Report of the Scientific Committee of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) on home photoepilators

Section of Food Safety and Nutrition

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Abstract

This scientific report by the Scientific Committee (Consumer Affairs Section) of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) evaluates the usage risk of home photoepilators. It analyses the potential adverse effects (direct and indirect) and sociological aspects of their use. Based on the scientific and technical information available, the scientific committee concludes that it is not possible to analyse the safety of using these devices. There is a shortage of data from scientific and technical studies into the potential direct and indirect risks of short- and long-term exposure to the different classes/types of home photoepilators, the potential to develop reactions due to photosensitivity, or other adverse effects of exposure to volatile, potentially harmful substances released during the process of body hair removal.

The Committee considers it appropriate for the competent authorities to assess the need, for parties marketing these devices, to carry out scientific and technical studies evaluating the direct and indirect risks resulting from short- and long-term exposure to different classes/types of home photoepilators in order to be able to evaluate the safety of using them.

Although these devices are covered by several legislative, regulatory and administrative provisions, the existing legal framework is not sufficient to guarantee the safety of these devices before, during and after use. In the view of this Scientific Committee, there is also a lack of harmonised legislation for all technologies involved in this group of devices; the Committee suggests revising the existing regulations by developing specific legislation for this type of device, particularly home versions.

Keywords

Home photoepilators, laser, intense pulsed light, electro-optical synergy, safety of use, efficacy, risks, sociological framework and regulation.

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Acronyms

AECOSAN-Spanish Agency for Consumer Affairs, Food Safety and Nutrition
AENOR-Spanish Association for Standardisation and Certification
AEL-Accessible Emission Limit
ANSI-American National Standards Institute
EMA-European Medicines Agency
ELOS-Electro-Optical Synergy
US-FDA-United States-Food and Drug Administration.
IEC-International Electrotechnical Commission
IPL-Intense Pulsed Light
LASER-Light Amplification by Stimulated Emission of Radiation
LA-Limitation Aperture
MPE-Maximum Permissible Exposure
SESPA-Princedom of Asturias Health Service
TRT-Thermal Relaxation Time
UCE- Union of consumers of Spain Units

Units

Fluence: Joules / centimetre squared-J / cm2
Shot per second: number-num
Beam diameter: millimetres-mm
Pulse duration: milliseconds –ms
Spectrum: nanometres-nm
Wavelength: nanometres-nm
Molecular Weight: Daltons-Dal
Power: Watts-W
Temperature: Degrees Celsius-°C
Time: milliseconds-ms

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1. Introduction: terms of reference

The Spanish Agency of Consumer Affairs, Food Safety and Nutrition (AECOSAN) has consulted the Scientific Committee (Consumer Affairs Section) on whether the use of laser-type domestic devices (photoepilators) involves health risks associated with the temperature and power of the device, the frequency of exposure and presence of volatile compounds produced during the hair removal process.

The Scientific Committee (Consumer Affairs Section) of the AECOSAN has drafted, in response to the request, this report on the assessment of the safety of using home photoepilators (laser, intense pulsed light (IPL) and electro-optical synergy (ELOS), with regard to the direct or indirect, short- or long-term risks derived from their normal. foreseeable or inappropriate use.

To prepare this report (December 2014 to December 2016) the PubMed, SciFinder, ScienceDirect and Web of Knowledge databases were systemically consulted, together with the national legislation, European Union (EU) and the United States of America (USA) regulations with respect to the use of home photoepilators.

2. Recognised uses and sociological framework

Lasers and IPL systems are devices which are widely used today in dermatology practices to treat a variety of aesthetic and medical problems. Epilation systems for the removal of hair, blemishes and photo-rejuvenation are the most common uses.

The use and marketing of these technologies in hair removal systems as an alternative to conventionally used systems such as waxing, depilatory creams or shaving has increased in recent decades thanks to its effectiveness in removing body hair permanently or semi-permanently.

At first, these devices were only used professionally. However, they are now commonly used in households. Since 2003, this type of photoepilator has been available in the market (Table 1) for use at home (Town and Ash, 2010).

Table 1. Historical development of portable laser devices in the last decade. Source Town and Ash, 2010, *Journal of Cosmetic and Laser Therapy* 11(3):157-68

Year	Chronological development of domestic industrial devices by companies
2003	Palomar exploits their patent for the professional laser device valued at 7 million dollars with the agreement signed with Gillette* to develop a domestic device. In 2013 Palomar is purchased by Cynosure. INC.,
2003	Tria Beauty. Inc. in 2005 launches their home hair removal device in Japan and obtains the approval of the FDA in 2005.
2003	The E-Onees medical home device is approved and developed by Vincent Brotter in France and launched on French TV in 2007,
2006	The Dezac Ltd. group launches the first domestic laser device developed in Europe.
2006	Home SkinInovations Ltd. develops Silk'n photoepilators system in Europe.
2007	SyneronR Medical Ltd. develops home photoepilator and launches it under the name " MeMyElos", signs exclusive agreement with P&G, based on the development of home devices with rejuvenating effect.
2008	Phillips launches Lumea, a home photoepilation device followed by RéAura a skin rejuvenating device in 2010-2011. From this moment, Phillips sets up a dedicated unit (Philips Light & Health) with the aim of developing light-based technology.
2008	Radiancy, Inc. launches the no!no! "hot wire" in 2008 which rapidly appears in audiovisual media, creating an uproar on Teletienda with sales of more than 5 million units at global level.
2009	Unilever signs a long-term contract with Cynosure, Inc. for the development of a home anti-wrinkle device.
2009	Remington launches its own photoepilation system.
2009	CyDen Ltd. launches together with the brand Boots SmoothSkin, their IPL photoepilation device, capturing the attention of P&G, and signing an exclusive global distribution agreement.
2011	Photomedex, Inc. and the company NASDAQ-listed US purchase Radiancy. Inc., becoming the global leaders in this category following the agreement.
2014	Unilever Ventures, Ltd. announces a merge with Syneron, called iluminage, Inc. All Syneron home devices are sold under this new company as Skin Smoothing Laser in March 2014.

The use of laser devices and IPL and ELOS systems has increased exponentially in the last decade. According to the journal of the American Society for Aesthetic Plastic Surgery, in 2007 in the USA, approximately 1.5 million patients used this epilation system. Although no data has been found published in the EU, the use of these photoepilation systems has also been significant, with demand increasing with respect to previous years, particularly among the male population. Major laser producing companies are signing agreements with large cosmetic companies with a high level of consumption to develop new dermo-aesthetic systems for home use (Palomar and Johnson & Johnson, Gillete and Procter & Gamble). There is no doubt that this is a huge market which has not gone unnoticed by the large firms involving, in addition to scientific and medical criteria, commercial and marketing objectives (López- Estebaranz y Cuerda, 2010).

