JOINT MARKET SURVEILLANCE ACTION ON SUNBEDS AND SOLARIUM SERVICES PART 2

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2. Introduction

Starting September 2008 and continuing till the 31st of December 2009 10 market surveillance authorities from 10 European Union Member States participated in a cross border action to enforce the safety requirements for sunbeds and indoor tanning services. During the action tanning salons and similar facilities were inspected, as well as the sunbeds offered there for use to the general public. In this joint action, which was cofunded by the European Commission, inspections at more than 300 locations were carried out, and more than 500 sunbeds were investigated.

Immediate reason to initiate this first joint action on sunbeds and solarium services was the publication of the SCCP report on the safety of sunbeds¹, which led the market surveillance organizations and the European Commission², ³, ⁴ to the conclusion that sun beds might very well violate the safety requirements of the Low Voltage Directive, while the companies offering tanning services might be in violation of the General Product Safety Directive.

At the time the tanning services industry (including the providers of indoor tanning services) was not accustomed to and probably unaware of legislation based on the GPSD and LVD. The joint action aimed to alert the industry to the requirements they had to fulfil by providing information about the new legislation. Cooperation with the industry organization (ESA and national industry associations) was established to provide information as effectively as possible, while enforcement activities were performed to convey to the industry a sense of urgency. Several participants also called on the media to make both industry and users aware of the risks of UV radiation and the need to comply with the legal requirements.

The market surveillance activities performed during this first joint action on sunbeds showed that it was proper to address this industry. Though many tanning services claimed to inform their customers about the responsible use of the tanning facility and advise with proper tanning schemes, few could substantiate their claims.

Checks of the sunbeds offered at service providers showed that a substantial percentage fails to comply with the labelling requirements, which was also true for the obligatory warning that UV radiation may cause injury. The level of UV radiation emitted from the sunbeds was more than the accepted legal limit of 0,3 W/m2 in more than 80% of the sunbeds measured during the action. (sampling was not random, so this figure is probably overestimated).

¹ SCCP: "Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes.

² 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

³ The declaration of the LVD AdCo group with regards to sunbeds of 22 January 2007

http://ec.europa.eu/enterprise/sectors/electrical/links/index_en.htm

⁴ The mandate to CENELEC in the field of the Low Voltage Directive 73/23/EC Brussels, 21st of December 2006, M/397 EN

A Norwegian study ⁵ on UV radiation from indoor tanning devices in Norway confirms that radiation is frequently higher than allowed, while customer guidance is regularly insufficient.

Considering these results, continuation of both awareness raising and market surveillance action in this field appears the obvious strategy to further stimulate compliance.

The present joint action aims to consolidate the progress made in the first joint action. It aims to extend the cooperation already established with the branch associations for the sunbed industry and the providers of tanning services. It also intends to expand the cooperation with stakeholders by establishing contact with that part of the medical scientific community that is involved in diminishing the incidence of skin cancers due to UV radiation. Both activities are meant to contribute to raising awareness of the risks of UV radiation from sun beds, the importance of proper consumer guidance and the legal requirements in operators of tanning studios and similar businesses. Finally, market surveillance on indoor tanning services is continued, both to directly improve the safety of tanning services and as a means to impress urgency on the industry.

⁵ Nilsen LT, Aalerud TN, Hannevik M, Veierød MB.: UVB and UVA irradiances from indoor tanning devices.; Photochem Photobiol Sci. 2011 Jul;10(7):1129-36. Epub 2011 Mar 28.

3. Background Information

3.1. Summary of Project Description

3.1.1. Title of the Joint Action

Joint Market Surveillance Action on Sunbeds and Solarium Services part 2.

The joint action was supported financially by the European Commission under Grant Agreement No: 2009 82 03.

3.1.2. Participating Member States

The application for the joint action was signed by Stichting PROSAFE, 11 Member States and Norway. A list of the participants is given in Table 1.

