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grant agreements (No 17.020200/08/509475)

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Cross border action supported by the European Commission
DG-SANCO, Consumer Affairs Directorate

Joint action on sunbeds 2008 - 2009

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Contents

Summary

Since September 2008 10 market surveillance authorities from 10 European Union Member States have participated in a cross border action to enforce the safety requirements for sunbeds and sunbed services. During the action, which will end December 2009, tanning salons and similar facilities were inspected, as well as the sunbeds offered there for use to the general public. The joint action on sunbeds was partly funded by the European Commission – DG-Sanco.

The Market surveillance authorities participating in the sunbed cross border actions carried out inspections at more than 300 locations and investigated more than 500 sunbeds. The great majority of these inspections were at service providers (tanning salons, wellness centres, etc) and concentrated on the safety information and advice provided to consumers (including age restrictions), the labelling of the sunbeds, the availability of eye protection and the UV –radiation emitted by the sunbeds.

Requirements for tanning salons

The European safety requirements for sunbeds are based on the Low Voltage Directive and for sunbed services on the General Product Safety Directive. Tanning salons should provide the consumer with Information and advice about the tanning schemes suitable for their skin type, block the use of sunbeds by consumers under the age of 18 and give clear information about the hazards of UV radiation. Preferably intake interviews with new customers should ensure that the information and advice provided is tailored to the specific consumer and that consumer under the age of 18 are not allowed to use the sunbed. The sunbeds must carry warnings and for consumer use the UV radiation emitted is restricted to 0,3W/m^2.

Industry

Under EU law manufacturers, importers, distributors and retailers have primary responsibility for the safety of the products that are put on the market. Service providers are responsible for the safety of products used in services, so tanning salons must assure that sunbeds are safe and are used sensibly. At the European level the tanning industry is organized in the European Sunlight Association, which is playing an important role in ensuring operating standards in sunbed services. In regular consultations and with support of the market surveillance officials of the sunbed joint action ESA actively promotes adoption of the rules in the tanning sector, including the 0,3W/m2 limit on UV radiation emitted from sunbeds. To support tanning services in complying with EU legislation ESA is developing a European Code of Conduct for tanning services, training materials for tanning studios and organizes information seminars in cooperation with national associations in the Member States.

The impact of these activities is dependent on the degree of organization in the sector. As yet the degree of organization of the sector is low, as the results of this actions show, which may limit the impact of the industry initiatives.

Joint action results

Though the industry itself makes significant efforts to assure the safety of its services and is adapting to the new rules, the process is far from complete. The percentage of artificial tanning service operators that claimed to provide sufficient information varied between 75% and 94%. Similar percentages of the providers of tanning services indicate that they have intake interviews with new

customers. Only in Finland, where sunbed used is often unsupervised (coin operated sunbeds) the percentage of tanning service providers that have intake interviews was low.

As yet few of the proprietors can substantiate their claims and little is known of about the quality of the information provided. Best practice in providing tanning services should therefore aim to register intakes and tanning programs for their customers.

Checks of 207 sunbeds at service providers on the compliance with the labelling requirements in the LVD and in EN 60335 Part 2-27 (including EN 60335-2-27/a1/2008 and EN 60335-2-27/A2/2008) reveal that a substantial percentage fails to comply. For the common labelling requirements for electrical equipment (e.g. CE-marking, brand name, name and address of manufacturer) more than 20% of the sunbeds did not comply. Sunbed type was not listed on 32% of the inspected sunbeds and the warning that UV radiation may cause injury was not present on 52% of the sunbeds.

The risks of artificial tanning are not only determined by the way consumers use the sunbeds, but also by the amount of UV radiation emitted from the UV-tubes. This radiation, measured as erythemally weighted irradiation (EWI), should not exceed 0,3 W/m^2. In the sunbed joint action the EWI values of 84 sunbeds were determined with equipment partly financed by the joint action program. Of the 84 sunbeds that were tested 70 gave EWI values exceeding the limit of 0,3 W/m^2 (83,3 %). The highest value measured was 1,43 W/m^2

The overall conclusions from the results of the inspections in this first action on sunbeds are that:

- consumer guidance in tanning studios is regularly not given and, where it is claimed to be given this is often not verifiable,
- the labelling of the sunbeds fails to comply in at least 20% of the cases,
- How often the maximum EWI values for sunbeds are violated varies between the Member States. In several Member States the percentage may be above 90%, while in others the fraction of sunbeds that does not comply is estimated to be minimally between 10% - 20%, but probably higher.

Introduction

The Joint market surveillance action on sunbeds and solarium devices was conceived as a cross border market surveillance project that addressed both the compliance of sunbeds and solarium devices with safety requirement of the Low Voltage Directive and the compliance of sunbed and solarium serves as supplied in tanning studios and similar facilities with the General Product Safety Directive. The action was initiated by the VWA (Voedsel en Waren Autoriteit - Food and Consumer Products Authority in the Netherlands) in response to a request from Prosafe's EMARS project for proposals suitable to apply for funding from the joint action program. Reason to propose sunbeds as the subject of a cross border action was the growing scientific consensus about the carcinogenity of UV radiation, expressed in evaluation of the risks of artificial tanning by the Scientific Committee on Consumer Products and culminating in a mandate to the standardization bodies to adapt the standard for sunbeds to include maximum radiation levels.

The proposal was elaborated in cooperation with PROSAFE's EMARS project and submitted as an application for the joint action program. The application for the sunbed cross border action was accepted and the grant agreement (No 17.020200/08/509475) was signed the 18th of September2008. Main contractor was the Stichting Prosafe.
Participants in the action and subcontractors in the grant agreement were market surveillance organizations from Belgium, Cyprus, the Czech Republic, Denmark, Finland, Germany, Hungary, Latvia, the Netherlands and Poland. Belgium and Germany participated in specific parts of the project.

Design, coordination of the action, handling and analyzing reported results and reporting were managed by the VWA, supported by a Prosafe consultant.
The period during which the action was undertaken covered the period between September 2008 and September 2009, during which period all market surveillance activities within the scope of the project took place, except reporting. These activities included training of inspectors, establishing contacts with stakeholders, inspections of manufacturers/importers and of tanning facilities where sunbed use was offered as a service.

The cross border action on sunbeds and tanning devices is unique, as it is the first cross border market surveillance action that not only checks the compliance of tanning devices offered for sale, but also addresses the conformity of appliances offered in the framework of a service (tanning salons,etc.).

Risks of UV-exposure

Nourished by an increasing incidence of skin cancers concern about the adverse effect of UV radiation on humans, particularly its carcinogenic effects on the skin, has risen quickly over the last decades. Now skin cancer is the most common cancer worldwide, its incidence is doubling approximately every 15-20 years. Likely causes include aging of the population, increased UV exposure because of behavioural changes in sun exposure and increased UV light intensity at the earth surface due to ozone depletion.

The evidence for a causal link between UV-exposure and skin cancer incidence is presently such, that scientific consensus exists that UV radiation from sun exposure is a determinant for skin cancer[1]. This has prompted prevention campaigns in several countries, including the USA, Australia and South Africa, while prevention campaigns have also been initiated in European countries. Usually these campaigns aim to make consumers aware of the dangers of exposure to the sun's rays, trying to change behaviour in such a way that exposure of naked skin is avoided, especially during the early afternoon hours, by covering exposed skin with clothing. Evidence also indicates that overexposure to UV light resulting in sunburn during youth is a determining factor in the occurrence of skin cancer in later age.

Consensus about the carcinogenic properties of UV light inevitably raised the question if similar effects might be induced by exposure to artificially generated UV radiation. Similar effects can reasonably be suspected, but the differences between the radiation spectrum of sun light and artificial UV emitters are such that such a correlation is not immediately obvious to everyone. Until now, according to IARC[2], "epidemiologic studies do not give consistent evidence that use of indoor tanning facilities in general is associated with the development of melanoma or skin cancer". IARC also concludes that there is a prominent and consistent increase in risk for melanoma in people who first used indoor tanning facilities in their twenties or teen years and notes that the data suggest "that the risk of squamous cell carcinoma is similarly increased after first use as a teenager".

There are a number of reasons that epidemiological evidence is not unequivocal to date. There is considerable lag between exposure to UV radiation and the appearance of its carcinogenic effects. Because wide use of indoor tanning is also of relatively recent date, detection of these long term effects is still difficult. Also, the levels of UV exposure from indoor tanning are imprecisely known.

Nevertheless, IARC concludes that, "although the available findings are therefore not conclusive, the strength of the existing evidence suggests that policymakers should consider enacting measures, such as prohibiting minors and discouraging young adults from using indoor tanning facilities, to protect the general population from possible additional risk for melanoma and squamous cell carcinoma".

In 2006 the Scientific Committee on Consumer Products evaluated the hazards of artificial tanning on the request of the European Commission, which asked the Committee a number of questions related to health effects of the different categories of UV radiation and about the necessity of and the

[1] National Toxicology Program (2002). Report on Carcinogens, 10th Edition, Substances Profiles, National Toxicology Program, Research Triangle Park, NC.
[2] IARC Working Group on Risk of Skin Cancer and Exposure to Artificial Ultraviolet Light (2005 : Lyon, France); Exposure to artificial UV radiation and skin cancer; (IARC Working Group Reports ; 1)

possibility to set limits to UV radiation from sunbeds. The main conclusions of the SCCP, published in SCCP /0949/05[3] and adopted June 2006, can be summarized as follows:

- the use of UVR tanning devices to achieve and maintain cosmetic tanning, whether by UVB and/or UVA, is likely to increase the risk of malignant melanoma of the skin and possibly ocular melanoma.
- There is no justification for the presence of UVC in tanning devices
- The maximum erythemally weighted irradiance should not exceed 0.3W/m2, or 11 standard erythema doses (SED) per hour.

The latter irradiance is equivalent to tropical sun, which the WHO terms extreme.

The SCCP also concludes that people with known risk factors for skin cancer, especially malignant melanoma, should be advised not to use UVR tanning devices. Specifically, these are skin phototypes I and II and the presence of freckles, atypical and/or multiple moles and a family history of melanoma. Because of the possible risk of ocular melanoma eye protection from UVB and UVA should be worn if sunbeds are used.
Furthermore it is noted that the risk of melanoma seems to be particularly high when using sunbeds at a young age and that UVR tanning devices should not be used by individuals under the age of 18 years.

[3] SCCP: "Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes.

Legislation

Sunbeds are electric equipment and, in the European Union, must comply with the requirements of the Low Voltage Directive (LVD). The LVD requires (a) *that persons and domestic animals are adequately protected against the danger of physical injury or other harm which might be caused by direct or indirect contact*, and, more specifically with respect to radiation, (b) *that temperatures, arcs or radiation which would cause a danger, are not produced* (Appendix I).

Until recently the standard EN 60335-2-27:1997 "Safety of household and similar electrical appliances - Part 2-27: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation" applied. Sunbeds that fulfil the requirements of this standard are presumed to fulfil the requirements of the LVD. However, with increasing awareness of the unwanted health effects of UV-radiation, doubts about the safety of sunbeds rose, culminating in safeguard procedures against the standard initiated by the Spanish and Finnish authorities against the standard, which was thought not to address all the safety issues in a way that met the requirements of the LVD. As a reaction to the safeguard procedures initiated by Spain and Finland, the Commission withdrew the presumption of conformity for EN 60335-2-27:1997 - Part 2-27 due to the non-existence of values for the maximum effective irradiance for the types of sunbeds covered by the standard and mandated CENELEC to revise the standard to ensure that this risk was addressed [4].

At the time the joint action on sunbeds was conceived EN 60335-2-27: 1997 therefore did not lawfully address the safety aspects covered by the conclusions in the evaluation of the SCCP. In practice this meant that only the general requirements of the LVD as given in the first paragraph gave footing to any activities the market surveillance authorities would undertake. These general safety requirements need interpretation into clear technical requirements that can hold up in court to be useful for market surveillance purposes. In practice this means that for a sunbed to comply with the LVD it has to fulfil the requirements of EN 60355-2-27: 1997 "Safety of household and similar appliances – Part 27: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation", while taking into account:

- the SSCP report SCCP/0949/05[3];
- The opinion of the European Commission with regard to sunbeds[4];
- The declaration of the LVD AdCo group with regards to sunbeds of 22 January 2007http://ec.europa.eu/enterprise/sectors/electrical/links/index_en.htm
- The mandate to CENELEC in the field of the Low Voltage Directive 73/23/EC Brussels, 21st of December 2006, M/397 EN

From the documents above the conclusion was drawn that in order to fulfil the safety requirements of the LVD, sunbeds must fulfil the requirements of EN 60355-2-27: 1997, but in addition should not exceed an EWI value of 0,3W/m^2. Also, sunbeds should be accompanied by user instructions that inform the consumers of the hazards of UV radiation and the safe use of sunbeds for their particular skin type. The latter includes a warning that sunbeds should not be used under the age of 18.

[4] COMMISSION OPINION of 27 October 2004 within the framework of Council Directive 73/23/EEC relating to electrical equipment designed for use within certain voltage limits - Safety of tanning devices for cosmetic purposes (2004/C 275/03); Official Journal of the European Union C 275/3, 10/11/2004

Since the start of the joint action CENELEC has issued two amendments on EN 60355-2-27: 1997, EN-IEC 60335-2- 27/A1 and EN-IEC 60335-2- 27/A2, which implement extensive user instructions and limits the emitted UV radiation in accordance with the requirements the market surveillance authorities employed in this joint action.

