

COMMISSION OPINION**of 27 October 2004****within the framework of Council Directive 73/23/EEC relating to electrical equipment designed for use within certain voltage limits****Safety of tanning devices for cosmetic purposes**

(2004/C 275/03)

(Text with EEA relevance)

Article 9 of Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits ⁽¹⁾ stipulates the procedures where a Member State, for safety reasons, prohibits the placing on the market of electrical equipment or impedes its free movement. In such a case, the Member State informs the other Member States concerned and the Commission, indicating the grounds for its decision and stating in particular whether the non-conformity is attributable to a shortcoming in a harmonised standard referred to in Article 5 of the Directive, incorrect application of a harmonised standard, or failure to comply with good engineering practice referred to in Article 2 of the Directive.

Article 5 of the Directive confers a presumption of conformity to harmonised standards adopted by the European standards body Cenelec to the requirements of Directive 73/23/EEC. The references of these standards are published for information purposes by the European Commission in the *Official Journal of the European Union*.

In the context of a safeguard clause notification from the Spanish and Finnish authorities under Article 9 of the Low Voltage Directive, a shortcoming in the harmonised standard EN 60335-2-27:1997 has been brought to the attention of the European Commission.

The shortcoming relates to the risks associated with the exposure to ultraviolet radiation ⁽²⁾ (UVR). Excessive exposure to UVR can cause sunburn and damage to the cornea and conjunctiva of the eye. It may also lead to accelerated ageing of the skin and might increase the risk of both non-melanoma and melanoma skin cancers.

In accordance with Article 5 of Directive 73/23/EEC, a reference to the harmonised standard EN 60335-2-27:1997 was published in the *Official Journal of the European Union* ⁽³⁾.

This standard, as adopted by the European standards body Cenelec, is entitled:

— EN 60335-2-27:1997 'Safety of household and similar electrical appliances — Part 2-27: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation'.

The standard defines four different types of tanning appliances emitting UVR, as follows:

— UV type 1 appliances are those that emit UV radiation such that the biological effect is caused by radiation having wavelengths longer than 320 nm and characterised by a relatively high irradiance ($\geq 0,15 \text{ W m}^{-2}$) in the range 320 to 400 nm. The emission at wavelengths less than 320 nm is limited to $0,5 \text{ mW m}^{-2}$,

⁽¹⁾ Council Directive 73/23/EEC (OJ L 77, 26.3.1973). Directive amended by Directive 93/68/EEC (OJ L 220, 30.8.1993).

⁽²⁾ The International Commission on Illumination (CIE) defines ultraviolet radiation (UVR) as optical radiation between 100 and 400 nm. The spectral region is divided into three photobiological spectral regions: UVC (100- 280 nm), UVB (280-315 nm) and UVA (315-400 nm).

⁽³⁾ OJ C 103, 29.4.2004, p. 2.

- UV type 2 appliances are those that emit UV radiation such that the biological effect is caused by radiation having wavelengths in the UV-A and UV-B range and are characterised by a relatively high irradiance ($\geq 0,15 \text{ W m}^{-2}$) in the range 320 to 400 nm. The irradiance at wavelengths less than 320 nm is in the range 0,5 to 150 mW m⁻²,
- UV type 3 appliances are those that emit UV radiation such that the biological effect is caused by radiation having wavelengths in the UV-A and UV-B range and are characterised by a limited irradiance ($\leq 0,15 \text{ W m}^{-2}$) in each UV radiation band,
- UV type 4 appliances are those that emit UV radiation such that the biological effect is mainly caused by radiation having wavelengths shorter than 320 nm (at an irradiance greater than 0,15 W m⁻², and in the wavelength range 320 to 400 nm, the irradiance is limited to 0,15 W m⁻²).

The following shortcomings have been identified in EN 60335-2-27:1997:

- for UV type 1 and 2 appliances no limit for the maximum effective irradiance for UV-A radiation is provided,
- for UV type 4 appliances no limit for the maximum effective irradiance for UV-B radiation is provided,
- for UV types 1, 2, 3 and 4 no limit for the maximum effective irradiance for UV-C radiation is provided.

The safety objectives, as laid down in Annex I, Sections 2(b) and (c) of Directive 73/23/EEC, require that electrical equipment should be designed and manufactured so as to ensure:

- protection against hazards which may be caused by radiation,
- protection against hazards which may be caused by non-electrical dangers from the electrical equipment.

The current version of this standard does not adequately address the risks related to exposure to UV radiation because it does not provide all necessary limit values for the effective irradiance on UVR for the different tanning devices.

As a consequence, EN 60335-2-27:1997 as listed in the abovementioned publication in the *Official Journal of the European Union* is not regarded as giving a presumption of conformity with regard to the risks related to the exposure to UV radiation due to the non-existence of values for the maximum effective irradiance for UV-A and/or UV-B and UV-C radiation.

These conclusions have been supported by experts from national administrations at the meeting of the Administrative Cooperation Working Group of 1 October 2003 and the experts from national administrations at the meeting of the LVD Working Party of 24 and 25 February 2004.

The European standards body Cenelec has been requested by the European Commission to revise this standard to ensure that the abovementioned risks are adequately addressed.

In the absence of a revised harmonised standard, the manufacturer will need to make a risk assessment regarding tanning devices for cosmetic purposes in order to ensure that the risks related to exposure to UV radiation are adequately addressed, when establishing compliance of these devices with the requirements of the Low Voltage Directive.

As a result of the above, the Commission is of the opinion that:

- EN 60335-2-27:1997 as listed in the abovementioned publication in the *Official Journal of the European Union* is not regarded as giving a presumption of conformity to the Low Voltage Directive 73/23/EEC due to the non-existence of values for the maximum effective irradiance for the following appliances and types of UV radiation:
 - UV type 1 and 2 appliances with regard to the risks related to exposure to UV-A radiation,

- UV type 4 appliances with regard to the risks related to exposure to UV-B radiation,
 - UV type 1, 2, 3 and 4 appliances with regard to the risks related to exposure to UV-C radiation.
- Member States' Authorities shall take account of this opinion in the context of market surveillance. Member States should base their market surveillance measures on a case-by-case evaluation and respect the principle of proportionality.
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