Table 1: lists of participants

Country	Body
Belgium	FPS Economy, SME's, Self-employed and Energy - Directorate General of Energy - Division Infrastructure and Controls
Cyprus	Competition and Consumer Protection Service
Czech Republic	Czech Trade Inspection under the Ministry of Industry and Trade
Denmark	Danish Safety Technology Authority
France	Direction Générale de la Concurrence de la Consommation et de la Répressions des Fraudes
Germany	Regierungspräsidium Kassel
Hungary	Trade and Market Surveillance Authority of the Hungarian Trade Licensing Office
Latvia	Consumer Rights Protection Centre // Health Inspectorate
Norway	Norwegian Radiation Protection Authority
Portugal	Food and Economic Safety Authority (ASAE)
The Netherlands	Food and Consumer Product Safety Authority

Country	Body
United Kingdom	Essex County Council

For Latvia the grant agreement was signed by the Consumer Rights Protection Centre. During the action the responsibility for the market surveillance of tanning facilities was transferred to the Health Ministry, in particular to the Health Inspectorate. The Health Inspectorate continued the activities required in the grant agreement.

The applicant body that took overall responsibility for the joint action was PROSAFE (The PROSAFE organisation is an informal cooperation between product safety enforcement officers in Europe.)

Four of the twelve participants participated with smaller contributions than the 77 man days required for full participation. Those are Norway (54 working days), Germany (35 working days), France (6 working days) and Belgium (5 working days). One reason for these significant differences is that some of the Member States have chosen only to follow the development in the project to benefit from findings from the other participants. Another reason is that some other Member States have sufficient knowledge about the situation in their markets to know that a lower effort is necessary than for the average participant.

After the joint action started, The French Direction Générale de la Concurrence de la Consommation et de la Rèpression des Fraudes decided to inspect indoor tanning facilities, too. France also agreed to report the results of their activities according to the templates developed and provided by the joint action. However, because internal French agreements do not allow for the Direction Générale de la Concurrence de la Consommation et de la Répression des Fraudes to perform measurements of sunbeds itself, France could not report UV measurements. Nevertheless, the actual participation of France in the joint action far exceeded the originally planned effort.

The coordination of the project was subcontracted to a consultant, Jan Willem Weijland. Issues related to the daily management of the project were discussed between Marijn Colijn (project leader), Evert van Wilgenburg (nVWA) and Jan Willem Weijland.

3.1.3. Budget

The total estimated eligible budget for this project was $518.627, 19 \in$, out of which the Commission funds a maximum of $346.394, 94 \in$, corresponding to 66, 79% of the estimated total eligible cost.

3.2. Risks of UV exposure

3.2.1. Risks of artificial tanning

The primary reason to continue the joint action on indoor tanning services is found in the health hazards posed by exposure to UV light.

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 and from artificial tanning is a determinant for skin cancer⁶. 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.

The carcinogenic properties of exposure to UV from the sun inevitably raised the question if similar effects might be induced by exposure to artificially generated UV radiation. Until now, according to IACR⁷ in 2005, "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 concluded at the time 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".

Nevertheless, IARC concluded in that, "although the available findings are 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 possibility to set limits to UV radiation from sunbeds. The main conclusions of the SCCP, published in SCCP /0949/05¹ 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.

⁶ National Toxicology Program (2002). Report on Carcinogens, 10th Edition, Substances Profiles, National Toxicology Program, Research Triangle Park, NC.

⁷ 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)

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 consistent evidence of a positive association between the use of UV-emitting tanning devices and ocular melanoma eye¹⁰ 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.

Since the SCCP report was published many scientific papers have underlined the correlation between the use of indoor tanning devices and the incidence of melanoma. which by now can be considered scientific consensus (see for example $^{8}, ^{9}$).

In 2009 IARC ¹⁰ accentuated its conclusions about the hazards of UV radiation and artificial tanning, concluding that "the risk of cutaneous melanoma is increased by 75% when use of tanning devices starts before 30 years of age", while classifying UV radiation from indoor tanning devices as "carcinogenic to humans".

3.3. Regulation and Standardization

The final report of the first joint action on sunbeds and solarium devices extensively discussed the regulatory status at the time¹¹. Meanwhile the situation with respect to the standard has changed, simplifying the legal situation and clarifying the requirements.

Sunbeds remain of course within the scope of The Low Voltage Directive, which requires sunbeds to be safe when placed on the (European) market. Because the LVD cannot assure that sunbeds remain safe when made available for use to the consumer by a service provider, the General Product Safety Directive (GPSD) still has to provide the legal framework that allows the authorities to intervene when consumer safety is endangered by the use of equipment made available in the context of services.