Bringing newly marketed sunbeds in compliance with the LVD does not protect the public making use of already installed sunbeds in tanning studios and similar facilities. The safety of sunbed use for tanning offered as a public service needs also be addressed. Safe use of sunbeds is critically dependent on the way the service is provided. Particularly important is the way in which consumers are informed about the proper use, involving advise on tanning schemes for their skin type and prohibiting tanning under 18. Moreover, tanning studio proprietors have been found to regularly interchange the UV tubes of sunbeds for tubes with stronger UV radiation in order to provide for shorter tanning times.

Enforcement of sunbeds used in facilities that offer tanning as a service can only be based on the requirements of the GPSD. Interpreting the GPSD with respect to its scope for services raised many questions, however, with considerable risk for diverging policies for the market surveillance in the Member States.

Taking into account the DG Sanco view[5] on the applicability of the GPSD to sunbed services the GPSD was interpreted so, that Directive 2001/95/EC applies to products made available to consumers in the context of the provision of a service, including at the premises of a service provider, under the following conditions:

- That the product is in a way intended or likely to be used by the consumers themselves. Meant by use is an active use, involving an appreciable degree of control. In other words that they operate the product themselves e.g. by starting the appliance, have the option of stopping it earlier by pushing a stop button and possibly can change the position or intensity during the use.
    - This means that the consumers are not under constant supervision by the service provider, as opposed to the use of the product (in the physical sense of operated) by the service provider.
    - The use by the consumers must be an active use, involving an appreciable degree of control. A merely passive use, such as the use of a bus by its passengers, or the use of shampoo by a person whose hair is washed by a hairdresser, does not qualify as use by consumers.

An extensive explanation how these conclusions were arrived at is given in Appendix II.

Legal situation in the participating member states

All the participating Member States have implemented the Low Voltage Directive and the General Product Safety Directive in their national legislation and are basically able to perform market surveillance on sunbeds. As can be seen from the discussion in the previous chapter the margins for interpretation are wide. The risks of different interpretations is therefore considerable and one of the main stakeholders, ESA (European Sunlight Association), has expressed concern about

[5] Note to the Members o f the General Product Safety Directive Committee, the Low Voltage Administrative Cooperation group and the Consumer Safety Working Party; DG Sanco, Brussels 11/10/2007: SFS/GS/fm D(2007) 230385

differences in the way enforcement is approached in the Member States both before and during the sunbed joint action (see also Appendix IV, document 2).

Partly differences in approach exist for historical reasons. A number of Member States have had regulations in place for tanning salons and similar facilities long before the start of the sunbed joint action. This was the case for example in Finland, where regulation of tanning facilities has been in place since the end of the 1980's and where inspections of tanning facilities have taken place since 1998. Belgium, too, has had specific legislation on the use of tanning salons and equivalent in use since 2002, revised in November 2007 to include the 0,3 W/m2 limit and other recommendations from the LVD-AdCo Declaration and the SCCP-report.

Other Member States rely solely on the national implementation of the LVD and GPSD, but here may be differences in the way these are applied. For example, in Germany sunbeds in use already at the time it became clear that the EWI value should be limited to 0,3W/m^2 cannot be forced to comply with the new limit under the present legislation. Meanwhile legislation is under development that will bring Germany in line with the other European countries.

A second likely reason for diverging enforcement approaches between Member States is the difference in the organization of market surveillance that exists. Enforcement of sunbeds services requires the market surveillance authority to be responsible both for the LVD and the GPSD. In several Member States this authority is split between different organizations, one organization responsible for the LVD and another for the GPSD, complicating effective enforcement.

An overview of the implementation of legislation with regard to sunbeds, the situation with respect to market surveillance and new developments in these areas for several of the participating Member States can be found in Appendix I.

Project Aim & design.

Main aims of the action

The principal objectives of the sunbed cross border action were to ensure that:

- new sunbeds offered on the European market comply with the safety requirements of the LVD,
- sunbeds offered for use in services are safe and comply with the requirements of the GPSD, in particular with respect to the emitted UV radiation and the instructions for safe use.

Secondary purposes were to gather further experience related to the best practice techniques in cross border market surveillance actions involving many participants, i.e.:

- promotion of a harmonized approach to the market surveillance and enforcement of the safety requirements for (new) sunbeds and for sunbeds used in premises of service providers
- promotion of the cooperation between market surveillance authorities, in particular with respect to the harmonization of inspection procedures for sunbeds and the measurement methods and measuring equipment used.
- Effective use of enforcement communication to influence compliance behaviour in the target group and so promote compliance of both tanning equipment and tanning services.

Design and Management of the action

In line with the main goals of the cross border action, the design of the action incorporated a combination of inspections (enforcement) and enforcement communication. Inspections allow for immediate correction of non compliances, and thus aid in reaching the goal of the action directly. Besides, inspections convey the impression that the authority is serious in correcting violations of the regulations, especially when used in conjunction with enforcement communication.
In this action communication is not only meant to enhance the effectiveness of enforcement, but also to educate the proprietors of tanning salons and similar facilities about the requirements their sunbeds and services have to fulfil. Since the requirements for sunbeds and tanning services are relatively recent, many proprietors are likely to be unaware of these regulations. Raising awareness promotes compliance in those proprietors that are willing to comply but as yet do not know how to comply.

To achieve the secondary purposes of the project design included collective training of the inspectors from the different participants, the development of standardized inspection lists and the use of a common 'measurement train' for expensive accurate measurements.

Each of the scheduled activities is briefly discussed hereafter:

- *standardized inspection lists*
  To realize as high a degree of harmonization of the inspections between the participants as possible a common inspection list was developed. Originally proposed by the project management, the inspection list was discussed with the participants to assure that the list was suitable for all the participants.
  The inspection list addressed e.g. which kind of business was inspected (manufacturer,

service provider, etc.), self service or supervised tanning, presence of personnel, availability of instruction for use, intake interviews on admission, presence of goggles, labelling of the sunbeds, etc. The inspection list was developed as an excel file, designed to be 'inspector' friendly.

- *collective training*
  the project included training for the field inspectors who were to perform the inspections at manufacturers/importers and at businesses providing tanning services. Two 2- day trainings were intended to promote a common understanding of the legislation involved, to harmonize the way in which the inspections were to be performed and to provide a working understanding of the measurements involved.

- *exchange of information*
  Exchange of information was scheduled as part of the collective training, where time was scheduled to inform each other on the situation in the home member states. In addition electronic communication was to be used, both by the management to inform the participants on progress of the joint action and external developments, as well as for the exchange of information between participants.

- *common measuring train for expensive accurate measurements.*
  Measurement of the erythemally weighted irradiance (EWI) of sunbeds is not straightforward and requires an expensive UV spectroradiophotometer capable of accurate measurement of UV radiation over the UV range of wavelengths, followed by digital data reduction to arrive at the erythemally weighted irradiance values. Operating the equipment requires trained personnel. Since most of the participants do not have this equipment nor trained personnel at their disposal, the cross border action used a single apparatus accompanied by its operator for measurements in the member states that had no such equipment available. The required equipment was purchased with partial funding under the grant agreement.
  EWI measurements are lengthy and because sunbeds of tanning service providers cannot be taken to the laboratory the measurements have to take place on site. Taking into account the logistical complications and expenses of transporting such equipment all over Europe, the measurement of the EWI of a sunbed is quite expensive. Therefore EWI measurements were to be restricted to those cases where previous inspection rose suspicion of non compliance with the 0,3 W/m^2 limit value.

- *enforcement communication & consumer awareness*
  Besides the manufacturers and EU importers of sunbeds, the main target group of this cross border action are the proprietors of tanning studios and similar facilities, offering sunbeds as a service to the public. Most of these businesses have not been inspected before with respect to the requirements their sunbeds have to fulfil. Especially because the regulations on sunbeds are relatively recent, many proprietors can be expected to be unaware of these requirements. Raising awareness is then likely to promote compliance in the part of the target group that is willing to comply, thus contributing to the main purpose of the action. Publicity about the cross border action also can raise compliance levels, because the target

group is made to perceive an increased probability of being inspected.
Enforcement communication was therefore part of the sunbed cross border action. Participants were stimulated to generate publicity about the action on a national level in their member state, both in public media and in media specializing in information for the target group.

- *stakeholder involvement*
  Stakeholders, in particular from industry, can also play an important role in improving compliance. Industry organizations representing the tanning branch can have significant influence on their members. Therefore the action intended to establish contacts with the stakeholders to inform about the action and to discuss its developments, both at the national level and at the European level.

Time schedule

The cross border action on sunbeds was scheduled to take place from September 2008 until the end of December 2009. Roughly three stages can be distinguished:

- *First phase (September 2008 - December 2008):*
  - General preparations for the action, planning of the project in participant meeting; meeting with stakeholders
  - First training of inspectors; subsequently:
  - Onsite inspections of producers, importers and tanning services in the participating member states.
- *Second phase (January 2009 – June 2009):*
  - Project meeting evaluation of progress and preparation of subsequent activities
  - Second training of inspectors
  - Second round of inspections in the participating member states with measurements by the 'travelling' measurement train.
  - Corrective actions when justified by the results of the measurements
- *Third phase (July 2009 – December 2009)*
  - Evaluation of the action (process & progress)
  - Reporting
  - Final workshop for participants and stakeholders
  - Informing consumers

A detailed planning and time schedule can be found in the grant agreement $ 3.3.1.

Participation

For different reasons Belgium and Germany participated only partly in the activities described above. However, the market surveillance organizations of both Belgium and Germany thought it important to share in the experiences gained in the action and in the information exchange between the participants and between participants and stakeholders. Both Belgium and Germany took part in the project meetings and the project training session. Germany also made use of the possibility to have UV measurements performed. Belgium contributed results of inspections performed within the scope of their usual activities in this area. Since Belgium can do its own UV-measurements, there was no need to participate in the measurement part of the joint action. Denmark contributed the results of their own inspection program and made use of the training and UV-measurements offered in the action.

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Activities and results:

Training

Two 2-day trainings were organized in the course of the project.

The first project training was held in Zwijndrecht the 6th and 7th of October 2008. Participating were 16 inspectors from 10 participants. Aim of this training was to inform the participating inspectors about the project and to prepare them for the inspections scheduled in phase 1.

Various aspects of the project relating to organization, planning, risks of sunbeds, legal situation and how to perform inspections were presented and discussed. The presentations given in the training are accessible via the following link:
http://prosafe.project.webexworkspace.com/docs/docapp.aspx?_command=list&fid=19888

Following the presentations a number of aspects relating to the inspection of sunbeds, both in tanning studios and manufacturers, distributors were discussed. The discussion included legal aspects, national aspects and practical aspects of inspections, e.g. where and what look at, what to ask for, what to report and what kind of enforcement could take place.

The training also included an "example inspection" at a tanning studio/beauty parlour, indicating point of attention and demonstrating how inspections can be approached.

Conclusions from the discussions during the training were used to adapt the proposed inspection list for multinational use. Also several practical issues were addressed and decided.

The second project training took place in Zwijndrecht on the 19th and 20th of February 2009. Participating were 15 participants from 9 market surveillance organizations. Beside the representatives of the VWA, who are involved in the management of different aspects of the joint action, technicians from the VWA involved in the measurement of UV radiation were present.

The training was mainly concerned with the preparations for the second phase of the project, during which UV measurements of sunbeds were to take place in all the participating countries. The VWA measurement experts, who had made the UV measurements operational at the Zwijndrecht laboratory, presented theory and practice of the UV measurements during the training.

The presentations are available via:
http://prosafe.project.webexworkspace.com/docs/docapp.aspx?_command=list&fid=20356

Also, organizational and logistical issues for the second phase were discussed and agreed upon.

To facilitate the selection of candidate sunbeds suspected of violation of the UV-radiation limit, during this training handheld UV-filter meters have been made available to all participants in the joint action. The participants were instructed in the use of the handheld meters. These handheld meters are inexpensive small devices, which can conveniently be used to obtain a first impression of the UV radiation emitted from a sunbed. They are not very accurate and cannot be calibrated. Readings obtained with these devices are therefore unsuitable as legal evidence. However, they are useful tools in the selection of sunbeds that emit high levels of

Figure 1: hand held UV-filter meter

radiation, which can then subsequently be measured with the more expensive accurate method. Used this way as a screening instrument, they were thought to enhance the effective use of the travelling equipment in phase 2 of the action.

As a result of the training the participants were prepared to take the necessary steps for facilitating the measurements planned in phase two, to assure smooth execution of the measurements with the 'travelling' UV measuring equipment a time schedule for these measurements was agreed upon.

Inspections

Inspections performed in phase 1 (October 2008 – December 2008) can be roughly distinguished in two kinds: those performed at producers and importers and those performed at service providers like tanning studios.

The first kind of inspections, of manufacturers and importers, is primarily aimed at the conformity of the sunbeds offered for sale with the requirements of the LVD. Within the framework of this project the main items addressed are compliance with the requirement that the EWI does not exceed 0,3W/m^2, the labelling requirements, including the warning concerning the hazard of UV-radiation, as well as the availability of the Declaration of Conformity and technical file.

Inspections at service providers not only involve checking the compliance of the sunbeds used at the facility, but also check that the service is delivered in such a way that the safety of the user is not compromised. Important issues are the information provided to the customers, the availability to the customer of instructions for safe use, state of maintenance of the sunbeds, the availability of UV protection goggles, interviews on admissions, complaint registration, etc. None of these issues is covered by the LVD and inspections and any measures taken rest on the implementation of the GPSD.

