



The Director General

Maisons-Alfort, 19 December 2012

OPINION

of the French Agency for Food, Environmental and Occupational Health & Safety

**relating to a draft decree concerning the sale and provision to the public of certain
tanning devices that use ultraviolet radiation**

ANSES undertakes independent and pluralistic scientific expert assessments.

ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.

It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are made public.

This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 19 December 2014 shall prevail.

In an email dated 29 November 2012, the Directorate General for Health (DGS) sought an opinion from ANSES on a draft decree designed to amend the Decree of 30 May 1997 relating to the sale and provision to the public of certain tanning devices that use ultraviolet (UV) radiation. This draft, which follows an earlier proposal for amendment on which the Agency had given its opinion on 31 May 2012, was submitted for open consultation from 29 November to 19 December 2012.

Compared to the version currently in force, the text submitted for public consultation includes amendments designed to regulate more strictly the terms of public access to tanning devices for cosmetic purposes.

The Agency is not ruling on the provisions that relate to devices for therapeutic purposes.

1. BACKGROUND AND PURPOSE OF THE REQUEST

On 6 September 2004, the Agency (known as AFSSE at the time) had been asked by the Ministries of Health and Ecology to reassess the health risks associated with exposure to natural radiation and with the use of tanning facilities. The Agency had issued a report [AFSSE, 2005] and an opinion in May 2005 in which it primarily recommended avoiding exposure to artificial UV radiation.

On 3 February 2010, the National Cancer Institute (INCa) called on the Agency (known as AFSSET at the time) and the French Institute for Public Health Surveillance (InVS) to apply their expertise to an analysis of the cancer risk associated with ultraviolet radiation emitted by artificial tanning facilities. The INCa report [INCa, 2010a] published in April 2010 strongly advised against exposure to artificial UV radiation for cosmetic purposes.

The draft decree that is the subject of the public consultation comes against a background of considerable developments in scientific knowledge on the health risks associated with

exposure to ultraviolet radiation since the 1997 publication of the regulatory text currently in force.

In particular, in 2009, the International Agency for Research on Cancer (IARC) classified artificial UV rays as "Carcinogenic for humans" (Group 1), especially after determining that the risk of developing cutaneous melanoma is increased by 75% for individuals using tanning booths at least once before the age of 35 years [IARC, 2007].

Subsequent to the classification by the IARC of artificial UV rays in Group 1, four major studies ([Veierød, 2010], [Lazovich, 2010], [Cust, 2011], [Zhang, 2010]) and an epidemic of melanoma in Iceland [Hery, 2010] further reinforced this assessment. In addition, a recent meta-analysis [Boniol, 2012a] re-evaluated at 87% the increase in the risk of developing melanoma for individuals using artificial tanning at least once before the age of 35 years.

In France, of all cancers, cutaneous melanoma is the one seeing the fastest increase in incidence and mortality, particularly among young adults. Between 1980 and 2005, the annual number of new cases of melanoma more than tripled, to approximately 7,400 cases in 2005 [Belot, 2008] and 9,780 in 2011 [Boniol, 2012a].

In terms of mortality, the annual number of deaths from melanoma more than doubled between 1980 and 2005, with 1,440 deaths in 2005 [Belot, 2008] and 1,620 in 2011 [Boniol, 2012a].

Moreover, unlike many other cancers, there has been no significant improvement in the curative treatment of melanoma in more than 40 years: the only effective treatment to date remains surgical removal at an early stage, which is unable to combat metastatic forms [INCa, 2010b].

UV exposure, whether this irradiation is of solar or artificial origin, is the primary known risk factor in the development of cutaneous melanomas and carcinomas. The World Health Organization (WHO) estimates that the share of skin cancers attributable to solar radiation or artificial UV rays could be between 50 and 90%.

A joint study [Boniol, 2012b] from the InVS and the International Prevention Research Institute (IPRI) using Inpes (National Institute for Prevention and Health Education) data estimated for France "that 4.6% of the cases of cutaneous melanoma, or 347 cases annually, are attributable to the use of tanning booths. Women bear this risk more than men, and account for around 76% of cases. Different alternative scenarios lead to the assessment that each year, between 91 and 350 cases of melanoma are due to the use of tanning booths." The number of annual deaths from cutaneous melanoma associated with exposure to artificial UV rays from tanning booths may be between around twenty and 75.

However, there has been a huge increase in the practice of tanning in France, whether by artificial or natural UV rays. According to the French National Union of Tanning Booth Professionals (SNPBC)¹, in 2012, there were more than 15,600 tanning booths in France, located in 10,700 establishments. The leading chain of specialised centres, *Point Soleil*, alone reports that it received more than 9,000 customers a day for 3 million tanning sessions a year². The number of tanning centres more than doubled between 2002 and 2009, and this growth is expected to continue over the next few years.