In 2010 EN 60335-2-27:2010 was published, a consolidated version of EN 60335-2-27 :2002, MOD; EN 60335-2-27:2002/A1:2004, MOD; EN 60335-2-27:2002/A2:2007, MOD. This new version of the standard, modified the previous version to bring it in line with the report of the SCCP, the Commission opinion and the Commission mandate for change of the previous standard.

⁸ Indoor Tanning and Risk of Melanoma: A Case-Control Study in a Highly Exposed Population: DeAnn Lazovich1, Rachel Isaksson Vogel2, Marianne Berwick, Martin A. Weinstock, Kristin E. Anderson and Erin M. Warshaw9; Cancer Epidemiol Biomarkers Prev; 19(6); 1557-68. ©2010 AACR

⁹ Indoor Tanning — Science, Behavior, and Policy: David E. Fisher, M.D., Ph.D., and William D. James, M.D.; N Engl J Med 2010; ¹⁰ El Ghissassi F, Baan R, Straif K, et al. A review of human carcinogens – part D: radiation. Lancet Oncol 2009: 10: 751–752

¹¹ Joint Market Surveillance Action on Sunbeds and Solarium Services 2009 - 2009, PROSAFE, published 3/12/2009, Report.

Sunbeds that fulfil the requirements of this standard are therefore presumed to fulfil the requirements of the LVD and the GPSD.

In practical terms the requirements translate into the following:

- 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 other vulnerable groups;
- give clear information about the hazards of UV radiation;
- the sunbeds must carry warnings;
- for consumer use the UV radiation emitted is restricted to 0,3W/m²;
- UV protecting goggles should be available for eye protection.

Presently within IEC a new standard for sun beds is developed, which (via the parallel voting procedure) is also offered to Cenelec. Within CLC TC61, the technical committee responsible for the standard, objections have been brought forward against this proposed standard. One of the objections concerns the proposed measurement method, which may not assure that the limit of 0,3 W/m2 for the sun beds, as meant in the SCCP report, is upheld. Because the proposed measurement method is likely to measure lower values for the UV emission than was previously the case, adoption would imply de facto a higher limit for UV radiation, making it doubtful that sunbeds complying with the proposed standard are also complying with the LVD and GPSD.

3.4. The European Situation

An overview of the legal situation in many of the participating member states in the first action was given on page 11 and in Annexe I of the report of the first sunbed joint action (11). Since the present joint action has several new participants and because in the meantime the regulatory status in other participants member states has developed, un updated version of the annex in (11) is appended to this report (<u>Annex II</u>). This annex adds information from the new participants Norway, the United Kingdom, France and Portugal, describes important developments in Germany and Latvia and gives updates for the remaining participants.

Note that for Norway the Norwegian Radiation Protection Authority (NRPA) participated in this joint action. The NRPA is not the responsible authority to enforce the LVD or GPSD, and therefore cannot enforce some of the requirements checked in this action. This is for example the case for 18 year age limit and other requirements concerning the operation of tanning facilities. (see also <u>Annex II</u>, Norway)

4. Project aim and design

4.1.Objectives

This 2^{nd} joint action on sunbeds and solarium services aims to consolidate and extend the progress made in the first joint action on sunbeds and solarium services¹¹. The primary objective of both joint actions was and is to ensure that new sunbeds and sunbeds offered for use in services are being used safely. In the context of market surveillance this means that the tanning services are operated in such a way that the UV radiation from the sunbeds offered remains within the legal limit of $0,3 \text{ W/m}^2$, that due care is taken to inform the customers of indoor tanning services of the risks of UV radiation, that the customer is given advice about a tanning scheme in accordance with his skin type, that persons under 18 years of age and other vulnerable groups are refused and that UV protection goggles are available.

The means employed in this joint action to achieve this objective are threefold:

4.1.1. Raising awareness of the rules

The first part of the approach attempts to raise awareness of the requirements for operating indoor tanning services in an industry that only recently was confronted with this kind of regulations and to convince the operators to comply with these regulations.

Whenever new legislation is introduced initially many affected businesses are not aware of the requirements. Compliance is likely to be low and the sector has to pass through a transition process to create a situation where compliance is the standard. Typically such a transition processes is characterized by several distinct phases, which have to be passed before the transformation takes root. Figure 1 shows the phases which can be seen universally when new legislation is imposed, depicted here for the sunbed action.