Results phase 1

During the period from October till the 31st of December 2008 the participating market surveillance organizations performed inspections at 312 locations. All inspections reported were first inspections, so none of the locations was visited before.

Characterization of inspection locations

An overview of the inspections by participant and by business type is given in Table 1.

Table 1: overview of inspections by participant and by business type during phase 1

Participant	total nr. of inspections	manufacturer	EU-importer	importer	dealer	service provider	otherwise
Belgium	12	-	-	-	-	7	5
Cyprus	23	-	-	2	-	21	-
Czech Republic	27	-	-	1	-	26	-
Denmark	25	-	-	-	-	25	-
Finland	23	-	-	-	-	23	-
Germany*	2	-	-	-	-	2	-
Hungary	13	1	-	3	1	8	-
Latvia	84	-	-	4	-	80	-
Netherlands	87	**	**	1	1	84	1
Poland	16	4	-	6	6	-	-
Total	**312**	**5**	**-**	**17**	**8**	**276**	**6**

* Limited participation of Germany due to the ongoing legislation process on both the products (sunbeds) and sunbed services.

** The Netherlands inspected sunbed manufacturers and EU-importers outside the scope of the joint action at an earlier stage.

Note that operators active in the tanning and sunbed market regularly combine several business types in a single company. For example, importers may also function as a dealer and operate a tanning salon, i.e. as a service provider. In these cases table 1 lists the type of business as the type that is highest in the supply chain. In the example above the business is listed as importer.

The majority of inspections in phase 1 was clearly at service providers. These include facilities like tanning studios, wellness centres, fitness centres, etc.. For tanning studios tanning is the core activity, but for many of the other categories of businesses making available sunbeds is a secondary activity. An overview of the types of service providers inspected by the participants is given in Figure 2. By far the most inspections have taken place in tanning studios and beauty salons. Other locations offering tanning were less frequently inspected. (The category 'otherwise' in Figure 2 includes facilities like swimming pools, nail studios, sporting facilities, etc., where tanning is offered as a secondary service.)

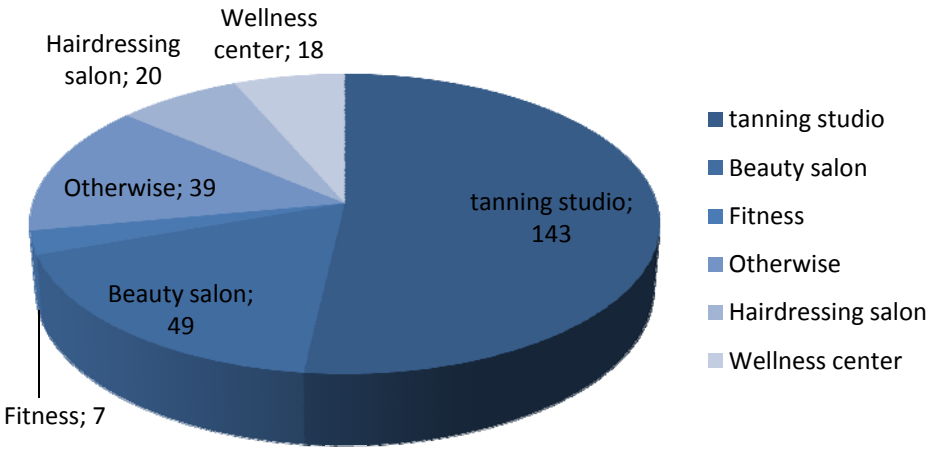


Figure 2: distribution of inspections over service providers

The distribution of inspections over the various types of service providers varies considerably between the participants.

Remarkable is for example that the majority of inspections in Cyprus was in fitness studios, while tanning salons were visited relatively rare. It is likely that this reflects the actual situation in Cyprus, with few specialized tanning salons and artificial tanning offered as a side service in fitness centres.

In the Czech Republic, Denmark and the Netherlands most inspections took place at specialized tanning studios, while in Latvia a remarkable number took place at beauty and hairdressing salons. Though only indicative this variation in the frequency of visits to specific location types probably reflects differences between the Member States in the way tanning services are embedded in the local markets.

Operational characteristics service providers

Key aspects of operational management of the inspected tanning facilities for the safe use of the sunbeds involve proper counselling of their customers. Customers should be provided with information on safe tanning in relation to their skin type, the hazards of tanning at young age and about safe frequencies and duration of tanning sessions. A number of these aspects were explicitly subject of the inspections performed. Results are given in Table 2, which lists the percentages that do comply with the parameters.

Table 2: characteristics of service providers.

Participant	n	membership sector organization	supervision	Consumer operated	instructions provided?	interview on admission	goggles available
Belgium	7	0%	100%	14%	86%	86%	100%
Cyprus	21	76%	100%	90%	90%	81%	90%
Czech Republic	26	12%	92%	38%	81%	96%	92%
Denmark	25	-	-	-	-	-	*
Finland	23	0%	70%	96%	88%	4%	100%
Germany	2	0%	100%	50%	100%	50%	50%
Hungary	8	8%	100%	100%	75%	75%	100%
Latvia	80	3%	100%	14%	94%	95%	99%
the Netherlands	84	45%	-	99%	88%	88%	90%
Poland**	-	-	-	-	-	-	-

* Denmark reported missing goggles for 108 out of 111 sun beds investigated

** No service providers checked.

- No data available

Membership of sector organization

Membership of a sector organization of providers of tanning services facilitates communication with the operators providing tanning services, because they can be approached directly via their organization. The sector organization then provides an effective communication channel that can inform its members about the consequences of the present scientific insights and the regulations for their operations. The effectiveness of this approach obviously depends on the fraction of operators that is organized in such sector organizations.

Table 2 shows that the fraction of tanning service providers that are members of such organizations is rather low in all participating member states, except Cyprus (76%) and the Netherlands (45%). In Cyprus there is no specific sector organization for operators of tanning facilities . The sector organization referred to by the service providers organizes gyms (fitness studios), which corresponds with the observation that in Cyprus the majority of tanning services are provided by fitness studios, which may be less interested in matters concerning artificial tanning. The low degree of organization obviously undermines the effectiveness of communicating information via the sector organizations and is a clear indication that alternative approaches are desirable.

Supervision

This column in Table 2 lists the percentage of inspected locations which is supervised, i.e. where the provider/owner/employees is present. Locations where no supervision is present are for example locations with coin operated sunbeds. In general supervision is almost always present at locations for artificial tanning in Europe. Only in Finland an appreciable fraction is without supervision. The reason is that in Finland (and Scandinavia) coin operated sunbeds are common.

Consumer operated

When the customer operates the sunbed himself in any way, the General Product Safety Directive applies and the proprietor has to fulfil the requirements of the GPSD. When the service provider operates the sunbed without any intervention of the customer the GPSD does not apply and no measures legally based on the GPSD can be taken. See also Appendix I.

Instructions provided?

Providers of artificial tanning services should instruct their customers about the sensible use of sunbeds in order to keep the exposure to UV radiation within sensible limits for their type of skin. Nearly all operators claim to inform their customers about the safe use of their services. In Finland, where coin operated sunbeds are common and supervision often is missing, service providers usually make the information available via wall mounted instructions beside each sunbed.

Interview on admission

Best practice in delivering tanning service requires that customers get an intake interview, during which they are advised about the safe use of sunbeds. The interview should address the age of the customer (i.e. above 18?), the skin type of the customer, advise about the preferred frequency and length of the tanning sessions for his skin type, etc. Aim of the interview is to make sure customers make use of the tanning service in a safe way. In most of the participants member states the inspected businesses claim to have such intake interviews, the percentage claiming to do so often exceeding 80%. Finland is a notable exception with 50% claiming to have intake interviews.

Presence of UV protection goggles

UV light is potentially harmful for the human eye and should therefore be protected while artificially tanning. From the inspections performed it appears that the great majority of service providers makes UV protection goggles available to their customers; the percentage lies mostly above 90%. (the 50% for Germany is based on two only locations and therefore not informative about the actual situation.)

Inspection of sunbeds

During the inspections the compliance of sunbeds offered for sale or use was also checked. Checks concentrated primarily on labelling requirements and the UV radiation(EWI) emitted. Labelling requirements checked included CE-marking, name and address manufacturer, sunbed type designation, warning about the hazards of UV radiation, the presence of the declaration of conformity and the availability of the technical file.

The number of sunbeds at the inspected locations generally varied between 1 and 10, with outliers up to 36. Some of the participants checked more than 1 sunbed at locations where they were present, so the number of inspected sunbeds exceeds the number of inspected businesses, as can be seen from Table 3. As a note to Table 3 it should be remarked that not for all the sunbeds listed all of the parameters listed above were reported.

Table 3: Overview of inspected sunbeds by participant and Business type

Participant	inspected sunbeds	Manufacturer	EU-importer	importer	dealer	service provider	otherwise
Belgium	42					37	5
Cyprus	28			2		26	
Czech Republic	27			1		26	
Denmark	111					111	
Finland	23					23	
Germany	2					2	
Hungary	22	1		6	2	13	
Latvia	84			4		80	
the Netherlands	124		1		1	121	1
Poland	53	7		25	21		
Total	516	8	1	38	24	439	6

Labelling requirements

As far as the administrative labelling requirements (CE marking, Declaration of Conformity and the presence of the technical file) and the warnings and instructions required by EN 60335-2-27 inspections are concerned, inspections performed at the beginning of the chain (manufacturers and EU-importers) are the most efficient from the market surveillance point of view. After all, when it can be realized that sunbeds entering the European market comply with the LVD requirements in time the sunbeds available to the public will automatically comply with the LVD requirements. Future market surveillance can then concentrate on the way the tanning service is delivered. There is one exception: the checks on emitted UV radiation, since that parameter can be influenced by the service provider via the exchange of the UV transmitting tubes. Inspection lower in the chain may still be useful, but the effects of action there is likely to remain regional.

An overview of the results of the checks on the compliance with the labelling requirements is given in Table 4, which lists the percentages of the sunbeds not fulfilling the requirements. In phase 1 of the action only 8 sunbeds were investigated at manufacturers and none at EU-importers. For each of the labelling requirements there was at least 1 bed that did not fulfil the requirement, and in two cases the technical file was not available. The number of sunbeds investigated at the manufacturers is too low for serious conclusions, though, and future actions should aim to do more inspections at manufacturers and EU-importers.

Table 4: overview of non compliance with labelling requirements for sunbeds per business type

	n	name address manufacturer	brand name	type sunbed	warning radiation may cause injury	CE marking	DOC	Tech File
Manufacturers	8	13%	13%	13%	13%	13%	13%	25%
EU-importers	-	-	-	-	-	-	-	-
importers	38	11%	8%	13%	37%	11%	63%	82%
dealers	28	25%	32%	25%	29%	25%	39%	36%
service providers	207	27%	22%	32%	52%	43%	86%	89%

Note: only those inspected sunbeds are listed for which all relevant data were available

Lower in the chain the percentages of non-compliance with the labelling requirements increases with a worrying 52% of sunbeds investigated at service providers without the obligatory warning about the dangers of exposition to UV radiation.

EWI limit

At the point in time of these inspections most of the participants did not have the handheld UV meters available. Checks of the UV radiations therefore depended in most cases on statements by or records held by the proprietor. Incidentally some of the participants were able to take measurements, either by hand held meters or with spectrophotometers capable of EWI measurements.

Where either measurements or records plausibly demonstrated that sunbeds complied with the requirement and that the EWI value did not exceed 0,3 W/m^2 the sunbed is listed in Table 5: compliance with EWI<0,3 W/m2 requirement as fulfilling this requirement. Similarly, when records or measurement showed the sunbed to exceed the 0,3 W/m^2 limit, they were listed as failing to comply.

Table 5: compliance with EWI<0,3 W/m2 requirement

business type	inspected sunbeds	Comply	Non compliant	no proof	No data*
Manufacturers	8	50%	38%	0%	13%
Importer	38	24%	29%	39%	8%
Dealer	29	24%	24%	28%	24%
service provider	328	31%	8%	50%	11%
Otherwise	8	38%	25%	0%	38%
total	411				

* no reliable data about this requirement

Note: only those inspected sunbeds are listed for which all relevant data were available; no data from Denmark

For many of the sunbeds inspected no reliable information assured that the sunbed complied with the radiation requirement. These are listed in the table in the column 'no proof'. It seems reasonable to expect that at least part of these will not comply with the requirement, in which case the fraction of sunbeds with EWI values higher than the limit is higher than listed in the column non compliant.

Summarizing the results from Table 5 it can be concluded that approximately a quarter to a third of the sunbeds investigated at manufacturers, importers and dealers exceed the 0,3W/m2 limit. Surprisingly the fraction of non compliant sunbeds found at service providers is much lower. It is highly likely, however, that the 8% non compliance scored in this investigation will increase upon actual measurement; in 50% of the cases no reliable proof of compliance was available. Moreover, there are indications that the documents that certify the compliance with the 0,3W/m^2 limit not always reflect the real UV-emission. On measurement several sunbeds were found where the UV emissions exceeded those listed in the documents.

In fact, these results underline the necessity of measuring equipment for effective market surveillance.