From a sociological viewpoint, it is important to note that the cultural stereotypes generated through the ideal-type models shown in magazines, film, television or fashion influence the way males and females act to control their body (Williams and Germov, 2008; Martínez Barreiro, 2004). Displaying your body and the beauty it represents is encouraged in today's society "within consumer culture the body is proclaimed as a vehicle of pleasure" (Featherstone et al., 1991). This new consumer culture affects all social groups but in particular, women, who have been and continue to be under more social pressure to maintain and reproduce certain aesthetic standards and a beautiful body with more intensity than men (Williams and Germov, 2008; Gracia Arnaix, 2010; Rivera Garretas, 2011). From different analyses with a gender perspective it has been confirmed that a large part of the female identity is sustained in the bodily image (Aleman and Anchel and Velasco Laiseca, 2008; Muñiz García, 2010).

Some studies have analysed the feminine response to social pressure to hide body hair. The study carried out by Fahs shows how a small group of university students anticipates possible rejection if they fail to remove hair from legs and armpits. It confirms that it is not easy to adopt a line of behaviour that contradicts traditional social norms on how the body should be displayed (Fahs, 2011). Removal of body hair is seen by women as a part of femininity and several studies have demonstrated that they accept it as an obligatory task, taking steps to remove hair from legs, the pubic area, eyebrows and armpits (Toerien et al., 2005; Rigakos, 2010). This is not something exceptional but a type of behaviour which starts in adolescence and is common among the young population without differences of gender or race (Toerien and Wilkinson, 2003; Tiggemann and Kenyon, 1998; Rigakos, 2010). The study by Rigakos (2010) mentions 12 possible types of hair removal methods, including laser, but does not analyse differences between them. No studies have been found which explore a differential use of the existing methods of hair removal.

But hair removal is not limited to women. Men are also starting to feel the social pressure which leads them to manipulate their body in line with dominant values. The removal of body hair is perceived as a way to improve image (Braun et al., 2013; Diego, 2006). At present, hair removal practices among men reflect a new body image of masculinity. Hairy bodies are rejected and seen as aesthetically inappropriate (Terry and Braun, 2016).

This is the context into which the appearance of photoepilators for the removal of body hair should be placed, in a society that encourages the display of flawless skin and the removal of hair that covers up the qualities of the body. This all seems to indicate that we face a very favourable consumer environment for the development of home hair removal devices, as has occurred with the more traditional hair removers (creams, razors or waxes). Therefore, we should consider two relevant questions from the sociological viewpoint: on the one hand, it is necessary to guarantee that the function it claims to perform, the definitive removal of body hair, is really the case, as the consumer expects to find a service different to those already existing on the market. On the other hand, the possible direct or indirect risk derived from the domestic use of the product must be considered. This should take into account that a generalised use is foreseeable in any section of the population regardless of the individual's level of knowledge about hair removal and the level of experience they may have previously acquired through the use of other hair removers.

3. Definition and characterisation of the photo epilation devices

The linguistic analysis of the word photoepilation, adopted some years ago, by breaking down the terms into "photo" and "epilation" establishes that it means "hair removal using light". That is, the term refers to those technologies which use light to remove body hair. Existing technologies on the market are marketed as "photoepilation devices" and their publicity declares that they remove body hair semi-permanently or in some cases, "definitively".

Photoepilation is applied using a number of technologies, including laser, IPL and ELOS.

Lasers and sources of IPL, when used as intended, emit photon energy to induce a thermal effect (photothermal induction) on the skin able to provoke, thanks to the interaction on the hair bulbs, the removal of the hair. Light incident on the surface of the skin is directly reflected (approximately 5% of the energy), or refracted and absorbed or dispersed within the layers of the skin (95% of the energy). The skin has different chromophore molecules which absorb visible and close infrared radiation from the light. The absorption spectra and dispersion coefficients for the melanin pigment, the haemoglobin protein and other porphyrins with tetrapyrrole ring prosthetic group have been well researched (Town et al., 2012).

In addition, the cutaneous phototype affects the effectiveness and safety of the laser epilation and defines the skin´s capacity to react to the radiation. The Fitzpatrick scale of phototypes (1975) provides information about the sensitivity of the skin to radiation and the way it reacts to radiation, defining six different types ranging from very pale skins to very dark skins (I- VI); the higher the number, the more melamine is generated by the skin. Laser photoepilation was the first to be applied at a professional level in 1994. The Ruby high power laser was the first to be used for hair removal. The limiting factor of this type of laser was that it could only be used on very pale skins due to the risk of burns (Williams et al., 1998).

As a result of scientific and technical developments, laser photoepilation has been replaced by other types of laser or photoepilation technologies that permit its application on skins with different types of photo-pigmentation. The IPL emerged as an alternative to the laser method. It was approved by the US-FDA based on the requirements of the FDA Act of 1997 ("Medical Device Provisions"). The operating principle of the system uses light pulses through a xenon lamp. This light is discharged very close to the skin, between 1 and 5 mm and its energy is absorbed by the chromophores in the skin and the hair. The wavelengths declared by the leading manufacturers of IPL devices are in the range of 475 to 1100 nm and the energy pulse of an IPL device is in the range of 7.5-30 J, with a pulse duration of 2.5 to 60 ms in the 450-1200 nm spectral range and for skin treatment areas of 2-6 cm^2. Only one device, E-One IPL (E-Swin, France), with the CE marking (European Community) as a medical device but which is marketed for home use, emits in a margin higher than the above energy range, with a maximum pulse energy of 72 J. Devices with these maximum energies existing on the market should be classified as "professional medical devices" (Town et al., 2012). There is one device on the market called the Tria laser (TriaBeauty, Dublin, CA 94568, EE.UU.) which aims to deliver up to 22 $Jcm^{-2}$with pulse durations of up to 600 ms and a skin treatment area of 0.79 cm^2 (Town et al, 2012). The IPL technique corresponds to a more recent generation of photoepilators than

those based on laser technologies, and is used on a greater range of skin types and body hair colours.

Lastly, the latest model, approved by the US-FDA in 2004, is ELOS. This technology combines two energy types, light energy and electromagnetic energy generated by the emission of radio frequencies.

The action mechanism of this new technology is based on two combined actions: (a) IPL-based technology, with photothermal mechanism, where the different chromophores are preheated, producing temperature differences between the biological target and the tissue surrounding it and (b) radio frequency-based technology (RF) where the creation of stress waves on the surface of the skin produces a uniform heat, at controlled depths, in the skin layers. Therefore, both energies create a "thermal wound" in the skin defined as the biological target, with the subsequent remodelling and reorientation of the collagen fibres and the formation of new collagen, obtained after months of treatment (Moetaz et al., 2011).

With the ELOS method, according to the sales companies, it is also possible to treat dark skins without the appearance of adverse reactions, and to remove red or even grey body hair, as the heat not absorbed by the melanin is compensated for by the electromagnetic energy generated by the emission of radio frequencies.

The application of a light source from a photoepilator, on body tissue may produce certain effects measured by the theory of selective photothermolysis (Anderson and Parrish, 1983) and by the nonspecific deep heating of the skin produced as the photoepilator energy is transmitted to the intracellular water component (Trelles et al., 2008; García y Sánchez,2008).

The ELOS photoepilation mechanism is based on a photothermolysis and selective thermal kinetic process (Sadicket al., 2000). This principle has made it possible to establish selective applications with photoepilators. The tissue damage depends on the wavelength and the power supplied to the tissue (García y Sánchez, 2008).

