board (NRPB), among others. Specifically, WHO recommends that customers carefully read the recommendations and sign the consent form before each tanning session, so as to make them fully aware of their responsibilities.

EUROSkin

EUROSkin dedicated an international meeting to the problems arising from the use of tanning appliances. The outcome of the conference was published in the European Journal of Cancer Prevention (Greinert *et al.*, 2001). The document presents general statements about individuals

who should avoid such practices, and makes specific recommendations on the information to be given to customers and on how to use UV-emitting appliances.

National Radiological Protection Board (NRPB)

In 2002, a group of public health scientists in the United Kingdom published a report through the National Radiological Protection Board on the health effects of UV radiation (NRPB, 2002). The document advises against the use of UV-emitting appliances for tanning purposes and recommends that the potential risks for detrimental health effects be clearly outlined to the users and to the general population at large.

National Toxicology Program (NTP)

In 2002, the National Toxicology Program in the USA published the 10th Report on Carcinogens (NTP, 2002) in which UVA, UVB and UVC radiations were included in the list of "known carcinogens to humans". One chapter of the document is dedicated to solar radiation and exposure to UV-emitting appliances. In fact, the American Medical Association had asked in 1994 for a complete ban of exposure to UV for non-medical purposes. In the USA, 27 states have a regulation regarding availability of indoor tanning facilities to the general population.

Regulations

Regulations and recommendations of health authorities from those countries where they are available are listed in Table II. The following findings can be highlighted:

For consumer safety reasons, Scandinavian countries authorise only type-3 appliances with an emission limit of 0.15 W.m^{-2} for both UVA and UVB, i.e. a total UV intensity of 0.3 W.m^{-2} . Some countries specify that these appliances may also be sold to individuals.

The organisations responsible for radioprotection and the health authorities of five Scandinavian countries (Denmark, Finland, Iceland, Norway and Sweden) released a joint

public health advice recommending that more stringent safety procedures be adopted regarding the use of UV tanning appliances. This advice is in line with the position of international (WHO, ICNIRP), European (EUROSKIN) and national organisations.

The countries that produce the majority of UV tubes and UV tanning appliances (Germany, Italy and the Netherlands) have no legislation limiting the manufacturers.

The USA has its own restrictive regulation imposed by the FDA.

The European Commission has raised a concern about the lack of upper limits for the dose rate of type-1 and type-2 appliances (Type-4 appliances are not concerned).

The legislation in Spain requires that each individual sign a book, a registry and a consent form, and be given a tanning booklet specifying the details of the sessions in accordance with the characteristics of the UV appliance. This initiative corresponds to the recommendations of WHO (WHO, 2003).

The maximal cumulative annual dose of UV radiation currently established at 15 kJ.m^{-2} is calculated from the standard IEC 60 335-2-27. This cumulative dose by far exceeds the dose received from ambient natural UV. Finland wishes to set a maximal annual cumulative dose of 5 kJ.m^{-2} . In fact, the maximal annual cumulative dose should be adjusted to the phototype, i.e. 9 kJ.m^{-2} (NMSC) for phototype II, 15 kJ.m^{-2} (NMSC) for phototype III and 21 kJ.m^{-2} (NMSC) for phototype IV.

It is noteworthy that few countries regulate indoor tanning, and when they do, regulations are mostly silent on use of these appliances by adolescents. According to a recent review by Dellavalle et al. (2003), only France has adopted the age of 18 years as the legal minimum age for indoor tanning. In the USA, only 6 states have in place minimum age limits for tanning patrons: California, Illinois, New Hampshire and North Carolina restrict access to individuals younger than 14 years old, while Texas and Wisconsin restrict access to adolescents younger than 13 and 16 years old, respectively (Francis *et al.*, 2005).

In France, technical controls are performed periodically in all registered tanning

Table II. Regulations and recommendations from health authorities in those countries where information is available

Austria	Presnorme Önorm S 1132 : "Safety rules during the use of solarium emitting UV radiations" (1 January 2002)
Belgium	"Royal decision on requirements for exploiting solarium" (2000)
Canada	Territory, Province and State Committee on radioprotection : "Guidelines to owners, operators and users of tanning salons". Enforcement of regulations enacted to implement the « law relating to appliances emitting radiations – RED Act : Regulations of sun lamps » (2002-2003)
Germany	Bundesamt für Strahlenschutz, Munich : "Certification of solarium" (proposal) Currently, UV exposure in solarium must respect the German standard DIN 5050-2 (June 1998)
Finland	Decree on the limitation of public exposure to non-ionising radiation (294/2002) chapter 4, "Ultraviolet radiation"; SS 9.1 "Safety of solarium" (1989); SONT 9.1 "Safety and control conditions of solarium" (project) (2003)
France	Decree n° 97-617 (30 May 1997) and regulations of 10 September 1997, 09 December 1997 and 16 September 2002 enacted to implement the law
Italy	Istituto Superiore di Sanità "Devices must conform to the technical norm IEC 60335-2-27" (1995–2003); detailed information available at http://www.iss.it/sitp/sole/abbrart/leggi.html
Netherlands	No formal regulation. Several reports from the Dutch Health Council (1987, 1994)
Norway	Regulations of 8 April 1983 for solarium/alpine sun. Delegation of authority regulation fixing by royal decree the usage of UV radiations for cosmetic purposes (01 July 1983)
Spain	19574 Royal decree 1002/2002 : "Regulation of sale and use of tanning appliances emitting UV radiations" (27 September 2002)
Sweden	Regulatory code concerning sunbeds (SSI FS 1998:2) "The regulation of tanning appliances used by the public fulfils the criteria of the standard EN 60335-2-27." (28 September 1998 and 03 November 1998)
USA	FDA Sunlamp Performance Standard 21CFR1040.20 combined with a guide (1986) on timers and frequency of exposure (updated 01 April 2004)

establishments since 1999. The proportion of establishments compliant with the technical requirements increased from 51% in 1999 to 72% in 2003. Periodic visits in 2002 and 2003 to additional establishments showed a compliance of 85% and 81%, respectively. Non-compliance was mainly for minor infractions (AFSSE, 2005).

In addition, the Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF) proceeded to a series of controls and enquiries about indoor

tanning facilities in 2002 and 2003. The following comments were noted: the facility operators are well informed of the regulations in place; the compulsory declaration was generally satisfactory; in most places, at least one person had the required qualifications, but the need for continuing education was not perceived clearly; information to the customers were usually available to the users, but information on risks was often lacking (AFSSE, 2005).