Legal Measures

In all cases the locations that were visited were inspected for the first time. Besides obtaining an overview of the current market situation, the aim of these inspection was to confront the proprietors with the requirements the GPSD implicitly imposes, allowing them time to correct deficiencies encountered. No direct sanctioning was pursued, but where situations where encountered that required correction several of the participating authorities did take measures. Table 6 shows an overview of the measures taken as a result of the inspections performed at **service providers** during phase 1 of the cross border action.

Table 6: legal measures taken at service providers

Participant	Inspected locations	No Measure	Remark	Written warning	Official report/ Proces-verbal/Protocol	Otherwise
Belgium	7		1	1	5	
Cyprus	21	1	18	2		
Czech republic*	26			3	8	14
Denmark**	25	-	-	-	-	-
Finland	23	3	14		3	3
Germany	2		2			
Hungary	12	2				10
Latvia	80	3				77
the Netherlands	121	56	22	38	5	
Poland***	0					

* one location reported as Not applicable

** no data available

*** no service providers checked

The measures listed under the columns 'remarks' and 'otherwise' are not formally legal measures. They refer to remarks and commentary by the inspector that aim to inform and instruct the proprietor to improve the situation. Formal legal measures and sanctions are 'written warnings' and 'official report/Proces-verbal/Protocol'. The latter generally also implies that a sanction is imposed.

The intended sanctions reported by Belgium were issued either because sunbeds at the inspected business exceeded the 0,3W/m^2 radiation limit, or because of other shortcomings specified in Belgian legislation on tanning services (e.g. missing goggles). Similar reasons underlie the official reports reported by Finland and the Netherlands.

Measurements of sunbeds with the UV spectroradiometer.

Method

The limit on UV irradiation of sunbeds suggested by the SSCP is not a straightforward limit of total UV energy emitted. This is because a value for the total energy does not reflect the biological effects, because these effects of the UV radiation are wavelength dependent. Instead a limit that aims to reflect the potential for biological adverse effects was chosen, in particular the ability to induce erythema (or sunburn). The measure that describes the ability of UV light to induce erythema is the EWI (erythemally weighted irradiance). The SCCP advice limits the EWI acceptable for sunbeds to 0,3W/m^2.

Irradiance is defined as the total radiant flux incident of a particular wavelength on an element of surface divided by the surface area of that element (W/m^2). Effective irradiance summarizes the total energy/m^2 over all wavelengths. To arrive at the EWI value the irradiance has to be measured in small wavelength increments, corrected for the potential of that wavelength to induce erythema and then integrated over the whole UV spectrum.

Determination of the EWI of sunbeds requires an expensive and complicated UV spectroradiometer, capable of measuring the flux over small wavelength increments with sufficient accuracy and processing power to calculate from these results the EWI value. In practice the equipment is susceptible to variation in temperature and humidity and to obtain reproducible results lengthy acclimatization is required. This is particularly the case for the measurements of sunbeds for market surveillance purposes, as these cannot be transported to the laboratory for measurement, but must be measured on site.

To avoid the expensive necessity of buying UV spectroradiometers by all participants, this joint action used a single UV spectroradiometer[6] with double monochromator, partly funded by DG-Sanco within the scope of the grant agreement for the joint action. The Food and Consumer Product Safety Authority in the Netherlands developed the standard operating procedures and calibration procedures for the EWI measurements of sunbeds and trained personnel to operate the equipment.

[6] Spectroradiometer: OL756; Integrating Sphere: IS670; Dual Calibration Check Source: OL756-150; Irradiation; lampstandard Model 220 and Programmable Current Source OL65A

In phase 2 of the joint action a trained operator that took along the equipment performed measurements in all the participants member states, with the exception of Belgium. Belgium operates its own measuring equipment and did not need the 'travelling EWI measurement train'. In each participant's member state the equipment and crew was available for one week, which in practice meant 3 – 4 days for measurement. Between visits to participants a week was allowed for recalibration of the equipment.

EWI measurement in the Czech Republic

Prior to these measuring visits the participants selected sunbeds to be measured, preferably selected on the basis of suspicion of non-compliance. Participants also prepared the visits by providing suitable transport and storing facilities for the equipment during the visit.

Results

In all the participant member states visited the EWI of a total of 84 sunbeds were measured. In general for each sunbed the EWI values from the bottom, top and face sections were measured where possible, providing a total of 3 measurements for most of the sunbeds investigated.

Of the 84 sunbeds measured with this equipment, 70 gave EWI values for at least one of the measurements made exceeding the limit of 0,3 W/m^2 (83,3 %). The highest value measured was 1,43 W/m^2 . An overview of the distribution of the measurement values is given in Table 7 and summarized in Figure 3: distribution of results of EWI measurements.

Table 7: distribution of results of EWI measurements

EWI in W/m^2	Bottom	Top	Face
<0,3	24	21	32
0,3 - 0,6	22	24	37
0,6 - 0,9	25	22	6
0,9 - 1,2	10	13	1
>1,2	2	3	0
Total nr of measurements	83	83	76

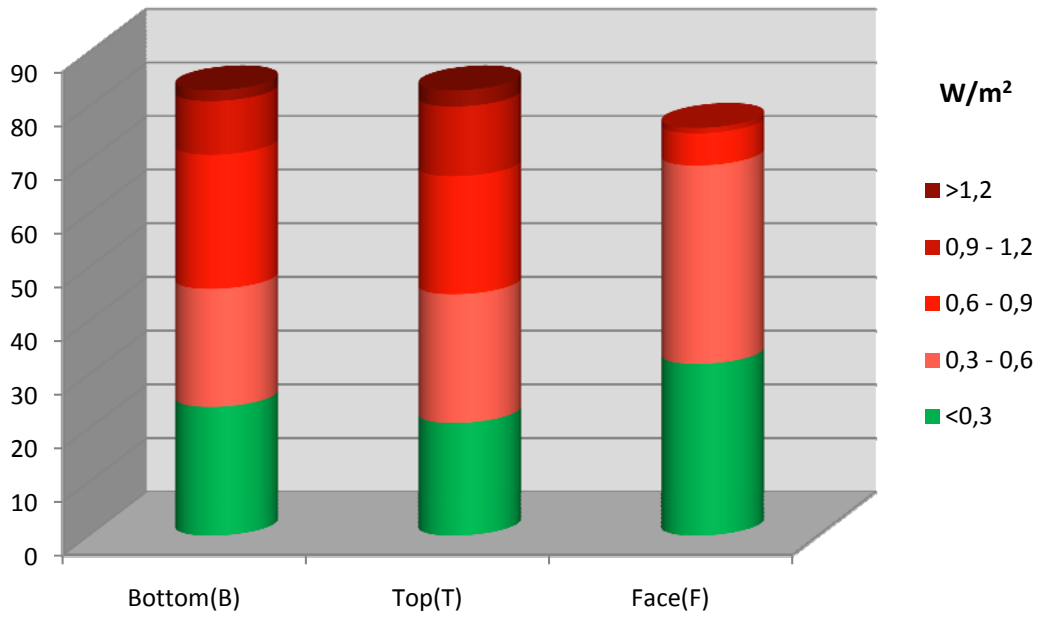


Figure 3: distribution of results of EWI measurements

Significance of measurement results

As already stated above participants were asked to select sunbeds that were likely to violate the EWI limit. From an market surveillance perspective this is efficient, because performing expensive measurement on apparatus that turns out to comply does not contribute to enforcement. The project thus asked for selective sampling. Not all the participants selected samples they suspected to violate the limit, however.

Latvia indicated that the tanning facilities measured were actually chosen randomly, without previous inspection or knowledge about the sunbeds measured. For these countries the percentage that on measurement failed the EWI limit indeed is an estimate of the degree of non-compliance with the limit. In Latvia the EWI values of 11 sunbeds were measured. All of these exceeded the limit (with EWI values between 0,4 and 1,06 W/m^2), leading to an estimated non-compliance of 100%.

Also in Hungary the EWI values of 29 randomly selected sunbeds were measured with the hand held meters. The indicative results were that only one of the sunbeds complied with the limit. Based on these indicative measurements the percentage non-compliance amounts to 96,5%. Though these estimate is based on handheld meter results, the estimate gets credibility from the spectroradiometer results. Ten of 30 sunbeds (the 29 referred to above + one additional sunbed) were accurately measured and in all cases the sunbeds were found to exceed the 0,3W/m^2 limit. Values found varied between 0,5 and 1,29 W/m^2.

Both for Hungary and Latvia the samples upon which the estimate for the fraction non-compliances is based were small, so the confidence interval is rather large. Nevertheless the probability of the actual fraction of no-compliances being less than 70% is very low and it can safely be concluded that in Latvia and Hungary a high fraction of the sunbeds in use exceeds the limit.

Again, the project plan for the action asked to select for measurement sunbeds suspected to exceed the EWI limit, for example from indicative measurements or for other reasons. Therefore a high fraction of non-compliance in the sunbeds measured with the spectroradiometer was to be expected. In general the ratio of compliance/non compliance for these measurements is therefore not an valid estimate of this ratio for the population of sunbeds actually in use with service providers.

For the remaining participants better estimates of the ratio compliant/non compliant for the EWI limit can be obtained when the results of the measurements are seen as a selective sample from the population of the sunbeds investigated during phase 1. This is illustrated in Figure 4.

Figure 4 shows the numbers of locations inspected during phase 1 of the action and the total number of sunbeds inspected. The latter is larger, because at some location several sunbeds were inspected. The figure also shows how many sunbeds were accurately measured using the spectroradiometer equipment and the number of sunbeds found to exceed the EWI limit.

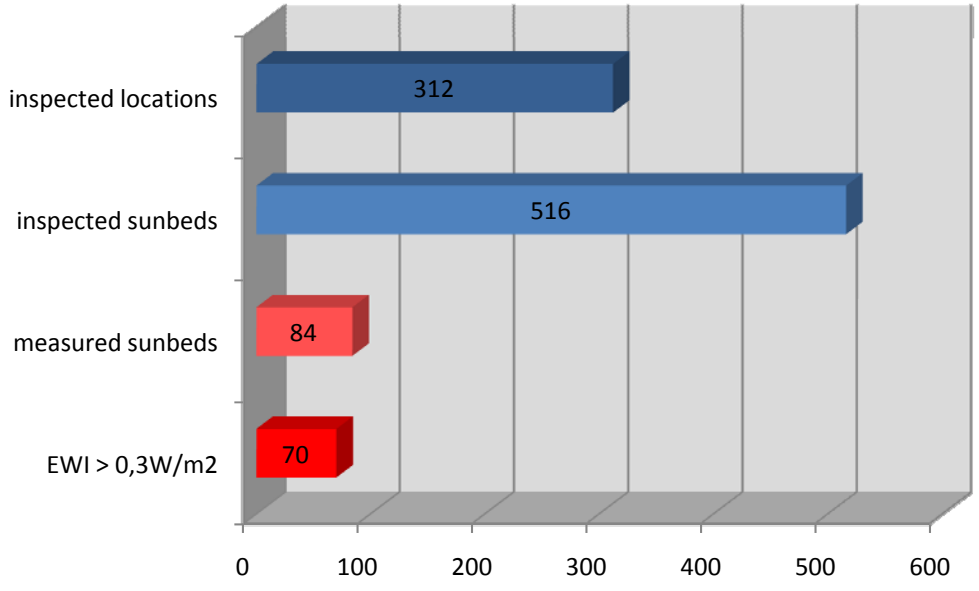


Figure 4: overview of numbers of locations and sunbeds inspected and sunbeds measured

Assuming that the number of sunbeds investigated during these inspections (n = 516) is representative for the population of sunbeds in use at tanning facilities (not unreasonable, since these were all first inspections), the number of sunbeds found to exceed the limit gives an estimate of the non compliance in the inspected population. Since it has already been argued that the EWI

measurements in Latvia and Hungary are were random samples themselves, giving the best estimate for non-compliance with the EWI limit themselves, the data for Latvia and Hungary should be excluded in the calculation of the estimate, leaving a population of 410 sunbeds.

As can be seen from Table 8 the fraction of sunbeds that do not comply with the EWI requirements of 0,3Wm2 varies considerably, with high fractions non-compliance for Belgium and Germany. The data for Germany, are based on a biased selection of the (very small) sample from the market, while for Belgium the population from which the measured sunbeds were taken are unknown. The reported results for Belgium are the results from measurements performed because complaints about the service were received, so the sample is certainly biased. Belgium does indicate, however, that non compliance with the 0,3W/m^2 restriction is high.

Table 8: sunbeds exceeding the 0,3 W/m2 limit as a percentage of all inspected sunbeds

Participant	inspected sunbeds phase 1	EWI measurements	>0,3 W/m2	% of Total inspected sunbeds
Belgium*	42	42	35	83,3%
Cyprus	28	7	5	17,9%
Czech republic	27	8	8	29,6%
Denmark	111	6	3	2,7%
Finland	23	7	3	13,0%
Germany	2	2	2	100,0%
the Netherlands	124	21	16	12,9%
Poland	53	12	12	21,8%
Total	410	105	84	20,4%

* Measurements by participant; no information about the population from which these results are drawn

Based on all the data in Table 8 the percentage of sunbeds that exceed the 0,3W/m^2 amounts to an estimated 20,4%. When the data from Belgium and Germany are excluded for the reasons indicated in the previous paragraph, the overall estimate for non compliance with the EWI limit in the remaining Member States (i.e. Cyprus, Czech republic, Denmark, Finland, the Netherlands and Poland) is calculated to be an average 12,8%, with the lowest percentage for Denmark (2,7 %) and the highest for the Czech republic (29,6%).