Laser, IPL, and ELOS all use energy in light form to remove body hair. The light energy emitted is transferred to the skin which absorbs it in the form of thermal energy. This heat reaches the base of the follicle and may heat the root to 70°C, thereby destroying it. The energy emitted by these devices may cross, depending on the type/class of device, the epidermis, dermis and subcutaneous fascia or hypodermis, which form the different layers of the skin (García y Sánchez, 2008).

The light wavelengths used are preferably in the red and infrared band between 600 and 1200 nm, and the maximum effectiveness of photoepilation has been observed to take place during the hair growth phase (Chang, 2005). In addition, the photoepilators function via a thermal kinetic effect which permits the energy transmitted to the follicular zone to reach all of the hair structure (Anderson and Parrish, 1983). In the case of IPL, it is based on the length of the pulses, which are calculated considering the relaxation time of the epidermis (3-10 ms) and below the relaxation time of the follicles (40-100 ms), where the thermal damage is concentrated on the structure (Bjerring, 2000).

The difference between both types of photoepilation lies in the type of light emitted. The laser applies a monochromatic light. This light is the easiest for the melanin, which gives colour to

the body hair and skin, to absorb. The photons are directed in the same direction and along the same wavelength, therefore it could be said that the laser technique is more timely and precise. In addition, the IPL is polychromatic and the light beam moves in all directions with different wavelengths. Therefore the same device can be used on different types of body hair. Both technologies have similar risks and uses (Bjerring, 2000).

For the action to take place, the light energy absorption by the hair shaft must be higher than that of the tissue. This energy must penetrate far enough so as to reach the hair bulb. The depth of penetration (Town et al., 2012) varies according to:

1. The fluence, determinate as the quantity of light energy emitted per area unit measured in J/cm^2.
2. The pulse length measured in milliseconds (ms) considering the time the skin is exposed to this emission.
3. The electromagnetic spectrum in its light region (nm).
4. The diameter of the light beam in mm.
5. The wavelength used.

The declared fluence, in these devices, ranges from 2 to 24 J/cm^2 and the pulse length from 25 to 600 ms (López-Estebaranz y Cuerda, 2010)

The wavelength is in relation to the depth reached in the skin: the longer the wavelength, he deeper the penetration. Therefore, a pulsed dye laser of 585 nm may reach 1 mm of depth, whereas a diode laser beam of 810 nm may go beyond 1.8 mm. In addition, with respect to the diameter of the light beam, which also conditions the penetration, a ratio is established such that the greater the diameter, the greater the penetration (García y Sánchez, 2008).

Lastly, to guarantee the photoepilation effect, the length of the pulse must be shorter than the TRT of the chromophore, considered as the time required for the temperature of the chromophore to drop to half after heating by a light pulse. To produce a selective effect, the pulse must be shorter than the TRT, confining the heat in the established target area before it has an opportunity to spread to the surrounding tissue and cause collateral damage. The TRT for the epidermis ranges from 2 to 5 ms, and is between 10 and 30 ms for a hair follicle. This factor essentially determines the selection of the length of the energy pulse (García y Sánchez, 2008).

These variables are modified by the type of home photoepilator used. (López-Estebaranz y Cuerda, 2010). Therefore, the wavelengths vary according to the type of laser beam or the type of photoepilator, from 694 nm in the case of Ruby laser beams, to 755 nm for Alexandrite laser beams, 810 nm for Diode type laser beams, 1064 nm for Nd-YAG laser beams, or up to 1200 nm which may be obtained by IPL photoepilators (Figure 1).

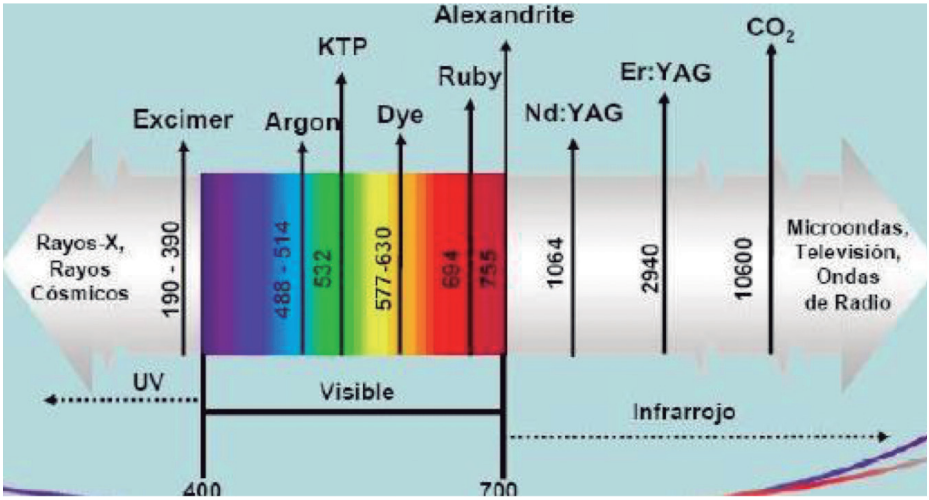


Figure 1. Wavelength of each treatment. Operating mechanism of laser type beam and intense pulsed light on the hair follicle.

Source: http://jaimecalderon.blogspot.com.es/2003/06/historia-del-láser.html. 2 November 2016 last entry.

The principal standard describing the safety of laser products is IEC 60825-1:2014, proposed by the International Electrotechnical Commission, which prepares and publishes international standards for all electrical, electronic and related technologies. This standard applies to the safety of laser products which emit radiation in the wavelength interval between 180 nm and 1 mm. The European Standard EN 60825-1 of 2014, on "Safety of laser products-Part 1: Equipment classification and requirements", which replaces the 2008 standard, adopts the IEC 60825-1:2014 international standard. This standard includes a system which classifies the lasers into eight categories (classes 1 to 4), depending on the level of risk to eyes and skin, to help in the assessment of risks and in determining the control measures by the user. The classification of a laser into risk categories is based on the Accessible Emission Limit (AEL) for the user, which is expressed in Watts (W) or Joules (J) and in the case of diaphragm opening in Wm2 or Jm2. Depending on the AEL, the laser will obtain a particular classification. The classification is determined by calculations based on the wavelength and mean power of the laser radiation and the exposure time to the radiation beam.

The development of new laser products, with intermediate powers, has rendered the initial laser classification obsolete. Thus, the former classes 1, 2, 3B and 4 remain unchanged and intermediate classes 1 M, 2M and 3R have been added.

Lasers do not form a homogeneous risk group as, depending on their technical characteristics they may emit radiation in a broad interval of wavelengths, with highly variable powers or output energies and with a time distribution that may be continuous or in pulses. In addition, the different applications condition the exposure time, which is a key factor for determining the risk. Table 2 lists the classification of the laser types in accordance with European Standard EN 60825-1:2014.