It is important to remember that the doses received during artificial tanning sessions are cumulative with those from natural UV exposure; they thus contribute to skin carcinogenesis whose effects have no dose threshold. The current growth in the availability of artificial UV tanning facilities and in their popularity is therefore alarming.

In addition, a market study on UV booths carried out in January 2011, at the request of the DGS, estimated that there were about 40,000 tanning booths in operation in France. The

¹ Data available from the SNPBC website on 13 December 2012: <http://snpbc.org/marche-du-bronzage-en-cabine/>

² <http://www.pointsoleil.com/index.php/soleil-notre-metier-reseau/>

annual reviews carried out by the DGS and the annual survey conducted by the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF) also confirm the observation of a reduction in the quality of tanning centres since 2006 (inadequate supervision, increase in the number of non-compliances—in particular the failure to declare booths to the Prefect of the *département* where the services are provided, failure to comply with the UV classes of tubes, lack of qualification of supervisory staff, etc.).

In view of these points, and with the aim of protecting the health and safety of the population and especially that of minors, as well as of professionals in the field, it seems essential to reinforce the measures for managing the risks associated with the practice of tanning by artificial UV rays, in particular the 1997 regulations, as well as the enforcement of their application.

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal falls within the sphere of competence of the Expert Committee (CES) on Assessment of the risks related to physical agents, new technologies and development areas.

In formulating its conclusions and recommendations, ANSES drew on the skills of three external rapporteurs.

The expert appraisal was carried out in accordance with French Standard NF X 50-110 “Quality in Expert Appraisals – General requirements of Competence for Expert Appraisals (May 2003)”.

3. ANALYSIS OF THE DRAFT DECREE

The main provisions of the decree

Chapter 1

Article 1 presents the characteristics of the four categories of devices that emit ultraviolet radiation intended to act on the skin.

Comment: The authorised values tolerate effective irradiance corresponding to sun exposure at UV index 12, and the constraints (in terms of duration, frequency of sessions and maximum annual dose) as well as the restrictions for sensitive people (those with fair skin, minors and young adults) proposed by this draft decree remain weak and insufficient to protect the health of tanning booth users.

Chapter 2

Article 4 prohibits the sale and provision to minors of type UV3 tanning equipment and prohibits making type UV1 devices available to them.

Comment: Although the ban on provision to minors of type UV1 and UV3 devices is already well known to professionals, the draft decree does not propose any regulatory mechanism enabling them to require that customers prove they are of age. Nevertheless, the Cancer Barometer produced by Inpes and INCa in 2010 revealed that 3.5% of people aged 15 to 18 years reported having undergone an artificial tanning session at least once in their life. Childhood exposure to UV rays in general and to artificial UV rays in particular is a factor aggravating the risk of skin cancer that should be prevented by all possible means.

Chapter 3

Article 5: "Type UV1 and UV3 tanning devices can only be provided to the public under the direct supervision of a person holding either one of the diplomas required to exercise the

profession of beautician, or a certificate of recognition of qualification. The conditions governing training and issuing of the certificate are stipulated by a joint order of the Ministers of Health and Consumer Affairs.

The diploma or the certificate of recognition of qualification must be displayed in the reception area and be clearly visible to the public."

Comment: The purpose of this supervision is not defined and its scope is limited to devices installed in establishments, which excludes those placed on the market via the internet, thereby limiting the deterrent effect of this measure.

In addition, the draft decree does not clarify situations involving direct purchase of tanning devices by the general population and primarily considers the single situation of cabins managed by professionals and made available to the public. According to Article 3, "type UV3 devices can be freely placed on sale or provided to the public, subject to the provisions of Articles 4 and 5 [...]". However, Article 5 of the draft decree specifies that type UV1 and UV3 devices may only be provided to the public under supervision. For the sake of consistency, therefore, the direct purchase of UV3 devices by the general population should be prohibited.

Concerning the training obligation for staff in charge of supervising sessions (whose objectives and content are reported in an order), it would be preferable for establishment managers to be bound by the same obligations, as this would reinforce the impact of the preventive measures stipulated by the regulations that they are supposed to be implementing.

Finally, in displaying the diploma, it is assumed that the customer can actually make the distinction between a person qualified to supervise and another who is not. In addition, this display, just like the supervision, could be construed as a guarantee of the safety of undergoing UV radiation. However, UV rays have been proven to be hazardous, and there is no exposure without danger, regardless of the frequency of exposure or the dose received. This is true from the very first use (carcinogen without a threshold effect). Indeed, epidemiological data show that the fact that a person has been exposed at least once in their life to a device emitting artificial UV rays leads to a 15% increase in the risk of developing cutaneous melanoma [IARC, 2007].