The calculated percentages are almost certainly underestimates, due to the restricted capacity to perform EWI measurements. It is very likely that more violations would have been found when more sunbeds could have been measured and that non compliancy is actually higher than calculated here. However, these estimates get some credibility because the percentages non-compliance reported from earlier market surveillance activities in Finland and the Netherlands estimate the non-compliances between 10 and 20%.

Enforcement communication

Stakeholder contacts

The joint action on sunbeds aims to raise the compliance of the economical operators involved in artificial tanning with new and sharpened regulations for the sector. This implies that the sector has to transform from a situation where there is most likely a low degree of compliance with the new requirements to a situation where compliance is the standard. Usually such transition processes are characterized by several distinct phases, which have to be passed through before the transformation takes root. Figure 5: transition phases shows the phases which can be seen universally when new legislation is imposed, depicted here for the sunbed action.

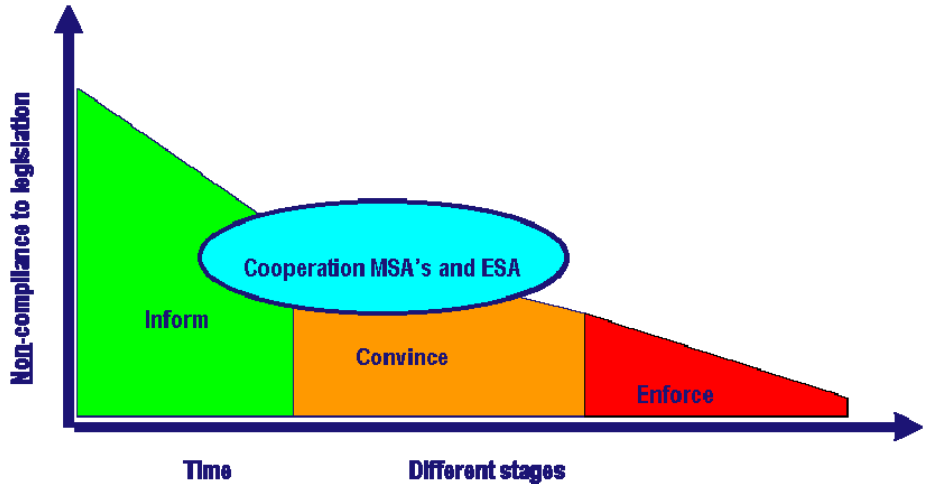


Figure 5: transition phases

In the first phase the new requirements should be brought to the attention of all operators involved; the manufacturers, distributors, dealers and providers of tanning services. Once the requirements are known, the second phase aims to convince the enterprises that they must comply with the requirements. During phases 1 and 2 operators who are aware of the requirements and who are convinced and willing to comply can be assisted in their compliance behaviour (compliance assistance), for example by making available information leaflets, intake forms for new customers of their business. In the third phase compliance with the new requirements at those operators still not complying is imposed. The instruments used here are market surveillance and law enforcement.

For the purpose of phase 1 and phases 2 the project management of the sun bed joint action established contact with the European organization for the sunbed and artificial tanning sector: the European Sunlight Association (ESA). The participating market surveillance authorities were asked to contact their national sector organizations.

As a results of the contacts with ESA the ESA Working Group Joint Action Sunbeds was set up. This working group's aim is to promote in collaboration with the market surveillance authorities

compliance of the sector with the new regulations. To that end the following activities were undertaken:

- the drafting of a Working Group Guideline intended to promote proper implementation and compliance with the legal requirements (see Appendix IV document 1). The ultimate goal is to secure optimal consumer protection,
- the development a *European sunbed passport*, to be issued by the manufacturer of the sunbed. The sunbed passport is intended to clarify which types of UV emitters should be placed in the sunbed if a maximal EWI of 0,3W/m^2 is to be obtained,
- the harmonization of the measurement protocols for the EWI values of sunbeds,
- consultation and agreement with the manufacturers of UV emitting tubes to implement a uniform coding system for UV emitters for use in sunbeds. That way service providers, consumers and market surveillance authorities can easily check if the proper emitters are used to obtain an EWI value of maximally 0,3W/m^2,
- The drawing up of an inventory of the national legislation with respect to sunbeds and sunbed services in all the member states and an analysis of the (obstructing) differences (see Appendix IV document 2),
- Proving information to ESA members about the implementation of the new rules,
- The development of training material (in English) for personnel of tanning studios. The material will for example discuss and train about skin types and the handling of the > 18 year restriction (see Appendix IV document 3),
- In cooperation with the *Consumer Rights Protection Centre* of Latvia and with participation of the management of the joint action on sunbeds a stakeholders meeting was organized jointly with the local tanning association on the 28th of September 2009 in Riga. Some 20 participants from local market surveillance and health authorities, industry and other stakeholders such as a dermatologist where informed about the new rules regarding sunbeds and the joint action. Similar events are planned in the Czech Republic for the beginning of 2010 and in a number of other Member States later 2010.

Media

As part of enforcement communication media exposure was actively pursued. Media coverage of the action increases the risk perceived by service providers of being inspected and underlines the urgency of improvements in tanning services. Where coverage is by public media the pressure to comply increases directly, also because consumers are informed of the risks of artificial tanning and the requirements good tanning facilities should adhere to.

The sunbed action was featured in TV-news shows in several of the participating Member States, including the Czech Republic and Belgium. TV coverage was also in consumer programs, for example in the Netherlands. Radio programs and newspapers paid attention to the sunbed action in several of the participating Member States, generally combining the coverage with information about the risks of tanning. Furthermore, in the Netherlands, but probably in more Member States, trade journals paid attention to the sunbed action. Many of these publications are still accessible via the

web sites of the TV – stations, newspapers and journals concerned. A list of the publications and press coverage (not exhaustive) can be found in Appendix III.

A number of participants also used the internet to inform both the industry and the consumers on the safety of tanning and the requirements tanning services must fulfill.

Participants in the action and stakeholders were informed about the action via newsletters.

Conclusions

The joint action on sunbeds aims to ensure that sunbeds offered for sale comply with the requirements of the LVD and that sunbeds offered for use in tanning studios comply with the GPSD. It marks the first cross border attempt to enforce product legislation at services and it does so in an environment that, for the first time, is confronted with requirements aimed to assure safe tanning services. Moreover, when the action started the legal requirements for sunbeds were formulated only in very general terms, with possible confusion about the exact requirements in the enterprises concerned and carrying the risk of diverging interpretations between the Market Surveillance Authorities in the Member States.

To minimize diverging interpretations between the participating market surveillance authorities and to promote a harmonized approach to the market surveillance in this field the joint action used uniform inspection checklists, provided for common training of the inspectors involved in the action and ensured regular information exchange. Relevant aspects of the action were also communicated to participants and stakeholders via newsletters.

To address the expected lack of familiarity with the regulations in the sector the joint action aimed to raise the awareness levels in the sector in two ways: via sector organizations and by initiating media exposure. Both approaches aimed to maximize the impact of the market surveillance activities of the participants: they were aimed to raise the knowledge of the sector, while at the same time stressing the urgency of compliance with the requirements by raising the perception of the possibility to become the subject of inspections. Communication efforts included TV-items in news shows in a number of participating Member States, publications in sector journals, newspapers and internet news sites in several Member States. Partly this media coverage coincided with increased interest in the safety of sunbeds due to news reports on severe side effects of artificial tanning and contributed to an already increasing public concern about the safety of artificial tanning.

The spearhead of the joint action were the enforcement activities by the 10 participating market surveillance authorities, during which more than 300 locations and more than 500 sunbeds were inspected. These inspections give an insight in the presently prevailing market conditions in the sector concerned.

Safe tanning requires proper guidance of the consumer, with clear information and advice tailored to the specific consumer. Though between 75 and 94% of the tanning facilities indicated to provide such advice, this claim is hardly ever verifiable. Best practice in providing tanning services should aim for verifiability of these activities, for example by keeping records of intake interviews and tanning advice. In this context the European Sunlight Association, that organizes the sector on the European level is working on a *Code of Conduct* for tanning facilities that will include such best practices. The management of the joint action on sunbeds actively supports this effort to assure correspondence of interpretation of the regulations by both the providers of these services and the market surveillance authorities. Remarkable is also that in some Member States, especially in Scandinavia, many sunbeds are coin operated by the consumer himself. No supervision is present on site, so personal guidance of the consumer lacks.

Besides guidance of the consumers safe tanning also requires sunbeds which comply with the safety regulations. These regulations include labelling requirements and restrictions on the amount of UV radiation emitted. Checks of 207 sunbeds at service providers on the compliance with the labelling requirements in the LVD and in EN 60335-2-27/A1 (10/2008) , Part 2-27 showed more than 25% failed to comply with the administrative requirements (CE-marking, brand name, name and address of manufacturer). Safety relevant information like the type of the sunbed was not listed on 32% of the inspected sunbeds, while the warning that UV radiation may causes injury was not present on 52% of the sunbeds.

The SCCP has advised the limit on the UV radiation emitted from sunbeds for cosmetic use to be set at an EWI (erythemally weighted irradiance) value of 0,3 W/m^2. The joint action has contributed to the wide acceptance of this limit, both with the European sector association (ESA) and the market surveillance authorities, as it has emerged since the beginning of the action. Meanwhile the 0,3W/m^2 restriction has also been formalized in the applicable standard for sunbeds EN 60335-2-27/A1 (10/2008).

Because the EWI value is not a simple measurement of UV radiation, but requires on site measurements with an expensive UV spectrophotometer capable of digital data reduction to calculate EWI values, the joint action shared a single EWI measuring device. Aim was to dispense with the need for all the authorities to invest in such expensive equipment and save resources. In practice EWI measurements were successfully performed in nearly all the participating Member States by a 'EWI measurement train' consisting of equipment and a specially trained Dutch crew, aided by local market surveillance officers.

Using this measurement train the EWI values of 84 sunbeds were determined, of which 70 sunbeds gave EWI values exceeding the limit of 0,3 W/m^2 The highest value measured was 1,43 W/m^2.

An estimate for the percentage of sunbeds that exceed the 0,3W/m^2 limit was calculated for all participating member states, except (for statistical reasons) Latvia, Hungary, Germany and Belgium, to be at least 12,8%. It is highly likely, however, that the actual percentage is higher, because the number of sunbeds measured was restricted for capacity reasons and additional measurements would almost surely have detected additional violations. For Latvia, Hungary and Belgium the percentage of sunbeds violating the UV limit is estimated much higher: above 80%.

The overall conclusions from the results of the inspections in this first action on sunbeds are that:

- consumer guidance in tanning studios is regularly not given and often not verifiable,
- the labeling of the sunbeds fails to comply in at least 20% of the cases,
- How often the maximum EWI values for sunbeds are violated varies between the Member States. In several Member States the percentage may be above 80%, while in others the fraction of sunbeds that does not comply is between 10% - 20%.

These data also justify continuation of the market surveillance of sunbeds, the more so when it is appreciated that the joint action has effected momentum in market surveillance authorities as well as sector organizations to improve the standard of service in the artificial tanning branch. Visible continuation of enforcement can support the efforts to raise these standards.

Under EU law manufacturers, distributors, retailers and importers have primary responsibility for the safety of the products that are put on the market, as have service providers for the safety of products used in services. At the European level the tanning industry is organized in the European Sunlight Association, which is playing an important role in ensuring operating standards in sunbed services. In regular consultations with the market surveillance officials of the sunbed joint action ESA actively promotes fast adoption in the tanning sector of the 0,3W/m2 limit on UV radiation emitted from sunbeds. To support tanning services in complying with EU legislation ESA is developing a European Code of Conduct for tanning services, training materials for tanning studios and organizes information seminars in cooperation with national associations in the Member States.

An important conclusion for this action was also that the participants agree such cross border activities make sense and are useful. Being able to travel to and communicate with colleagues about their best practices and to communicate and exchange information on a common activity has been found extremely valuable by the participants. Finally, this cross border action has shown the feasibility of sharing measurement equipment in an activity that required transporting the equipment 'cross borders'. In fact, after a massive media campaign on the safety of tanning in the Czech Republic the Dutch crew was invited for the second series of measurements. During these measurements Czech inspectors were trained to operate the spectroradiometer as well. The Czech Trade Inspections has meanwhile decided to acquire similar equipment for solaria measurements as well as hand held meters for screening. The equipment and crew will be available to other member states during the follow-up project to help to increase the number of sunbeds measured.

Recommendations

The cross border action on sunbeds has shown that both consumer guidance by the service providers and the compliance of the sunbeds in use should improve. Therefore continuation of enforcement by the market surveillance authorities is recommended.

This first joint action has contributed significantly to align the interpretation of the legal requirements by the market surveillance authorities in the participating Member States. Indirectly it also influenced legislation on sunbeds in some of the participating Member States in such a way, that market surveillance will have better legal tools to check tanning salons in the near future. The process of harmonization is not complete yet and further harmonization of market surveillance should remain one of the aims of future actions in this field.

Consumers can play a vital role in assuring their own safety when tanning. They can influence the quality of the tanning service when they insist on getting thorough advice and responsible tanning schemes and by asking for proof that the sunbeds comply with the radiation limits. To raise awareness of their own role in safe tanning it should be considered to approach the consumer directly. A specific project may be organized to inform the consumer about the hazards of tanning and how these can be minimized.