Table 2. Classification of the laser types in accordance with European Standard EN 60825-1:2014	
Class 1	Laser products that are safe under any reasonably foreseeable operating conditions, including the use of optical instruments in direct viewing.
Class 1M	Lasers emitting in a wavelength interval of 302.5 to 4000 nm are safe in reasonably foreseeable conditions, but may be hazardous if optical instruments are used for direct viewing.
Class 1C	Laser products intended for direct application on skin or internal body tissue for medical, diagnosis, therapeutic and beauty care applications, including hair removal. skin wrinkle reduction and acne reduction. Although the laser radiation emitted may be class 3R, 3B or 4, ocular exposure is prevented by one or more technical means. The level of exposure of the skin depends on the application, therefore this aspect is covered by vertical standards.
Class 2	Lasers which emit visible radiation in the wavelength interval between 400 and 700 nm. Protection is afforded to eyes by aversion reactions, including blinking. This reaction may provide adequate protection even when optical instruments are used.
Class 2M	Lasers which emit visible radiation between 400 and 700 nm. Ocular protection is normally obtained by aversion reactions, including blinking, but the viewing of the beam may be dangerous if using optical instruments.
Class 3R	Lasers which emit between 302.5 and 106 nm, direct viewing of the beam is potentially dangerous but the risk is less than that for Class 3B lasers. Fewer manufacturing requirements and user control measures are required than for Class 3B lasers. The accessible emission limit is less than 5 times the AEL of Class 2 in the 400-700 nm range, and less than 5 times the AEL of Class 1 for other wavelengths.
Class 3B	Lasers for which direct viewing of the beam is always dangerous (for example, within the Nominal Ocular Hazard Distance). Viewing of diffuse reflections is normally safe.
Class 4	Lasers which can also produce hazardous diffuse reflections. These may damage skin and may also cause fire. Their use requires extreme caution.

For the first time, the European standard EN 60825-1: 2014 classifies laser products aimed at the removal of hair in subclass 1C, defining them as laser products for direct application to skin or internal tissue for medical, therapeutic or cosmetic purposes. This class has been included in this standard because these products are currently available on the market and the control measures specified normally for laser products from classes 3B and 4 are not suitable. The technical committees which use class 1C have to develop the required safety specifications in their vertical standards.

There are numerous laser type devices currently available on the market with very diverse characteristics. Table 3 lists the characteristics and operating mechanisms for the main devices available on the market (López-Estebaranz y Cuerda, 2010).

Tabla 3. Intensity, power and wavelength of each treatment, Operating mechanism of laser type beam and intense pulsed light on the hair follicle

Model	**iPulse Personnel**	**No!No!**	**Rio Salon Laser**	**Rio Scanning Laser**	**Satinlux**	**Spa Touch**	**Silk´n**	**Teny Epil Flash**	**Tria**
Manufacturer	CyDen Ftd	Radiancy	Dezac Ltd	Dezac Ltd	Philips	Radiancy	Home Skin innovations	GHT innova-tions	Spectra Genics
Fluence stated	7.7-10 J/cm^2	5-8 J/cm^2	-	-	2-6.5 J/cm^2	7.5-10 J/cm^2	5 J/cm^2	20 J/cm^2	6-24 J/cm^2
Duration of pulse claimed	25, 40, 60 ms	-	-	-	-	35 ms	-	24-33 ms	125-600 ms
Declared spectrum	530-1,100 nm	400-1200 nm	808 nm	808 nm	475-1200 nm	400-1200 nm	475-1200 nm	600-950 nm	810 nm
Number of shots claimed	10,000	Replaceable heads	unlimited	unlimited	-	unlimited	750 per cartridge	20,000	>250
Beam diameter	3 cm^2	25 mm long	0.0019 cm^2	0.14 cm2	3 cm^2	12.10 cm^2	6 cm^2	2.64 cm^2	0.785 cm^2
Frequency of repetition	6.1 s	-	6.3 s	-	-	-	4.1 s	8.3 s	2.2 s
Phototypes	I-III	I-IV	I-IV	I-IV	I-IV	-	I-IV	I-IV	I-V
Protective eye wear	No	No	No	No	No	Yes	No	Yes	No
Weight	1500 g	200 g	300 g	700 g	790 g	5 Kg	1150 g	-	750 g
Bibliographic references	11	No	No	No	11	No	7-8	No	12

Source: López-Estebaranzy Cuerda (2010).

The majority of these are pulsed lights as these are easier to manufacture and maintain, and some laser devices too. These systems offer the user the comfort of being able to carry out the treatment at home, at reduced cost and with greater intimacy.

4. Safety

Until the appearance of home systems, the majority of these devices were used in clinics, and therefore they were handled by dermatologists and/or personnel trained in the use of these devices. Nevertheless, after they came on the market as domestic devices, in Spain they are marketed as dermo-aesthetic products due to the effects on corporal aesthetics. These devices are not legally classified as beauty products, as they do not contain chemical substances (Framework regulation (EC) No 1223/2009 and amendments). These devices are indiscriminately available for domestic use, without the need for any training, diagnosis or assessment, unlike those listed by the FDA (Town et al., 2012).

Although an excess of unwanted body or facial hair may be due to specific pathologies, such as hypertrichosis (excess hair on any part of the body) and hirsutism (excess hair on females in zones dependent on the action of androgens), the exaggerated growth of body hair may be due to secondary causes such as endocrine disorders, malnutrition, medication and virilising tumours (Kvedar et al., 1985).

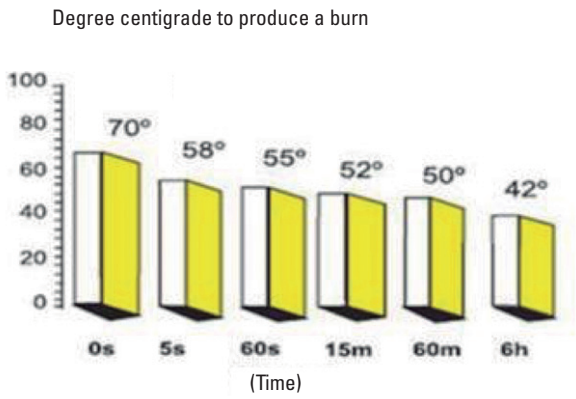
Nevertheless, these are medical conditions which require advice, diagnosis and treatment by a health professional, such that home photoepilators must be used only for the purpose of eliminating hair on individuals without underlying medical pathologies (Town et al., 2012).

Although photoepilation technologies are considered as non-invasive technologies as they are not ablative, the thermolytic operating mechanism may lead to damage of a varied nature, both as a result of normal use and inadequate use. Among the most common, after application, a range of injuries from burns to photopigmentations are described (Nanni et al., 1999).

There are two essential factors behind the origin of the burn: the temperature of the agent in contact with the skin and the duration of the contact. The skin is able to spread and dissipate heat quickly, but only up to a certain point. When the absorption of the heat exceeds the speed of diffusion and the regulatory mechanisms are exceeded, cellular disintegration takes place in the contact zone. When the temperature exceeds 44 °C, skin lesions take place. Above this temperature, cellular destruction doubles with each degree increase in temperature. (Table 4, Zapata Sirvent et al., 2005).

Depending on the spread and depth of the injury, the inflammatory process is generalised, altering a series of processes and increasing the release of endogenous bioactive substances (Zapata Sirvent et al., 2005).