In the first phase the new requirements are brought to the attention of all operators involved: the manufacturers, distributors, dealers and providers of indoor tanning services. Once the industry is familiar with the requirements, the second phase aims to convince the enterprises to 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).

In the third phase compliance with the new requirements at those operators still not complying must be imposed. The instruments used in this phase are market surveillance and law enforcement.



4.1.1.1. Cooperation with industry stakeholders

For the purpose of phase 1 and phases 2 the joint action extends the cooperation already established with the branch organizations for the sunbed industry and the providers of tanning services, in particular with the European organization for the sunbed and artificial tanning sector: the European Sunlight Association (ESA). Of course, care was taken to respect the independence of the market surveillance authorities and to acknowledging the respective roles of the participating actors. At the local level the participating market surveillance authorities were asked to contact their national sector organizations. Cooperation with these stakeholders plays an important role in improving compliance, because they have significant influence on their members. Any effort to convince the indoor tanning branch of the necessity to comply with the safety rules is more likely to succeed when it is backed by the branch itself.

In practice the cooperation continued the work of the ESA Working Group Joint Action Sunbeds, set up in the previous joint action on sunbeds. 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:

- Providing information to ESA members about the implementation of the new rules,
- Support in the development of training material (in English) for personnel of tanning studios;
- Support in the development of a standard for service in indoor tanning facilities;
- Participation in stakeholders meetings organized by ESA and local tanning associations to inform the local stakeholders about the regulations on sunbeds and operating of tanning facilities, as well as the joint action.

Though in many member states cooperation with the industry organization is considered a useful means to raise compliance levels, it is good here to remark that some other member

states have reservations about cooperation between market surveillance authorities and industry. Such cooperation has also been criticised by scientists¹². In spite of these criticisms the cooperation in the project had a positive impact in those Member States who actively cooperated with the tanning industry.

4.1.1.2. Enforcement communication

Publicity about the cross border action also can raise compliance levels, because the target group is made to perceive an increased probability of being inspected¹³. 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.

4.1.2. Consumer education

Raising compliance levels with regulations of indoor tanning services can also be supported by educating the customers about the risks of tanning and what they should do to use indoor tanning responsibly. Knowledge of the dangers of indoor tanning helps in choosing their provider responsibly and to avoid providers who neglect the rules for quick profit. Moreover, informed customers are likely to tan more responsibly, thus contributing to the minimization of health risks associated with tanning. Finally, informed customers that chose to neglect the rules for safe tanning do so by conscious choice and are aware of the risks.

The joint action included an effort to provide the public that uses indoor tanning facilities with information about responsible tanning using sunbeds. Initially the production of information leaflets was planned, but serious doubt about the effect of a campaign based on the production and distribution of leaflets by the market surveillance organizations involved led to a different approach. The approach adopted is heavily based on the distribution of the information provided via the use audiovisual material distributed via social media and web sites, both on the internet as well as mobile phones. While the web site can of course be accessed from smart phones, a special 'app' addressing the individual risks of the user was also developed for these mobile devices.

¹² Philippe Autier, Jean François Doré, Eckhard Breitbart, Rüdiger Greinert, Markus Pasterk, Mathieu Boniol: The indoor tanning industry's double game; The Lancet, Volume 377, Issue 9774, Pages 1299 - 1301, 16 April 2011

¹³ Enforcement Communication in Theory and Practice, report in the series: An Eye on Supervision; VWA, November 2005

4.1.3. Market surveillance

The third component of the joint action is enforcement; the action comprises inspections at importers and manufacturers of sun beds and at service providers that offer sun beds for use by consumers, like tanning studio's, hairdressers, health clubs, etc. Inspections allow for immediate correction of non compliances, and thus contribute directly in reaching the goals of the action. Besides, inspections convey the impression that the authority is serious in correcting violations of the regulations, especially when used in conjunction with enforcement communication.