The first joint action on sunbeds started to familiarize the tanning sector with new regulations for sunbeds and sunbed use, using both contacts with stakeholders and media exposure to raise awareness. Coinciding with frequent other publicity on incidents with artificial tanning, the awareness raising campaign has gained considerable momentum. To exploit this momentum continuation of enforcement communication is advised, along with support and cooperation with ESA's efforts to raise the industry standard.

During the present cross border action efforts were almost exclusively directed to service providers. Subsequent enforcement actions should pay more attention to the conformity of sunbeds offered by manufacturers and enterprises that import sunbeds into the European Union. Enforcing compliance of sunbeds at the source is the most efficient and effective method to ensure that only sunbeds fulfilling the requirements are available further down the chain.

Subsequent enforcement action should also aim to increase the number of EWI measurements. In the first cross border action action a high fraction of the measured sunbeds exceeded the EWI limit. It is likely that when more sunbeds are measured the fraction that violates the limit, now estimated as at least 12,8 % in some member states, but more tha 80% in others, will rise. Ideally every inspected sunbed should at least be measured with handheld meters to select sunbeds for measurement with the more accurate but also more expensive equipment.

Appendix I:

Legal situation in the participating member states

Belgium:

Belgium has specific legislation on the use of tanning salons and equivalent : the Royal Decree of 20th June 2002. This Royal Decree has been revised (Royal Decree of 22nd November 2007) to include the 0,3 W/m2 limit and other recommendations from the LVD-AdCo Declaration and the SCCP-report (e.g. no use under 18 years). The Belgian Market surveillance authority considers sunbeds above 0.3 W/m2 to be dangerous (*). Corrective measures are taken against such beds (ban, fees, ...) and saloons (closure, ...). The national legislation concerned falls under the Belgian law transposing the GPSD (Law of 9 February 1994 concerning the safety of products and services)

The market surveillance authority responsible for the market surveillance of the LVD in Belgium is: *Federal Public Service (FPS) Economy, SME's, Self-employed and Energy - Directorate General (DG) of Energy – Division Infrastructure and Controls*

The market surveillance authority responsible for the GPSD in Belgium is: *Federal Public Service (FPS) Economy, SME's, Self-employed and Energy - Directorate General (DG) of Quality and Safety - Division safety of products*

Cyprus:

In Cyprus new sunbeds are inspected under the LVD. Existing sunbeds are inspected under the GPSD. In all cases including sunbeds already in service the limit of irradiance is 0,3W/m2. National legislation is the one transposing LVD and GPSD into national law.

Cyprus has programmed along with other state services to launch a public awareness campaign about the risks of tanning by the use of sun beds, but development of this campaign is still in an early stage.

Czech Republic:

In the Czech Republic Act No. 22/1997 Coll., on technical requirements of products and the Act No. 102/2001 Coll., on general product safety, implements the GPSD and Government Order No.17/2003 on electrical equipment, implements the LVD. Furthermore, the "old" ČSN EN 60335-2-27 ed.2:2004 provides the framework for sunbeds, where the LVD ADCO Declaration and the SCCP Opinion in sense of "the state of the art and technology" according to the GPSD are used augment the requirements of this standard with respect to the requirements for safe use and radiation levels. Sunbeds above 0,3W/m2 are considered dangerous.
The Czech republic has no other national legislation specifically for sunbeds.

Market surveillance In the Czech Republic is based on this legislation. Normally three months time is allowed for a provider to bring the sunbed into conformity with the limit 0,3W/m2. During that period the sunbed is out of service. If, on follow-up inspection, the sunbed is still not complying a fine and a ban will be imposed.

Finland:

The general principles governing the surveillance of the radiation safety of solarium equipment in Finland are incorporated in the Radiation Act (592/1991) and in the Supervision of-Non-Ionizing Radiation Decree (1306/1993). STUK (Radiation and Nuclear Safety Authority) is the authority which regulates the use of radiation and it is under the Ministry of Social Affairs and Health in Finland. STUK is not enforcing the GPSD and LVD, but as a radiation safety authority STUK carries out surveillance of sunbeds and solarium equipment.

The first regulation concerning solaria equipment was given in 1987 in Finland. Supervision-of-Non-ionizing- Radiation Decree (941/1987) included type inspection and type approval requirements for solaria equipment. The first STUK's guideline SS-guide 9.1 "Radiation safety requirements and type inspection of solarium appliances and sun lamps" included UV type 3 requirements and it came into force 1.9.1989. For UV type 3 sunbeds the total effective irradiance limit is 0,3 W/m^2, but in the UVA and in the UVB range 0,15 W/m^2 shall not be exceeded. Higher irradiances were not accepted for safety reasons. UV type 3 requirements were implemented in the same year (1989) by starting type inspections. STUK made pre-marketing type inspections of sunbeds until the end of 1993. In 1994 when Finland joined the EEA and EU, STUK started market surveillance and inspections (spot checks) of tanning facilities.
In 1998, STUK launched a nationwide survey of the use of sunbeds in Finland. Inspections were carried out in co-operation with municipal health officials. Data covered 57% of Finnish municipalities. It was estimated that there were approximately 700 tanning facilities and 1000 sunbeds in commercial use in Finland. Those numbers maybe a little higher now about 10 years later. At present about 30 tanning facilities are inspected yearly by STUK. Deficiencies affecting the safety of sunbed users are discovered in nearly every tanning facility every year.

Since 1.5.2002 the Decree of the Ministry of Social Affairs and Health on the Limitation of Public Exposure to Non-ionizing Radiation (STM Decree 294/2002) has been in force. This new Decree regulates in more detail binding public exposure limits of non-therapeutic/cosmetic ultraviolet radiation use. The use of sunbeds (tanning appliances) shall be arranged so that the requirements presented in the standard EN 60335-2-27 will be fulfilled. Further in practice only UV type 3 sunbeds are accepted for cosmetic use. If another than UV type 3 sunbed is used for cosmetic or similar purposes, the treatment shall be performed under the supervision of a professional with an expertise in UV phototherapy.

UV chapter of the Decree (294/2002) and rationales can be found in the link: http://www.stuk.fi/sateilytietoa/sateilevat_laitteet/en_GB/solarium/_files/12222632510024445/default/STMasetus294-2002english.pdf. Finland has one clear deviation from the CENELEC (EN 60335-2-27) standard in which the recommended maximum yearly dose is three times higher than in the Finnish Decree 294/2002 (see rationales).

The Decree (294/2002, 11§) says that "persons under 18 years of age should not be exposed to the ultraviolet radiation of sunbeds except in cases where such treatment has been prescribed by a medical doctor". The aim of the provision is to inhibit offering sunbed services to adolescents under 18 years of age and also to increase the awareness of the youth of the health hazards of UVR exposure. The provision is a normative recommendation and it guides to safe use but it does not include any judicial sanction. An alternative to this recommendation is to issue a strict ban by a law. The ban will be taken under consideration in near future, because the International Agency for Research on Cancer (IARC) raised the classification of the use of UV-emitting tanning devices to Group 1 , “carcinogenic to humans” (IARC-News, 2009).

So, now the safety requirements of solarium equipment are based on the European standard EN 60335-2-27 and the STM Decree (294/2002).The requirements are stated in more detail in STUK's ST

9.1 directive (only in Finnish and in Swedish); the title is in English "Radiation Safety Requirements and Regulatory Control of Tanning Appliances". These instructions also deal with requirements concerning tanning facility and the person in charge.
http://www.finlex.fi/pdf/normit/17156-ST9-1.pdf (in Finnish)

Recently the radiation safety authorities in the Nordic countries (Denmark, Finland, Iceland, Norway and Sweden) have collectively issued a recommendation for a ban on commercial sunbed services to persons under 18 years. The Nordic Radiation Safety Authorities recommends the regulation of tanning facilities open to the public to include prohibition of commercial use, sale or hire of sunbeds to persons below 18 years of age. The Nordic recommendation (in English) can be found in the links of authorities (FI, NO, SE, IS) below. The press release can be found in English in the Norwegian web page:

http://www.stuk.fi/stuk/tiedotteet/fi_FI/news_575/
http://www.nrpa.no/index.asp?topExpand=&subExpand=&strUrl=//applications/system/publish/view/showobject.asp?infoobjectid=1007193&channelid=1000069
http://www.stralsakerhetsmyndigheten.se/Om-myndigheten/Aktuellt/Pressmeddelanden/Pressmeddelande-De-nordiska-stralsakerhetsmyndigheterna-rekommenderar-ett-forbud-mot-solariesolning-for-personer-under-18-ar-/
http://www.gr.is/

As mentioned earlier besides STUK also municipal health authorities in Finland make tanning facility inspections. Particularly inspections are made before tanning facilities are taken into use. There is a regulation for this action: the Health Protection Act (763/1994).

Germany:

During most of the period the action took place no special legislation was in force regarding the safety of sunbeds the safety of sunbed services in Germany. As far as the safety of these products is concerned, sunbeds are covered by general product safety legislation:

Geräte- und Produktsicherheitsgesetz (legal act on the safety of technical work equipment and consumer products) and the Niederspannungsverordnung (ordinance on low voltage products).

According to this legislation the 0.3W/m2 limit is a prerequisite for the first placing on the market of (new) sunbeds.

For the assessment whether old sunbeds are safe Germany legally has to apply the regulations (legislation and standards) that were in force at the time of the first placing on the market of those sunbeds. So if old sunbeds in Germany meet the requirement of 0.6 W/m2 previously in force, there is no legal basis for corrective action.

Experience in Germany is, that studio owners in most cases change the lamps of old (and new) sunbeds, so that the beds exceed even the 0.6 W/m2 limit. By this action the studio owners change the safety properties of the sunbed and are to be seen as manufacturers. The relevant sunbeds do not comply to any standard and are seen as unsafe products. So we can act in these cases.

The German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety prepared a law on the protection from non-ionising radiation that passed the parliament in July 2009 and came into force on the 4th of August 2009 (see attachment). Paragraph 4 of this law contains a ban on commercial sunbed services to persons under 18 years.

Based upon this law the Federal Ministry is currently preparing a regulation setting up more detailed requirements for sunbed services according to the recommendations of the scientific committee. As a result of this market surveillance in Germany becomes in line with the other EU-countries.

Hungary:

The transposing legislation of the LVD in Hungary is the Decree No. 79/1997. (XII. 31.) IKIM of the Minister of Industry, Trade and Tourism on safety requirements of certain electrical equipment and assessment of conformity with those requirements. This decree came into force on 1st of April 1998 and is applicable from this date. The GPSD is transposed mainly by the Law on Consumer Protection No. CLV. 1997. There is no additional national regulation for sun beds in this respect, in Hungary.

We consider that the essential safety requirements in the Directive are to be fulfilled whether or not the limit is defined in the harmonised standards. We share the opinion that standards without limit of radiation level no longer give a presumption of conformity with regard to the aspects involved.

The Netherlands:

For new sunbeds, for second hand sunbeds and for sunbeds provided in a service the national implementation of the LVD is used in the Netherlands. Special is that in this national legislation also some relevant parts of the GPSD are covered. The essential safety requirements in the Directive have to be fulfilled and are of more importance than requirements in the standard. Because of the report of the SCCP and the commitment to that report of the Commission and the mandate for a change of the relevant standard it became clear that that standard no longer give a presumption of conformity with regard to the aspects involved. In fact this must be effective as soon as it became clear that the essential safety requirements were not covered completely in the standard and the date of withdrawal of the standard is therefore in this specific case not important. Levels higher than 0,3 W/m2 for the sunbeds are not acceptable with regard to the Directives and the national legislation. To assure that all relevant business is informed, an LVD-ADCO declaration was published and even a transition period was taken into account and the LVD Working Party was informed.
There is no additional national regulation for sunbeds in the Netherlands because such a provision would be superfluous.

Latvia:

In Latvia there is no specific legislation to cover sunbeds. The Law on the Safety of Goods and Services implements the GPSD and Regulation Nr.187 (30.05.2000. Nr.187) Safety of electric equipment, implements the LVD. To assess if services comply with the safety requirements also LV EN 60335-2-27:2009 and SCCP report are used. Latvia is preparing a new Regulation connected with requirements of hygiene, that will include the 0.3 W/m^2 norm as well (expected to come in force from 01.01.2010.).
The Consumer Rights Protection Centre of Latvia is responsible for the market surveillance of both the LVD and the GPSD.
In Latvia the tanning sector is organized by the Solarium and Sunlight Association of Latvia, which is a member of the European Sunlight Association. There is information that a new association is in the process of being formed: Association of tanning studio owners of Latvia. Presently the number of tanning salon operators that is member of these associations is still rather low.

Poland:

In Poland, the inspection procedures of the New Approach Directives have been implemented by the *Law of the 30 August 2002 on the System of conformity assessment (OJ 2004 No. 204, item. 2087,*

with amendments). However, the essential requirements for electrical equipment with the LVD Directive have been implemented by the *Law of Ministry of Economy of the 21 August 2007 on Essential requirements for electrical equipment (OJ 2007 No 155 item. 1089)*. Requirements for the GPSD have been implemented by the *Act of 12 December 2003 on General Product Safety (OJ 2003 No. 229, item. 2275, with amendments)*. In addition, inspectors are obliged to comply with the provisions of the *Act of the 2 July 2004 on Freedom of Economic Activity (OJ 2007 No 155, item. 1095 with amendments)* which introduced, among others: limits on the duration of control in the economic entity and the obligation to notify to the controlled entity the intention to carry out the inspection.