Table 4. Contact time required to produce a burn



Source: Zapata Sirvent et al., 2005.

The principle of selective photothermolysis was introduced by Anderson and Parrish (1983) to explain how chromophores are able to selectively absorb specific wavelengths, causing selective and confined damage or thermal injury. To ensure that this damage or thermal injury is localised, only affecting the target zone, two other variables must be considered: TRT and pulse duration. TRT is defined as the time required for a particle to reduce the temperature reached immediately after the impact of a laser by 50 % (Anderson and Parrish 1983). Consequently, according to the theory set out by Anderson and Parrish (1983), the thermal injury or damage is selective and confined to the biological target zone when the thermal exposure time is lower than the TRT of the biological target. Nevertheless, flat, spherical and cylindrical structures with irregular pigmentation may be treated with a pulse far longer than the TRT without unspecified thermal injury or damage to the adjacent structures. In the case of hair follicles, a pulse length of 30 to 400 ms can be used without observing unspecified thermal injury or damage to the surrounding tissue. In this type of target structure with irregular pigmentation, a part (the most pigmented area) selectively absorbs the light energy and converts it into heat, dissipating it to other less pigmented regions of the biological target zone. Consequently the selective thermal injury or damage of the target structure occurs thanks to diffusion of heat from the more pigmented regions, and therefore with a higher absorption coefficient, to the less pigmented regions with little or no absorption. This new theory is known as the "extended theory of selective photothermolysis" (Altshuler et al., 2001).

In the case of domestic photoepilators, although the majority of these have a lower energy intensity than the medical devices, the direct or indirect adverse risk has not been adequately recorded in either the short- or long-term. However, it has been found that an unsuitable use may have a rebound effect, defined as the paradoxical effect (Lolis y Marmur, 2006).

At national level, different beauty and hairdressing salons have reported that the use of photoepilators is not harmless, as inappropriate use may result in pain, dermatitis, blemishes and burns, although they recognise a legal void and recommend medical supervision. Certain consumer organisations, including UCE from Asturias, have demanded a campaign to control the use of IPL in beauty and hairdressing salons following the sentence against a company for causing skin burns on both legs of a customer who required medical attention after being exposed to IPL photoepilation treatment (Verbal sentence 0109/2014 No 4 Instance Court 1 in Oviedo).

4.1 Identification and characterisation of the hazards

On the whole, the mechanism by which the radiation induces the damage or injury to the biological systems is similar in all the photoepilators and may involve heat exchanges, photochemical processes and non-lineal effects.

The thermal effects are due to the absorption of energy from the radiation leading to an increase in the heat content. Of note among the most common damage and injury that may occur as a result of using laser-type photoepilators, on generating a heating of the absorbent tissue or tissues, are inflammatory reactions (dermatitis), erosions and/or abrasions and burns of varying degrees. It is known that, at temperatures of 65-70°C, commonly reached in the dermis with the use of photoepilator devices, there is a denaturation and destruction of cellular protein structures, lipid oxidisation, and the partial or complete denaturation of the types of ribonucleic acid (RNA) and specific deoxyribonucleic acid (DNA). Nevertheless, the effect on the normal variation of the rate of mutations derived from these effects is unknown.

The photochemical effects are generated by the absorption of energy from the radiation, resulting in chemical reactions which, in many cases, are not reversible. Of particular note among the adverse effects are the reactions leading to post-inflammatory hyperpigmentation. This is the reason why these injuries or damage may be irreversible and this effect is responsible for damage or injury from low levels of exposure.

The non-lineal effects are associated with laser-type photoepilators with a short pulse and high peak power where the energy is supplied to the biological target zone in a very short time and high radiation is produced. There is a marked dependence between chromatic dispersion and some of the non-lineal effects. This chromatic dispersion causes an amplitude of the pulse due to the dependence of the wavelength of the skin refraction index. Ocular exposure to the radiation produced by photoepilators may cause damage or injury associated with heat, and may affect the cornea (lasers which emit ultraviolet or far infrared radiation) or the retina (visible wavelengths and close infrared). Some of the most common pathologies found among the damage and injuries include photokeratitis, photochemical cataract, photochemical and thermal retinal damage, retinal photochemical cataract and turbidity of the aqueous humor (corneal burn cataract) (Town et al., 2012).

The effects derived from the thermal processes are more tolerable on the skin than in the eyes (Town et al., 2012). The effect of skin exposure with photoepilators emitting in visible (400-700 nm) and infrared (over 700 nm) spectral regions may vary from a minor erythema to the formation

of severe skin blisters; and, consequently, in changes to pigmentation, blemishes or ulceration in case of extremely high radiation. Latent or accumulative effects have not been found to be frequent. However, some studies have suggested that in exceptional situations sensitisations may occur. In addition, different studies suggest the possible association between the thermal injury or damage process and cascading secondary processes leading to photobiological damage as observed in patients who have suffered other types of burn (Zapata Sirvent et al., 2005).

An increase in vascular permeability and the consequent degradation of collagen fibres may occur in the case of severe burns, as an adverse physiological response, the accumulation of fluids in the interstitial space and decreased tissue perfusion, favouring ischemia and tissue necrosis. In addition, thermal injury on the tissues produces the denaturation of proteins and the release of potentially toxic compounds. The majority of these bioactive compounds, with toxic action, seem to correspond to polypeptides (between 40 000 and 160 000 Daltons of molecular weight) with a composition of 40 % lipids and 60% proteins. These toxins are responsible for causing local and systemic alterations due to burns (Arturson, 1996, Allgower et al., 1973, Kremer et al., 1981)

The effect of the light and intense heat may be involved in cascading adverse photobiological effects, favouring the irruption of numerous metabolic processes including cell lysis, and may end in cellular death when the process is intense or sustained. The principal damage or injures are observed in the cytoskeleton through the disorganisation of the network, relocation of the actin fibres around the core, disruption of the microtubules and loss of mitochondrians and disassembly of oxidative phosphorylation (Kampinga et al., 1995).

In addition, photoepilation devices favour the release of significant quantities of bioactive inflammatory mediators (interleukin 1 (IL-1), interleukin-6 (IL-6), tumour necrosis factor (TNF) and free radicals; and processes increasing the heat stress proteins (HSP) which may, as is the case of HSP27, in some cases induce neoplastic cellular transformation, proliferation of tumour cells, the establishment of metastasis and in other cases be induced as a cell survival response, as for example the tumour cells which present resistance to medication used in cancer chemotherapy. This is one of the reasons why the use of photoepilators is not recommended for oncology patients (Coronato et al., 1999).

Different groups of proteins in different locations are damaged or injured successively until the cell exposed to the oxidative stress begins a necrosis process. The haemoglobin forms a group of protein chromophores which are the biological target zone for the thermolytic effects and production of cutaneous vascular injury, which occurs at temperatures close to 70 °C. At this point methaemoglobin is generated, formed by the photo-induced oxidation of the haemoglobin (García y Sánchez, 2008).