Chapter 4

Articles 7 and 7bis describe the question of providing proof of conformity of devices and their marking, in order to ensure traceability and control.

Comment: Article 7bis of the draft decree does not specify the methods for marking type UV1 and UV3 devices for the purposes of traceability and control of these emitters, referring rather to the methods stipulated in a joint order from the Ministers of Health and Consumer Affairs.

In addition, Paragraph II of Article 19 of the draft decree provides for a derogation from this marking obligation for "UV emitters equipping or intended to equip type UV1 and UV3 devices, prior to [1 July 2013]". In practice, this dual regime limits the scope of the control and traceability measures stipulated by the decree, which distinguishes between two groups of devices: recent controlled devices on the one hand, and older non-controlled devices on the other. It is likely to encourage the continued operation of older machines that would not be subject to control. It would therefore be preferable for the measure provided for by Article 7 to apply without distinction to all type UV1 and UV3 devices, regardless of their date of acquisition.

Article 9 includes a measure defining the obligation for an instruction guide intended for the purchaser, and Article 10 defines the obligation for a public warning notice visible on the device.

Comment: Article 10 of the draft decree does not define the methods of display and the content of the warning for users, which must appear on any tanning device made available to the public, and which were referred to in a joint order from the Ministers of Health and Consumer Affairs. However, the characteristics of this warning (text, graphics, colour, character size, scope, argument), despite being limited in terms of their dissuasive power, are a vital lever with which to inform the public about the increase in the risk of skin cancer and the effects associated with the use of tanning booths.

Article 11 includes a measure making it mandatory to display a warning in the vicinity of the tanning device.

Comment: The display of the warning in the vicinity of the tanning device is limited to devices installed in establishments, which excludes those placed on the market via the internet, thereby limiting the deterrent effect of this measure.

Article 12: "Any advertising relating to type UV1 and UV3 tanning devices or to tanning sessions, as well as any sales presentation, shall be accompanied by a warning whose content and methods of display are defined by a joint order from the Ministers of Health and Consumer Affairs.

The advertising mentioned in the first paragraph may in no case be such as to make users believe that exposure to artificial UV rays has a beneficial effect on health".

Comment: Article 12 of the draft decree does not define the methods of display and the content of the warning accompanying the advertising, and which were referred to in a joint order from the Ministers of Health and Consumer Affairs. However, the characteristics of this warning (text, graphics, colour, character size, scope, argument), are a vital, though limited lever in terms of their dissuasive power, with which to inform the public about the increase in the risk of skin cancer and the effects associated with the use of tanning booths.

Indeed, these measures, which are modelled on other provisions already applicable to food products or tobacco and which seek to change behaviour and improve information to the public, issue paradoxical messages to the public. In addition, it is necessary to place the scope in perspective, in light of the results of a study published in 2012 on exposure to artificial UV rays in France [Leon, 2012], which stated that 85.9% of people who had used artificial UV sessions for cosmetic purposes believe that this practice is a possible cause of cancer.

Moreover, provisions preventing the use of promotional rates and unlimited fixed-rate formulas, in the sense that this represents indirect advertising, should be included in the draft decree.

Chapter 5

Chapter 5 describes the methods of reporting and technical control.

Chapter 6

Chapter 6 provides for a regime of penalties relating to several articles in the draft decree.

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

In a context of rapid expansion of the marketing and use for cosmetic purposes of radiation-emitting devices with a proven carcinogenic effect, and moreover without any beneficial effect on health, associated with the reduced effectiveness of the control measures taken since the 1997 decree, ANSES believes that the draft decree constitutes only a partial and insufficient response in light of the proven risk of skin cancer for their users.

Indeed, regulations governing the methods of public access to tanning devices for cosmetic purposes are unable to prevent the health impact of artificial UV rays. For this reason, in 2009, Brazil prohibited the use of UV cabins for cosmetic purposes [ANVS, 2009]. The Australian state of New South Wales has also opted for this measure, which took effect in 2014.

ANSES therefore recommends the cessation, ultimately, of all commercial use of tanning by artificial UV rays and of the sale of appliances emitting artificial UV rays for cosmetic purposes.

Given the health data already presented, it would be preferable for the authorities to draw the attention of the European Commission to the safety of use of tanning devices.

The Director General

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KEYWORDS

Ultraviolet radiation (UV), tanning devices / booths, sunbeds, indoor tanning.

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