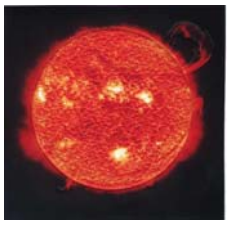
With regard to the sun beds placed on the market or put into service after the entry into force on 1 April 2009 amendments to the standard PN-EN 60335-2-27 we apply the provisions of the *Law of Ministry of Economy of the 21 August 2007 on Essential requirements for electrical equipment.*

However, devices placed on the market or put into service between the 1 May 2004 (date of Polish accession to the European Union) and 1 April 2009 shall apply standards that were in force at that time, i.e. level of effective irradiance not exceeding 0,6 W/m^2. For products placed on the market before the 1 May 2004 we cannot apply the provisions of the System of conformity assessment.

In order to protect users against the loss of health due to the use of sun beds with dangerous level of effective irradiance exceeding 0.3 W/m^2 inspectors apply the provisions of *the Trade Inspection Act of 15 December 2000, (OJ 2001, No. 4, item 25, with amendments)*. After completion of the inspection, to the controlled entities are directed letters, on the base of the Article 33, paragraph 1 of the Trade Inspection Act, informing about all detected deficiencies and requiring removal of non-compliances within 30 days. After 30 days, re-inspections are carried out to check the level of UV radiation in the sun beds and, if irregularities are detected again, the Regional Inspector of the Trade Inspection under Article 18 paragraph 1, point 1 of the Trade Inspection Act, shall issue a decision ordering the suspension of service for controlled sun beds.

Appendix II:

Applicability of the GPSD to sunbeds and solarium services



Sun Bed Cross Border Action

Applicability of the GPSD to sun-beds and solarium services

This note aims to clarify the applicability of the General Product Safety Directive 2001/95/EC to sun beds (ultraviolet emitting indoor tanning devices). In particular it gives information how the GPSD is to be used as the legal basis for enforcement against sun beds that do not comply with the irradiance limit or need for information set out in the Scientific Committee's (SCCP) opinion.

Remark: *The Scientific Committee on Consumer Products (SCCP) to the European Commission adopted an opinion on the biological effects of ultraviolet radiation relevant to health and its conclusions highlighted the risks linked to the use of sun beds and recommended a maximum irradiance limit.*

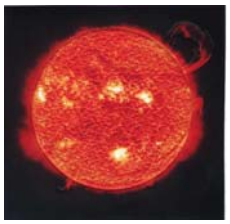
Summary and conclusion:

Under certain conditions, Directive 2001/95/EC applies to products made available to consumers in the context of the provision of a service, including at the premises of a service provider. Those conditions are:

- That the product is in a way intended or likely to be used by the consumers themselves. Meant by use is an active use, involving an appreciable degree of control. In other words that they operate the product themselves e.g. by starting the appliance, have the option of stopping it earlier by pushing a stop button and possibly can change the position or intensity during the use.
    - This means that the consumers are not under constant supervision by the service provider, as opposed to the use of the product (in the physical sense of operated) by the service provider.
    - The use by the consumers must be an active use, involving an appreciable degree of control. A merely passive use, such as the use of a bus by its passengers, or the use of shampoo by a person whose hair is washed by a hairdresser, does not qualify as use by consumers.

Applying this, it becomes clear that Directive 2001/95/EC applies to sun beds used at the premises of service providers (tanning salons, fitness centers, etc.).

The cross border market surveillance action on sun beds is supported by a grant from the European Commission, Health and Consumer Protection Directorate-General.



Sun Bed Cross Border Action

To the extent that the service provider's activity affects the safety properties of the sun beds, the service provider would be, for the purposes of Directive 2001/95/EC, a 'producer', and all the obligations incumbent on producers are applicable. To the extent that the service provider's activity does not affect the safety properties of the sun beds, the service provider would be, for the purposes of Directive 2001/95/EC, a 'distributor', and all the obligations incumbent on distributors are applicable.

Explanation:

The European Commission have taken the approach that Directive 2001/95/EC applies to sun beds supplied to consumers and also to those used at the premises of service providers (tanning salons, fitness centers, etc.), provided that the consumers themselves operate the sun bed. Meant by operate themselves is e.g. starting the appliance, have the option of stopping it earlier by pushing a stop button or leaving the sun bed and the possibly to change the position or intensity during the use. Because the consumers are normally not under constant supervision by the service provider, the Directive covers practically those mentioned situations. The impact of the above mentioned view is discussed and agreed upon at the meetings of the LVD-ADCO Group (Low Voltage Directive Co-operation group).

The purpose of the provisions of Directive 2001/95/EC is to ensure that products placed on the market are safe. This Directive shall apply to all the products defined in the scope. Meaning that it considers any product including in the context of providing a service, which is intended for consumers or likely to be used by consumers. Taken into account whether it concerns new, used or reconditioned products. *(Article l(l)) and Article 2(a))*

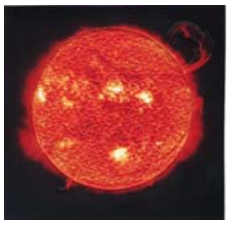
It is necessary to establish at Community level a general safety requirement for such products under consideration that these can pose risks for the health and safety of consumers, which must be prevented. *(recital 6)*

The Directive does not cover services, but in order to secure the attainment of the protection objectives in question, its provisions should also apply to products that are supplied or made available to consumers in the context of service provisions for use by them. The safety of the equipment used by service providers themselves to supply a service to consumers does not come within the scope of this Directive since it has to be dealt with in conjunction with the safety of the service provided In particular, equipment on which consumers ride or travel which is operated by a service provider is excluded from the scope of this Directive. *(recital 9)*

Products that are designed exclusively for professional use but have subsequently migrated to the consumer market should be subject to the requirements of this Directive because they can pose risks to consumer health and safety when used under reasonably foreseeable conditions. *(recital 10)*

The Directive contains the general safety requirement that producers shall be obliged to place only safe products on the market. 'Producer' is defined as the manufacturer of the product and other professionals in the supply chain, insofar as their activities can affect the safety properties of a product. 'Distributors' are defined as any professional in the supply chain whose activity does not affect the safety properties of a product. (Article 3(l), Article 2(e and f))

Within the limits of their respective activities, producers shall provide consumers with the relevant information to enable them to assess the risks inherent in a product. (Article 5(l))



Distributors shall be required to act with due care to help ensure compliance with the applicable safety requirements. In particular by not supplying products of which they know or should have presumed that they do not comply with those requirements. Within the limits of their respective activities they shall participate in monitoring the safety of products placed on the market. Especially by passing on information on product risks, keeping and providing the documentation necessary, for tracing the origin of products, and cooperating in the action taken by producers and competent authorities to avoid the risks. Within the limits of their respective activities they shall take measures enabling them to cooperate efficiently. (Article 5(2))

Where producers and distributors know or ought to know that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately inform the competent authorities of the Member States. (Article 5(3))

Producers and distributors shall within the limits of their respective activities, cooperate with the competent authorities, at the request of the latter, on action taken to avoid risks posed by products which they supply or have supplied. (Article 5(4))

The Commission adopted the view that for Non-food products supplied to or used by consumers as part of a service are covered by Directive 2001/95/EC. However, the safety of the equipment used by service providers themselves in order to supply a service to consumers is excluded from the scope of Directive 2001/95/EC and should, therefore, be considered within the scope of Community action on the safety of services. This is in particular relevant for equipment on which consumers travel or ride, but which is operated by a service provider. *(Paragraph 6, third subparagraph of the report adopted by the Commission referred to in Article 20 of Directive 2001/95/EC, COM(2003)31)*

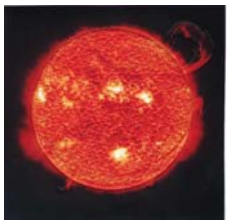
The GPSD also covers products supplied or made available to consumers in the course of a service provided to them. Consumer products are often made available in connection with certain services (for example renting of machines). The equipment used by the service provider to supply a service is beyond the scope of the GPSD, in particular, equipment on which consumers ride or travel operated by a service provider. (*Directive 2001/95/EC Decision 2004/418/EC, the third indent in Section 2.1)*

Analysis

It is clear from the wording of the Directive that it does not apply to services as such, but only to products used in a service. *(In particular its Articles I(I) and 20 and the recitals)*

It is equally clear from the wording the of the Directive that the fact that the consumer comes into contact with the product not through a purchase of the product, but in the context of the provision of a service to the consumer, does not as such exclude the applicability of the Directive. *(in particular its Articles 1(2) and 2(a) and its recital 9)*

The Directive applies to any product with which consumers come into contact in the context of the provision of a service and to be used by them, even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of the provision of service. *(The wording of Article 2(a))*



Sun Bed Cross Border Action

For products with which consumers come into contact at the premises of service providers, the decisive criterion is whether the products are used and partly operated by the consumer, as opposed to used exclusively (in the physical sense of operated) by the service provider. So the Directive includes not only products that are supplied to consumers but also products that are made available in the context of providing a service. *(Article 2(a) and recital 9)*

From the terms “use by consumers” and from the counter-example of equipment which is operated by a service provider, the “use” is an active use, involving some degree of control. A merely passive use, such as the use of a bus by its passengers, or the use of shampoo by a person whose hair is washed by a hairdresser, does not qualify as “use by consumers”.

Applying this it appears that Directive 2001/95/EC applies to sun beds used at the premises of service providers (tanning salons, fitness centers, etc.) if the consumers themselves operate the sun beds. Meant by use is an active use, involving an appreciable degree of control. In other words that they operate the product themselves e.g. by starting the appliance, have the option of stopping it earlier by pushing a stop button and possibly can change the position or intensity during the use.

This document is an extract of several documents and drafted by the project coordination of the known International Market Surveillance project regarding sun beds.

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Appendix III

Publicity for the sunbed action

Belgium:

Press releases were issued in August 2008 after which several the authority gave several interviews to the press. The sunbed and artificial tanning subject was also covered in a number of Television and radio shows. An inexhaustive list of the publications and the media coverage is given below.

http://www.fedramagazine.be/UserFiles/Pdf/pdf515_fr.pdf
http://www.7sur7.be/7s7/fr/1519/Beaute-Bien-etre/article/detail/632116/2009/01/22/Peu-de-centres-de-bronzage-respectent-la-reglementation.dhtml#
http://www.rtlinfo.be/info/archive/212461/les-centres-de-bronzage-ne-satisfont-pas-a-la-reglementation/?&archiveYear=2009
http://www.radio1.be/programmas/vand/1434891/
http://www.nordeclair.be/regions/bruxelles/2009-01-27/schaerbeek-controle-centres-bronzage-679864.shtml
http://www.actu24.be/article/regions/regionbruxelles/infosbxl/controle_de_centres_de_bronzage_a_schaerbeek_normes_non_respectees/244469.aspx
http://www.dhnet.be/infos/faits-divers/article/244602/bancs-solaires-vises.html
http://www.lalibre.be/societe/sciences-sante/article/436937/de-nouvelles-regles-pour-les-bancs-solaires.html
http://www.levif.be/belga/generale/78-6-83707/minorite-de-centres-de-bronzage-satisfont-a-la-reglementation.html
http://blogrtbf.typepad.com/auquotidien/2008/06/bancs-solaires.html

television coverage:
http://www.een.be/programmas/volt/volt-zonnebank

Belgium has also issued a leaflet with information for consumers of tanning studios. A copy is downloaded to the sunbed folder in the EMARS workspace.

Cyprus

Cyprus has programmed along with other state services to launch a public awareness campaign about the risks of tanning by the use of sun beds; as yet the development of this campaign is still in an early stage.

Hungary

A market surveillance newsletter was issued on the joint action and the legal situation. To inform all the interested parties this newsletter was published firstly on the homepage of the Hungarian Trade Licensing Office, together with the SCCP report and its Hungarian translation.

http://www.mkeh.gov.hu/sajto?page=details&oldal=1&news_id=292&parentID=778.

The newsletter was sent by e-mail or by post to hundreds of the interested parties of Hungarian sun bed business. Text from the newsletter will also be published in some newspapers and magazines in the very near future.

Latvia
Articles and stories in the National daily newspapers and internet portals:
http://www.diena.lv/lat/business/hotnews/ptac-liela-dala-solariju-pakalpojumu-latvija-nav-drosi-pateretajam
http://www.diena.lv/lat/business/expert/expertopinion/gederte-patiesiba-par-solariju-kampanu - this is the article by Marika Gederte (President of Solary Association of Latvia) opposing some investigations carried out during the Project and encouraging consumers not to quit using solariums.
http://www.delfi.lv/news/national/politics/11-solarijos-konstate-paaugstinatu-uv-starojumu.d?id=27830159
http://www.tvnet.lv/onlinetv/lnt/balss/article.php?id=347287
http://www.kasjauns.lv/lv/news/?news_id=11384
http://www.lv.lv/?menu=doc&id=200846
http://www.db.lv/a/2009/11/04/Latvija_liela_dala_solari?readcomment=1
http://skatiens.lv/nra/10112009-solariju_asociacija_dala_pateretaju_ne_vi
http://www.apollo.lv/apollo-ltv1/stream_page//14/9649/show
http://www.maminuklubs.lv/maminai/ptac--liela-dala-solariju-pakalpojumu-latvija-nav-drosi-pateretajam/

TV spots
http://www.ltvarhivs.lv/ltv/14/4837/page/3 (LTV Panorāma video)
http://www.tvnet.lv/onlinetv/play.php?id=347272&aid=0&category=288720 (Tautas Balss video)
TV3, News, (link not available).