In relation to the heat stress proteins (HSP), the thermal action of the photoepilators not only induces synthesis of new HSP known as "Chaperones", but also the phosphorylation of the pre-existing or constitutive forms and those formed de novo by this action. The phosphorylation of the HSP may have inhibitive or stimulating effects on cellular growth, depending on the stimulus used. If stimulated with heat, oxidative stress or tumour necrosis factor-alpha (TNF-a), the

phosphorylation effect inhibits growth. On the other hand, the presence of serum or mitogen stimulation of in vitro cellular cultures in normal temperature conditions, results in stimulation. In both situations, the same HSP residue phosphorylate, suggesting that the same kinase would act, activated by two different mechanisms (Coronato et al., 1999).

The tumour necrosis factor-alpha (TNF-a) controls the population of inflammatory cells, and intervenes in many of the factors of the inflammatory process including: the release of pro-or anti-inflammatory cytokines, the growth factors of vascular endothelium and the activation of the transcription factor NF-kB. The transforming growth factor -alpha (TGF-a) is also important for modulating the inflammation, both cytokines influence the inflammation and repair process in a positive and negative manner (Coussens and Webs, 2002).

The HSP27 also induces cellular protection against the action of the TNF-a, thanks to its capacity to reduce the level of reactive oxygen species (ROS) and increase the level of glutathione. The cytotoxic mechanism of the TNF involves oxidative damage of the cellular DNA. Only the HSP27 protein aggregation, formed when the serine residue is replaced by alanine, is able to modulate this protective response against TNF-a (Coronato et al., 1999).

The functional relation between inflammation and cancer is known (Virchow, 1863), where the cancer originated in areas of chronic inflammation, based on the fact that some irritating substances, connected to tissue damage and inflammation caused by this, increased cellular proliferation. It has been established that cellular proliferation alone is not the main cause of the appearance of cancer but rather it is the sustained cellular proliferation in an atmosphere rich in inflammatory cells, growth factors, activation of stroma and the agents which encourage the damage of DNA, are the factors with the highest risk in the appearance of neoplasia (Vallespí y García, 2008).

There are many cellular and molecular factors involved in the inflammation and cancer processes. The "chaperone" proteins (HSP), whose synthesis is activated immediately and significantly after heat stress, are projected with a fundamental role in the pathogenesis of inflammation and cancer. The HSPs were originally identified as a group of heat stress induced proteins. It quickly became clear that they could also be induced by other stimuli (for example, growth factors, inflammation and infection among others). The expression of these HSP proteins in different types of cancer is well documented, together with its association with the cell apoptosis. Although the cellular and molecular bases which govern the interactions between these stimuli and processes, remain unresolved (Vallespí y García, 2008).

It has also been found that several human neoplasia present overexpression of HSP. The tumour cells, on migrating to the lymph nodes encounter a hostile micro-environment, therefore these cytoprotective proteins are overexpressed which favour their survival and their posterior dissemination throughout the body. For this reason, the majority of authors find correlation between overexpression of HSP, growth of malignant cells and presence of positive lymph nodes (Nakopoulou et al., 1995).

It has been found that during the burn process, both with "ablative laser" and with "cauterising laser", in surgical operations, benzene, toluene and ethylbenzene between 300 different compounds described with potentially mutagenic capacity (Hill et al., 2012).

Some of these compounds are classified as "Category 1 (A or B)" carcinogenic by the EU, that is, recognised as "carcinogenic chemical agents or assumed to be carcinogenic for man" (EC Regulation 1907/2006 (REACH) and EC Regulation 1272/2008 and its adaptation to technical progress).

The degree to which any of these mechanisms is responsible for damage or injury to the body may be linked with certain physical parameters of the source. Consequently it is important to identify the type of laser, which in function of the differences, may have different effects. This will permit the establishment of suitable measures for use and for preventing damage and injury.

A study on IPL and UV light linked to skin tumour induction in hairless mice (bare mice) reported long-term effects (Town et al., 2012; Haedersdal et al., 2011).

4.2 Presentation and characterisation of the risks

It is important to highlight that the two types of most significant adverse risks, associated with this type of device, are:

1. Skin penetration: Penetration of radiation on skin.
2. Ocular penetration: Penetration of radiation in eyes due to reflection and/or direct exposure.

In addition, possible exposure to smoke should also be noted. This is linked to the production of possible mutagenic and/or carcinogenic toxic substances during the burning of the hair.

To date, the majority of clinical studies in humans have focussed on the evaluation of the efficiency of use in hair removal, and the possible direct or indirect adverse effect following its application to the area of treatment, and short- or long-term toxicological studies, mutagenic and/or carcinogenic studies, photosensitivity studies or photobiological effects, or studies of the inhalation of harmful substances during the hair removal process are not considered.

The studies demonstrate that the exposure time during treatment, and between treatments, is very important for reducing the direct or indirect risk. On the whole, the skin is thought to tolerate a greater level of exposure to energy than the eyes. The biological effect of photoepilators which function in visible spectral regions (400 to 700 nm) and those that function in infrared spectral regions (move than 700 nm) may vary from minor erythemas to skin blisters. For values higher than 1500 nm, the risk of biological damage to the skin has been found to be similar to that observed in the eyes (Town et al., 2012) Liew et al. (1999) observed that patients treated with a Ruby laser displayed surface clotting and burns in the area surrounding the hair. In the areas treated, the follicles observed to have adverse damage or injury were found to be randomly dispersed among intact follicles. Apart from any other macroscopic damage or injury to the skin, microscopic changes were observed at the base of the epidermis where the melanin is concentrated.

A low intensity inflammatory response was also observed after treatment, and was present for up to two weeks. In patients for whom blisters formed after the treatment, suprasal necrosis of the epidermis was observed. There was, therefore, selective damage to the hair follicles caused by the Ruby laser, with microscopic changes at the base of the epidermis.

Nanni et al. (1999) observed adverse effects from the laser treatment including pain, erythemas,

edemas, hyperpigmentation, blisters, erosions and folliculitis. The majority of these undesirable adverse effects occur in tanned skin or in patients with skin corresponding to phototype III of Fitzpatrick or higher.

Alster and Tanzi (2009) reported that the use of the laser eliminated between 40-75 % of hair for 6 months after the application on 20 subjects. The effectiveness on five different skin phenotypes (1-5) was assessed, using a power <5 J/cm^2 IPL (Silk'n®, Home Skinovations Ltd., Yokneam, Israel).

In the human population studies, no negative effects were observed after each treatment nor at the end of the exposure period.

Nuijs et al. (2008) developed a similar study where they assessed the effectiveness of the reduction for 4-6 weeks and damage or injury in the tissues where the laser was applied. It was found that the application of laser at 2 and 15 J/cm^2 in pulses at 600-950 nm at intervals of 2 weeks reduced between 70-80% of the hair after 4-6 weeks of treatment without any visible effect, although in vitro studies revealed localised trauma in the follicle matrix.

Wheeland (2007) reported a reduction of between 33-40% in the removal of hair in periods of 6 to 9 months respectively, carrying out studies with a population with skin phenotypes between 1-4. This reduction took place after one year in the studies which used diode laser between 7-20 J/cm^2. In this study, no incidents of adverse reactions associated with use were reported.

