

SCCP Directive:

The Triumph Of Anti-Tanning Politics Over Science And Common Sense

by Patricia E. Reykdal & Donald L. Smith

The recent notification that the European Commission's Scientific Committee on Consumer Products' (SCCP) Low Voltage Directive (LVD) Administrative Cooperation (ADCO) working group had decided the provisions of its June 2006 report titled "Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes" will become effective July 23, 2007 is a triumph of anti-tanning politics over science and common sense.

The onerous provisions in this directive—especially the provision to limit sunbed irradiance to 0.3 W/m^2 —will destroy the European indoor tanning industry, increase the number of Europeans who sunburn and damage their skin, and significantly exacerbate the already serious health problems caused by suboptimal vitamin D levels.

The two parties that will be most affected by the "unintended adverse consequences" of this ill-conceived directive are the European indoor tanning industry and European citizens. Therefore, consider the following points.

Point 1

The "effective date" is only *six months* after the SCCP report was first published, even though the average time of implementation for such directives is three to five years. The unusual fast tracking of the directive makes it very difficult for everyone—manufacturers, salon owners and the various countries involved—to implement, administer and control the provisions, and provides *prima facie* evidence that this directive was politically motivated.

Point 2

The SCCP ignored the recommendation of its own "expert panel" for a Maximum Effective Irradiance Limit (MEIL) of 0.7 W/m^2 ,

a level that would have allowed the use of the most common sunlamps being marketed in Europe today.

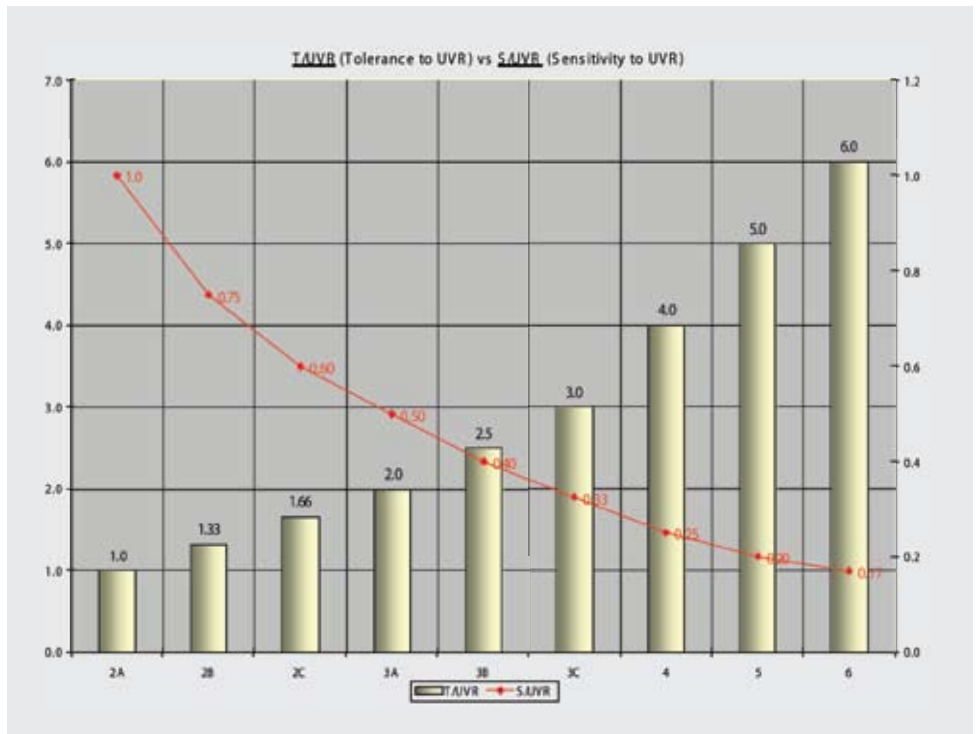
Discussion

Our analysis of the 20 most common low-pressure and HID/high-pressure sunlamps in use today showed an average irradiance level of 0.562 W/m^2 , which is well within the 0.7 W/m^2 level recommended by the panel. A 160-watt

sunbed meeting the 0.3 W/m^2 directive is very weak and requires a session time of 25-30 minutes. On the other hand, a 0.562 W/m^2 160-watt sunbed would have a session time of 12-15 minutes.