Czech Republic

The Czech television channel Televize Prima reported on the activities of the Czech trade Inspection within the framework of the sunbed joint action. The news show containing this item can be seen on:
<http://www.iprima.cz/index.php/plain_site/content/view/full/77864/(name)/date>
A subtitled version (english subtitles) of the item on sunbeds is available, but could as yet not be downloaded to the EMARS sunbed directories, because of its large file size.

Communication campaign in the Czech Republic:

The media campaign on the safety of tanning in the Czech Republic has led to a discussion which resulted in items in several TV – news shows, including Nova television news of 30-4-2009. Generally addressing the hazards of tanning, one of the items also pictured the measurements of UV radiation from sunbeds by the Dutch crew, thus highligting market surveillance cooperation(see also above). The item form the Nova TV show can still be seen on:

http://tn.nova.cz/zpravy/domaci/kozni-lekarka-on-line-solarka-jako-nebezpecny-zabijak.html

The discussion also made newspapers publish articles on the subject, for example the popular Dnes:

http://zdravi.idnes.cz/jak-se-vyhnout-tomu-abyste-si-ze-solaria-odnesli-rakovinu-p31-/vase-telo.asp?c=A090409_105830_vase-telo_pet

A conference on „Sunbeds, Tanning, Cancer and Skin Aging“ will be organized in the CR with participation of the peak of skin-cancer medical capacities of CR and other bodies concerned as well.

Several other media have paid attention to the hazards of tanning, often using the same video:

http://www.mediafax.cz/domaci/2857242-Ceska-obchodni-inspekce-se-chysta-kontrolovat-solaria
http://www.mediafax.cz/domaci/2857325-Opalovani-v-solariu-podporuje-vznik-rakoviny-kuze-stejne-jako-sluneni
http://tn.nova.cz/zpravy/domaci/nova-fakta-o-rakovine-kolik-ji-je-kdy-se-nejcasteji-objevi.html
http://www.vitalia.cz/aktuality/opalovani-v-solariu-podporuje-vznik-rakoviny-kuze-stejne-jako-sluneni/

The Netherlands

In the Netherlands the VWA web site features a section on the requirements for sunbeds and tanning studios. Part of the section is also aimed at providing information to consumers.

Information for professionals
Marijn Colijn has given interviews about the Dutch market surveillance efforts in two magazines for professionals in the tanning branch: Leisure Management and Tan*Biz. Both magazines are Dutch, but also publish similar magazines in several European countries. The interviews are to be published soon.

Item in Dutch news show on IARC conclusions:
The 29th of July Evert van Wilgenburg was on Dutch television to comment on the conclusions of IARC.

Appendix IV:

ESA documents

European Sunlight Association a.s.b.l.

ESA Working Group "Joint Action on Sunbeds" (JAS)

Working Group Guidelines

These Guidelines define the goals and tasks of this Working Group and are intended to stress the ESA commitment towards facilitating and supporting the implementation of the SCCP report findings and the EU declaration on sunbeds.

The following **general goals** are already part of the ESA Statutes and can also be applied for the ESA JAS Working Group:

- Promoting the use of reliable tanning equipment and tanning lamps.
- Cooperating in the development of European directives and national legislation in relation to UV radiation.
- Establishing the Association as a platform and a central European contact-point on the subject of solariums.

The **specific tasks** of this Working Group comprise, but are not limited to:

- **Liaise with other stakeholders** such as consumer protection authorities, market surveillance, national health ministries, radiation protection authorities, cancer fighting organisations, the WHO etc. and last but not least the consumers and the public **on all effects of indoor and outdoor UV exposure.**
- **Initiate** the development of **concrete measures** in the field of communication, training of tanning studio staff and facilitation of controls etc. to support the safe use of indoor tanning equipment and thus **facilitate** the implementation of **existing rules and regulations on sunbeds** within all European Union Member States, specifically in ESA member countries.
- **Promote** the above approach in all ESA member countries **through the implementation of national stakeholder meetings.**
- **Cooperate** with Prosafe and national market surveillance authorities on **enforcing the current rules & regulations.**

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Appendix IV - document 2

COUNTRIES		LEGISLATION													STANDARDISATION		
		General Information						Specific Information							EU Declaration on 0,3 W/m2 maximum irradiance		
Number	ESA Member Country	National Tanning Law	Reference No.	Start Date	Radiation limit	UVA/UVB Limits	Additional Remarks	Info to customer	Info about customer	Training of studio staff	Hygiene	Eye Protection	Way of Control	Other	0,3 for new sunbeds	Date for 0,3 with old sunbeds	Additional information
1	Austria	Ja	BGBl. 147/28.02.1995	28-02-95	0,3	0,15/0,15	nur unter bestimmten Voraussetzungen anwendbar; aktuellere ÖNORMEN bestehend (insbes. ON S1132)	Diverse Aufklärung über Risiken und Verhaltensweisen	Diverse	Ja, nicht genauer definiert	Ja	Ja	Lokale Behörden	-	23-7-2007	-	-
2	Belgium	Yes	BS N. 2007 — 4904	28-12-07	0,3	only home units	no	Legal prescribed form (writing agreement consumer on risks)	Age (+18), skin type, name, address, city, passport number	18hours course + examination. There always has to be a trained person in the studio.	Law: Sunbed cleaning after each session, desinfection once a day and desinfection of googles(eyes) after each session	goggles must be available to consumer	FPS Economy control: (1) technical 0,3 limit and (2) administration, see consumer info	Not applicable (WHO recommendation?)	23-7-2007	01-08-08	Controls as of 01/01/2008 penality 500-20.000,-EUR and more... based on the Law Safety of Products of 9 februari 1995
3	Denmark	Yes – (harmonised standard)	DS/EN 60335-2-	01-04-09	0,3	0,3 total	Classification by type	Information on risks...	age, skin type, skin cancer	N/A	N/A	Compulsory	National	Very limited	23-7-2007	Voluntary	Voluntary certification process
4	Estonia	Social Ministery Law for beauty salons and sunbed salons dated 20.12.2000	law nr 86	20-12-00	-	-	-	Information about potential risks, information about tubes replacement times should be available for customer	Skin type, age	4 hours training course for studio staff, staff not allowed to work without receiving a training	Use of special hygienic liquids only. Desinfection of sunbeds after every use by studio personel	highly recomended	National Healt Control department		23-7-2007	not confirmed yet	
5	France	Yes	Décret n° 97-617 du 30	01-06-97	Type III	0,15/0,15	Different information	Information on risks is mandatory,	skin type, current	8 hours	Disinfection of the sunbed by the	Compulsory. It	DCCRF (special	No information on	23-7-2007	No introduction planned	
6	Germany	Yes		01-07-09	0,3		Solarium decree be pending	risks	age, skin type	till today limited	desinfection required	voluntary	no controls	voluntary certification with some stricter rules	23-7-2007	waiting for solarium decree	penalty under 18 up to 50.000, beginning from march 2010
7	Hungary	yes	79/1997.(XII.31.) IKIM	starting date of last up-date is not clear	0,3		classification by type	info on positive effects, risks, skin, etc.	no records about customers	no training	disinfection by studio staff after every use	compulsory	Market Surveillance		23-7-2007	valid retrospectively	controls as of September 2008, warning to studio operators
8	Ireland	None	n/a	n/a	no limit	no limit	none	points of note	skin type, 18yrs +	only on bed supplied	left for client to complete	goggles	none	n/a	23-7-2007	no instructions yet	nothing in place
9	Italy	Yes	4 January 1990 - Rules for avtivity of beautycian - Annex nr. 7: Technical data sheet for UV appliances (UNDER REVISION, to include the latest amendments of EN 60335-2-27)	05-05-90	0,3W/m2	--	Position paper of italian NC, stating to follow the SCCP statement since July 2007 to ensure a correct CE declaration. National endorsement of EN 60335-2-27/A1 (CEI EN 60335-2-27/A1), in force since april 2009.	as per EN 60335-2-27 standard	as per EN 60335-2-27 standard	2 years - qualification of professional beautycian	as per EN 60335-2-27 standard	as per EN 60335-2-27 standard	National and local authority	--	23-7-2007	not yet issued	--
10	Latvia	no	-	01.01.2010. (planned)	0,3	-	-	information about potential risks should be in a visible place for clients	age, skin type	6 hours course including	Disinfection of sunbed by studio staff after every use	recommend	Ministry of health, Consumer Rights Protection Centre (CRPC)		23-7-2007		~ 2000 EUR
11	Norway	Yes	FOR-2003-11-21-1362	01-01-04	0,3	0,15/0,15	Clasification by type	Info on risks,times for exposure	No	No	Desinfection by sunbed by customer	Recommende use, info on where to get	Municipality	We can informa on benifits if wanted	1-1-1993	1-1-1993	Penality NOK 500 pr unit pr. day
12	Romania	None	-	-	none	none	none	through www.info.bronzare.ro	none	none	none	none	none	none	23-7-2007	unknown	unknown
13	Spain	Yes	Real Decreto 1002/2002	10-01-02	0,3		Other warnings are defined by law: no access for people under 18, UV rays warnings on the machines…	Regulation obliges users to sign an statement, prior to the first session, in which they reckon that they've been informed. This agreement sheet contains warnings established by the local governments.		20 hours + exam & certificate			Delegates control and application on Local Governments		?		Regulation obliges to place posters at the entrance of all saloons with warnings established by each of the local governments
14	Sweden	Yes	SSI FS 1998:2	01-01-99	0,3	0,15/0,15	Classification by type	Information on risks on	age, skin type	No training	Disinfection of sunbed by	Compulsory	Municipality	none	?	?	none
15	Switzerland	Yes	0	01-10-09	0,3		Cenelec	no	no	no	yes	yes	no		1-10-2009	no	no
16	The Netherlands	Yes	NEN.…	July 2007	0.3			Information on risk in the cubical	Skin type etc.	Yes, buth not by law	Yes, by studio staff	Must be giving	by visiting the	Its allowed	23-7-2007	1-8-2008	Controls 01-08-2007; penality
17	United Kingdom	No specific tanning regulation. However, tanning equipment being trated (placed on the market) must conform with the Electrical Equipment (Safety) Regulations 1994 which requires all electrical equipment placed on the market to be "safe". (These regulations implement the Low Voltage Directive in the UK)	S.I. 1994 No. 3260	9 January 1995	None in Electrical Equipment Safety Regulations*	None in Electrical Equipment Safety Regulations*	* However, manufacturing equipment to EN 60335-2-27:2009 provides a presumption of conformity with the Electrical Equipement Safety Regulations. Any supplier who trades equipment which is not compliant with the EN could be prosecuted for trading equipment which is deemed to be "unsafe"	None	In Scotland only, legal ban on sunbed use by anyone under 18 years coming into force shortly	None	None	None	Compliance with the Electrical Safety Regulations checked by local authority enforcement officers	None	01.04.2009 (compliance with the EN)	Date for compliance not yet announced be UK gouvernment	None

under 18 years old? Not just yet!

This information is correct. When you are not yet 18 years old, you are not allowed to use a sunbed.

A while ago a commission of scientists and specialist has decided, after a thorough investigation, that it is better for young people to avoid sunbeds.
Until the age of 18, the skin is still developing. When you get sunburn through UV-radiation before this age, there is a bigger chance to get skin cancer when you are older. That is why within the European Union there is now a rule that you are welcome in a tanning studio when you are 18 years or older.

Prevent skin cancer!

All responsible tanning studios consider the prevention of skin cancer as very important. They like it when people look good because of sunlight, have a nice tan and feel good and healthy, but obviously they absolutely do not want people to get ill because of it, neither now nor in the future. They also see the fast increase of skin cancer because of irresponsible use of the sun, which is diagnosed by dermatologists lately.

On the beach as well ….

The ’18 years – rule’ is only official when using a sunbed. But of course it also should be applied when tanning on the beach, in the garden or on the balcony. However, this cannot be checked by anybody. The only thing that is sufficient is good general advice.

Sun is good, but “moderation” is the key.

Sun is good for you! As long as you watch out that you don’t get to much sun and a sunburn needs to be avoided. Outside or with a sunbed (although with a sunbed you get good advice and the sunbed will switch of in time automatically).
Because of the light of the sun or the sunbed you will not only feel better and look healthy but your skin will also produce vitamin D. This Vitamin helps with all kinds of processes for a healthy body but for instance also when you are mentally in a ‘winterdip’. More and more medical research proves that vitamin D can help prevent a lot of internal cancers. Humans cannot live without sunlight. But once more: too much sun is not good.

Welcome to our tanning studios

From the moment persons are 18 years of age, they are welcome in tanning studios. Apart from the fact that our member studios handle the age limit sharply, the tanning studio staff can advice you on how you can enjoy the sunbed as much as possible, with the best effect, but without losing sight of the risks.

During your first visit there will always be an intake-interview during which your skin type will be analyzed. This determines how long you can use the sunbed and how the programme will be set up. Next to this the studio maintains a clear code of behavior. The sunbeds have to comply with strict European rules concerning radiation. The maintenance of the sunbeds should be optimal and the hygiene in the studio should be perfect.

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