Emerson and Town (2009) found a reduction of 41% in hair growth 6 months after the sequential application of treatments to 29 subjects with phenotypes between 1-3 using IPL of 11 J/cm^2 and pulses of 25 ms (Boots Smooth Skin, CyDen Ltd., Swansea, UK).

Whorapong et al. (2016) found that the use of fractional thermolysis processes using radio frequency leads to the genesis of neo collagen in the treated area and that the laser or IPL-based hair treatments produce a synthesis of heat stress proteins, types HSP47, HSP70 and HSP72.

Lolis y Marmur (2006) found that the application of laser as IPL may, on certain occasions lead to an increase in hair growth in the treated area, known as the "Paradox effect".

Town et al. (2012) describe a study on animals by Haedersdal et al. (2011) on IPL and UV light in the long-term relating to skin tumour induction in hairless mice (bare mice) which reported adverse effects.

5. Regulatory framework

5.1 Preliminary questions

Home photoepilators are industrial products intended for sale directly to consumers and users, and are subject to the regulations applicable to any electrical device which may be used for aesthetic purposes or other non-medical use.

It should be noted that home photoepilators are not health products, as their purpose is aesthetic and not medical. Nor can they be considered as therapeutic or diagnostic devices. Therefore, they are not included under the scope of application of Council Directive 93/42/EEC, of 14 June 1993, concerning medical devices; nor are the existing harmonised technical standards applicable for facilitating compliance of laser medical devices to the requirements

of this Directive; nor are they subject to the approval criteria and efficiency studies of medical systems.

Nevertheless, the draft Regulation of the European Parliament and the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation (EC) 1223/2009, which is in an advanced administrative phase and which will repeal Council Directive 93/42/EEC, includes in its scope of application "Specific groups of invasive products for which the manufacturer only declares an aesthetic or other non-medical purpose, but which are similar to medical devices as regards operation and risks". These groups of products will be listed in Annex XV of the Draft Regulation, and include photoepilators (Annex XV, point 6).

The draft Regulation anticipates the adoption by the European Commission of common specifications for each group of products not intended for medical use, to allow manufacturers to demonstrate the conformity of said products. These specifications shall be established considering the latest findings in the field of medicine and, in particular, the standards existing for similar products intended for medical use, based on a similar technology. The specifications shall refer, at least, to the application of the management or handling of the risk and of the general safety and performance requirements and the clinical research on humans, together with the clinical evaluation applicable to said products.

Among "the standards existing for similar products intended for medical use, based on a similar technology", the European standard EN 60601-2-22:1996 - Medical electrical equipment should be mentioned. Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment, which, according to the Commission Communication in the framework of the implementation of Council Directive 93/42/EEC, accords the presumption of conformity to the provisions of Council Directive 93/42/EEC (although it does not necessarily include the requirements introduced by Directive 2007/47/EC); and Standard UNE-EN 60601-2-22:2013 Medical electrical equipment. Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment endorsed by AENOR in April of 2013.

5.2 Industry regulations

Currently in Spain there is no specific Safety Regulation for home photoepilators. Therefore, without prejudice to other applicable provisions listed below, Royal Decree 1468/1988, of 2 December, approving the Regulation on labelling, presentation and advertising of industrial products intended for direct sale to consumers and users. This provision requires that the products include correct, adequate and efficient information about the essential characteristics and, in particular, that they advise "of the hazards of the product or its components, when its use may result in foreseeable risks", and that the labelling includes the information about the "essential characteristics of the product, instructions, warnings, advice or recommendations on the installation, use and maintenance, handling, hazards or safety conditions, in the event that this information is necessary for the correct and safe use of the product".

Photoepilators are also subject to the obligatory requirements applicable to household devices, and those relative to the use of certain hazardous substances in electrical and electronic devices.

5.3 Consumer protection legislation

The consumer protection regulations are also applicable to home photoepilators. Given the absence of specific regulations for these products, it is necessary to refer to Royal Decree 1801/2003, of 26 December, on general product safety, which incorporates Directive 2001/95/EC of the European Parliament and the Council into the Spanish legal system. According to article 3 of the Royal Decree, when there is no obligatory regulation applicable, or when this does not cover all the product risks, its safety must be assessed with consideration for the following elements:

1. National technical standards transposed from non-harmonised European standards.
2. UNE Regulations.
3. The recommendations of the European Commission which establishes directives on the assessment of product safety.
4. Codes of good practice with respect to the safety of products which are applicable in the sector, especially when Consumers and the Public Administration have taken part in their preparation.
5. The current status of information and technology.

5.4 Technical standards

Laser products

The harmonised technical Standard applicable to laser products is EN 60825-1: 2007 "Safety of laser products. Part 1: Equipment classification and requirements". Compliance with this standard accords the presumption of conformity to the safety requirements of Directive 2014/35/EU of the European Parliament and the Council, of 26 February 2014, on the harmonisation of the Member State legislation as regards the placing on the market of electrical material intended for use with certain voltage limits.

It should be noted that on 5 February 2014, after recognising that compliance of this technical Standard does not guarantee that a laser product is safe, the European Commission adopted a Decision proposing that the European standardisation bodies draft a new European standard, or an amendment to the current European Standard, which includes new safety requirements for consumer laser products and, in particular, the following:

a) Child-appealing laser products: "shall not cause, in the event of exposure to laser radiations, damage to eyes or skin which may occur in any scenario of use, including the long-term intentional exposure with optical instruments".

b) All other products: "shall not cause damage to eyes or accidental damage to skin in the event of exposure to laser radiation arising from the normal or reasonably foreseeable use, including casual or unintentional momentary exposure; any intentional damage to the skin by consumer laser products shall be compatible with a high level of protection of the health and safety of consumers".

The Commission added in their Decision that compliance with points 1 and 2 must be obtained by technical means and also indicated that "in the case of products that comply with that laid out in

point 2, if exposure to laser radiation might cause damage to eyes or skin under normal conditions of use other than those mentioned in point 2 (that is, other than the normal or reasonably foreseeable conditions of use, including casual momentary exposure), these products shall have the appropriate warnings in their labelling and be accompanied by instructions for the user containing all the relevant safety information".

At the end of 2014 the European Committee for Electrotechnical Standardisation (CENELEC) approved the EN 60825-1:2014 Standard, adopted by AENOR, on 1 April 2015.

On 19 June 2017 the EN 60825-1:2007 standard will no longer accord presumption of conformity with the special safety requirements of Directive 2014/35/EU of the European Parliament and the Council, such that the presumption of conformity, based on a harmonised technical Standard, may only be invoked in accordance with that laid out in UNE-EN 60825-1:2015.

Photobiology

For the revision of risks from light, several standards have been approved in recent years, including, in particular, UNE-EN 62471:2009: Photobiological safety of lamps and lamp systems,with a specific section on which the safety of IPL light products must be based (Part 3: Guidelines for the safe use of IPL emitting devices on the human body).