Point 3

Even though the directive *specifically agreed* with the Bunsen-Roscoe Law of Reciprocity, i.e., that it is dose, not dose rate, that determines the human



biological response to ultraviolet radiation (UVR), the adoption of the 0.3 W/m² MEIL means *no consideration was given to dose rate and/or session time*. This is a major and inexcusable failing of the SCCP directive.

Discussion

The indoor tanning industry controls the UVR dose of sunbeds exactly as the dermatology community controls PUVA lamps and as testing laboratories control the Xenon solar simulators used for sunscreen efficacy testing.

All three modalities adjust the maximum session time—based upon the effective (i.e., weighted by the appropriate action spectrum) irradiance of the source—in order to control the “delivered” dose. For example, the Bunsen-Roscoe Law of Reciprocity states an effective dose of 0.6 W/m² delivered in 15 minutes has the same biological effect as an effective dose of 0.3 W/m² delivered in 30 minutes, even though the dose rate is twice as fast in the former (0.6 W/m²) than in the latter (0.3 W/m²). In other words, a higher effective dose (0.6 W/m²) results in a shorter session time than a lower effective dose (0.3 W/m²). The biological result is the same since it is dose, *not dose rate*, that determines biological activity.

Therefore, it is not any more necessary to implement a limit of 0.3 W/m² on the indoor tanning industry than it would to impose a limit on PUVA therapy and/or sunscreen testing. In fact, it is counterproductive in all three situations.

Point 4

The directive stated the only two “positive effects” of UVR were the “synthesis of vitamin D” by the skin after exposure to UVR and the “feel-good factor” attributed to an increase in serotonin and melatonin.

Inexplicably, the report gave *absolutely no mention* to the increase in tolerance to ultraviolet radiation (T/UVR) and decrease in S/UVR (Sensitivity to UVR) due to constitutive pigmentation (natural skin color) and the development of facultative pigmentation—better known as a tan—along with the skin thickening that naturally and contra-volitionally results from sensible, moderate and responsible UVR exposure.

Discussion

The graph on page 30 shows T/UVR increases and S/UVR decreases as our

natural skin color gets darker. There is a sixfold increase in T/UVR, and an 83-percent reduction in S/UVR between skin subtype 2A and skin type 6.

Keep in mind the development of UVR-induced facultative pigmentation increases our T/UVR (and decreases S/UVR) in direct proportion to the level of the tan developed as an individual progresses from no tan to the maximum level of tan possible.