Household goods for the treatment of skin and hair

From the safety point of view (Directives 2006/95/EC and 2014/35/EU), there is no harmonised product standard, but there are general applicable standards including EN 60335-1 and the EN 60335-2-23 on household goods for the treatment of skin and hair, which may apply together with EN 60825. All the standards have been included as UNE standards by AENOR. These standards analyse the risks, normally electric, as they are powered by low voltage, including access to live components, leakage currents, dielectric rigidity, heating, stability to mechanical damage, etc. The above-mentioned standards fall within the harmonised standards to comply with the European Low Voltage Directive listed in the Commission Communication in the framework of the implementation of Directive 2006/95/EC of the European Parliament and the Council, on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (2016/C 126/03).

Conclusions

1. Regarding to the safety and efficacy of its use, there are not enough scientific-technical studies available that assess the direct risk in terms of the use of photodepilator devices, and of the scarce existing ones, most are focused on the immediate effect in the place - biological target after its use, being nonexistent the toxicological studies associated to a prolonged use, photobiological effect, sensitization and / or possible inhalation of harmful substances produced during the process of photodepilation.
2. The majority of the studies carried out focus on professional devices and there are few scientific and technical studies on home devices. As these have emission fluences, in some

cases lower than those of professional devices, neither the safety nor the adverse effects have been studied sufficiently.

3. Use of these devices may result in skin and/or eye damage or injury due to inflammation and burns which may lead to secondary damage.
4. Current home photoepilation devices, in general, do not have specifications in their labelling, defining characteristics such as fluence, pulse duration, spectrum, discharges by second, beam diameter and wavelength, clearly and differentiated, as these are parameters associated with the risk of using these devices.
5. The regulation existing for aesthetic systems and devices for home-use considers these systems as direct sales products, and therefore they may be marketed as any product in the dermo-aesthetic area. Nevertheless, there are many cases of type I and II laser systems and IPL systems which may emit fluence in many cases similar to that of a professional device and these require a series of precautions in their handling, and are not free of risk.

To conclude, this committee considers it is necessary to develop a specific legal framework for these devices. This legal framework should include the scientific and technical studies necessary for assessing the safety of their use. It considers that existing regulations associated with this type of photoepilator must be harmonised and revised with the aim of considering possible risks derived from their use and exposure.

Recommendations

The scientific committee of the AECOSAN (Consumer Affairs Section), following the analysis developed, issues the following recommendations with respect to the use of home photoepilators:

1. As the majority of scientific and technical studies have been carried out with photoepilators for professional use, studies of the safety and effectiveness of home photoepilators are necessary for the correct interpretation of the results.
2. The direct and indirect effects must be assessed, not only in the short-term, but also in the long-term, given the possible sensitisation of tissue or other photobiological effects that may appear. Therefore, it is necessary to conduct studies of mutagenicity (tests to reveal the possible genetic and/or chromosomal mutations); dermal toxicity (tests which reveal whether the device has inflammatory, irritant and corrosive effects), ocular toxicity and photosensitivity (tests revealing whether the device causes irritating effects, corneal opacity and corrosive effects), inhalation toxicity (toxic concentration of products resulting from the heat effect derived from the photolysis); and studies of the inhalation of harmful substances emitted during the hair removal process.

   The use of validated in vitro studies as pre-screening tests alternative to the in vivo studies on animals used for research may be a preliminary source of data for studying the potential adverse effects resulting from the application of photoepilators and establishing whether it is necessary to carry out other more prolonged studies, including in vivo studies. Always in compliance with the principles of the three Rs (replacement, refinement and reduction).

Conduct tests to confirm the effectiveness of these devices.

3. As the placing on the market and the use of home devices does not consider the advice of qualified professionals and incorrect use may result in direct or indirect injury of the biological target area, the following is recommended:
   a) The inclusion of measures which reduce the circumstances associated with the risk of use, such as ensuring that use is only with adequate eye protection, self-regulation depending on skin type (phototype), availability of smoke extractors to minimise the volatilisation of compounds during the burning process and the existence of devices which prevent or hinder their use by children.
   b) The inclusion of obligatory instructions for use which warn of the possible direct or indirect risks derived from the use of the product. These instructions must be clearly indicated, understandable for the consumer and visibly include the relevant indications advising of the risks of use.
   c) The inclusion in the labelling of clear and separate specifications defining characteristics such as fluence, pulse duration, spectrum, discharges per second, beam diameter and wavelength.
4. Revision and completion of the regulatory framework, including technical standards, in order to harmonize the whole set of technologies contemplated within domestic photodepilator devices and ensure that their use is safe, since at the moment their regulation does not correspond, In safety and efficacy aspects, with the possible toxicological and biological adverse effects that may arise from normal or reasonably foreseeable use.

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Legal Annex

1. Legislation

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Regulation (EC) 1907/2006 of the European Parliament and the Council, of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Official Journal of the European Union of 29 May 2007, No L 136).

Regulation (EC) No 1272/2008 of the European Parliament and the Council, of 16 December 2008, on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Official Journal of the European Union of 31 December 2008, No L 353). Council Directive 93/42/EEC, of 14 June 1993, concerning medical devices (Official Journal of the European Union of 12 July 1993, No L 169).

Directive 2001/95/EC of the European Parliament and the Council, of 3 December 2001, on general product safety (Official Journal of the European Union of 15 January 2002, No L 11).

Directive 2006/42/EC of the European Parliament and the Council, of 17 May 2006, on machinery, and amending Directive 95/16/EC (recast) (Official Journal of the European Union of 9 June 2006, No L 157).

Directive 2011/65/EU of the European Parliament and the Council, of 8 June 2011, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) (Official Journal of the European Union of 1 July 2011, No 174).

Directive 2014/30/EU of the European Parliament and the Council, of 26 February 2014, on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) (Official Journal of the European Union of 29 March 2014, No L 96).

Directive 2006/95/EC of the European Parliament and the Council, of 12 December 2006, on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (consolidated version) (Official Journal of the European Union of 27of December 2006, No L 374) (repealed with effect from 20 April 2016).

Directive 2014/35/EU of the European Parliament and the Council, of 26 February 2014, on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast) (Official Journal of the European Union of 29 March 2014, No L 96).

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Royal Decree 1801/2003, of 26 December, regarding the general safety of products (BOE No 9, of 10 January 2004).

Royal Decree 1468/1988of 2 December, approving the Regulation on labelling, presentation and advertising of industrial products intended for direct sale to consumers and users. (BOE No 294, of 8 December 1988).

2. Technical Standards

ANSI Z136.1 Standard (Z136.1-2000)

EN 60335-1:2012: Household and similar electrical devices. Safety. Part 1: General requirements. 53.

EN 60335-2-23:2003: Household and similar electrical devices. Safety. Part 23: Particular requirements for devices for skin or hair care.

EN 60601-2-22: versions 1996 and 2013: Medical electrical equipment. Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.

UNE-EN 60825-1, versions 2007 and 2015: Safety of laser products. Part 1: Equipment classification and requirements.

UNE-EN 62471:2009: Photobiological safety of lamps and lamp systems.

Part 3: Guidelines for the safe use of IPL emitting devices on the human body.

3. Other documents

Draft Regulation of the European parliament and of the Council on medical devices amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, [2012/0266 (code)].

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