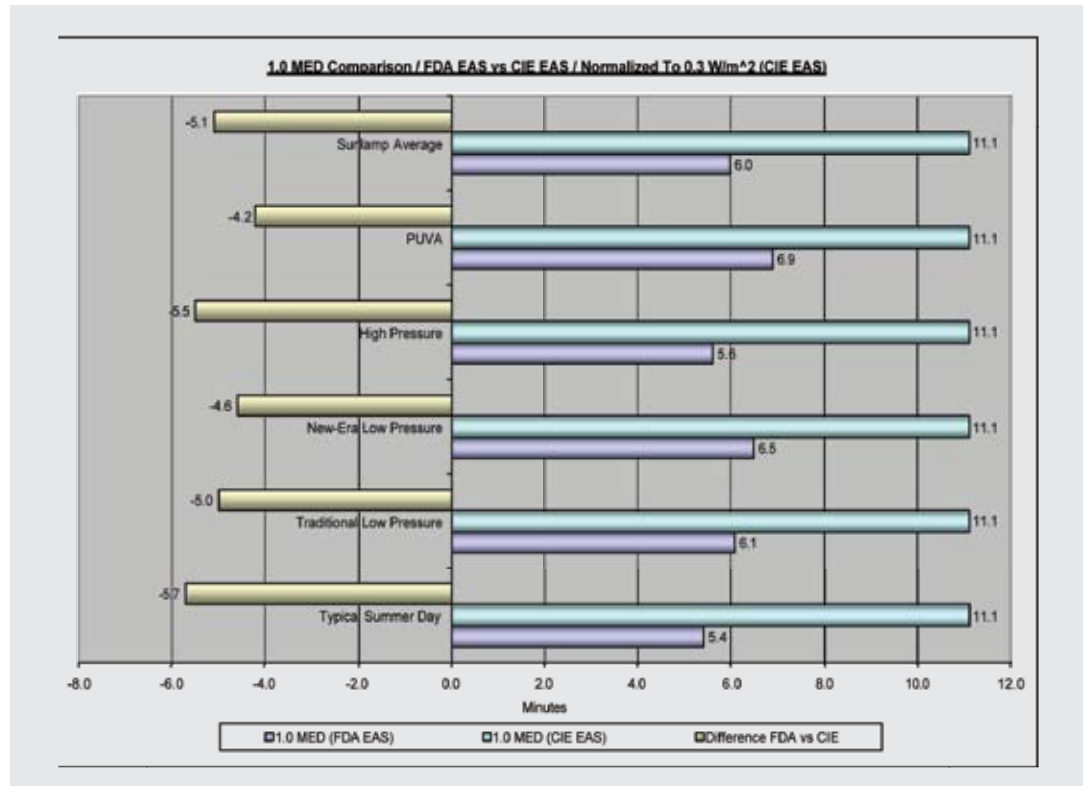
Therefore, attaining and maintaining a tan year-round dramatically increases our T/UVR (and decreases S/UVR), reducing the potential for damage to our skin by 85 percent to 95 percent.

Point 5

If the European Commission *really* wanted to protect the people in Europe who, *of their own free will*, patronize indoor tanning salons, all that would have been required was for it to adopt the more protective FDA Erythemal Action Spectrum (EAS) that has well served tanning salons in the United States for the past two decades.

Discussion

The graph below compares several irradiance sources normalized to 0.3 W/m² and shows the “more protective” FDA EAS significantly reduces the time to deliver a dose of 1.0 MED than the “less protective” CIE EAS. For instance, the session time for the average sunlamp to deliver a 1.0 MED dose is 5.1 minutes shorter when the FDA EAS is used—a 46-percent safety margin over the CIE EAS.



The bottom line is adopting the FDA EAS would accomplish several goals. It would harmonize and standardize the labeling of sunlamps and sunbeds in the United States and Europe, and increase the exposure schedule safety margin in Europe so it could match the enviable record achieved in the United States.

Note: Data provided to us by FDA a few years ago showed that, over a 15-year period, there was only one complaint regarding a commercial indoor tanning salon for every 100 million tanning sessions. *We challenge anyone to find another industry regulated by FDA with a better safety record!*

Be Vigilant

This article brings the European anti-tanning SCCP directive situation to the attention of the U.S. indoor tanning industry. We believe the dermatology community will make a *concerted attempt* to force FDA into adopting the SCCP 0.3 W/m² MEIL within the next year. If successful, it will adversely impact the industry and the health and welfare of the American public.

We must be prepared to present scientific data showing it is *not necessary* to adopt a MEIL given the stellar safety record of the U.S. indoor tanning industry. Moreover, we should start working proactively with FDA in order to bring the existing Sunlamp Standard regulations and guidelines up to date.

The regulations haven't changed materially since they were published in 1986. They need to be updated to reflect that constitutive and facultative pigmentation must be taken into consideration in the development of exposure schedules that neither overexpose nor underexpose clients to UVR; include a standard skin typing questionnaire and exposure schedule matrix; include a standardized informed consent and client release form; include a standard protocol for testing both low-pressure and HID/high-pressure sunlamps and sunbeds; and include a provision requiring vendors to provide low-pressure and HID/high-pressure sunlamp compatibility sheets that are based upon *real-world testing* in a sunbed.

Authors' Note: We have sent a complete response to the SCCP directive to Jose Manuel Barroso, president of the European Commission. To obtain a copy of the response, e-mail reyksmith@aol.com. ▲

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