The market surveillance part of the action was characterized as follows:

- Inspections addressed both the information available to the consumers and the conformity of the sun beds offered for use. The action made available portable UV measurement equipment, with which the UV emission of the sun beds offered can be screened. Sun beds that fail the screening test were then to be measured professionally with accurate (and regrettably expensive) equipment made available from the NVWA (and partially funded by the joint action program). When not in compliance, measures will be taken to force them into compliance. Thus, the activities expand on the inspections already performed in the first sun bed action and aim directly at diminishing the risks consumers who expose themselves to UV radiation from sunbeds in indoor tanning services which do not comply with the regulations;
- The action also aimed to collect many UV screening measurements of sunbeds with the hand held meters in order to gain an impression of the non-compliance/compliance ratio with respect to the 0,3W/m2 limit.
- The joint action provided for the training of inspectors from the participating member states, which contributes to both the expertise and Europe wide uniformity of market surveillance in this area;
- To realize a high degree of harmonization of the inspections between the participants a common inspection list was developed. The inspection was a reduced version of the list used during the first action, concentrating more on the items directly relevant for the safety of the service and sunbeds used. The inspection list was developed as an excel file, designed to be 'inspector' friendly.
- Common "measuring train" for expensive accurate measurements. Accurate measurement of the erythemally weighted irradiance (EWI) of sunbeds is not straightforward and requires an expensive UV spectroradiophotometer capable of accurate measurements of UV radiation over the UV range of wavelengths, from which the erythemally weighted irradiance values are calculated by a computer. 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 with the spectroradiophotometer 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/m2 limit value.

• The inspections reported here were performed from March 2010 till November 2011. Measurements with the spectroradiometer equipment were performed in the period from July 2010 till December 2010.

5. Results and Discussion

5.1. Introduction

This chapter presents the activities and results of the joint action on sunbed and solarium devices part 2. It addresses successively the training, the awareness raising activities and the results of the market surveillance activities performed by the participants.

5.2. Training of market surveillance inspectors

The joint action included a training intended to provide the participants information on the legal facets of market surveillance of tanning services, instruct in the inspection of such services within the framework of the joint action, instruct in the use of the hand held UV meters for screening measurements, give some hands-on experience of their use and inform about the UV measurements with the radiospectrometer. The training meeting was organized at the Zwijndrecht facilities of the NVWA in the Netherlands, as this allowed to demonstrate the handheld meters and UV measuring equipment using an actual sunbed. Some 18 participants from 9 Member States and from Norway attended the training.

The subjects referred to in the first paragraph were given in the form of presentations and demonstrations. For market surveillance organizations the presentations are available from the web-ex space:

http://prosafe.project.webexworkspace.com/docs/docapp.aspx?_command=list&fid=2236 4

Additional presentations were given by the participants Hungary and the Czech Republic, who discussed their experiences in the first sunbed joint action and informed about the progress and effects of market surveillance of tanning facilities.

During the meeting handheld UV meters were distributed. Each participating country received 1 handheld meter to perform UV measurements on sunbeds at inspection sites.

5.3. Dissemination and Awareness raising

5.3.1. Industry and tanning service operators

Together with the participating Member State Market Surveillance Authority the joint action management actively participated in 5 stakeholder meetings organized by ESA in the participant's member states. These meetings were primarily intended to discuss the requirements for tanning studios with local stakeholders, best practices in operating studios and to familiarize the local stakeholders with the activities of ESA. Participation in these events allowed the authorities to impress upon the local stakeholders the understanding that active market surveillance on tanning studios was taking place in the framework of the joint action. During the period of the joint action such meetings were held in Poland, Hungary, the Czech Republic, the United Kingdom and in Slovenia.

The joint action also supported the development of a training manual for tanning studio personnel by ESA, for which the project leader wrote an introduction. The training manual was published in September 2010¹⁴.

As a new development ESA initiated the development of a *European Standard for indoor sun exposure services*, which is presently under way in cooperation with CEN CENELEC. This initiative is endorsed by the joint action management, as a European standard for the operation of tanning services gives the service operators formal clarity about the requirements for such services and contributes to uniform standards and requirements across the European Union.

Several participants have also undertaken dissemination and awareness raising activities at the national level.

Hungary:

At the beginning of the year 2010 the Hungarian Authority translated and published the press releases issued by the European Commission and PROSAFE and a summary of the Report on the joint action in 2009. The Ministry of National Development and Economy (NFGM) issued a communication on the joint action and on the results of the Hungarian surveillance. These publications induced a large press interest about the joint solarium action. Many of TV channels, radio stations broadcasted reports on the joint action and its results. Also several journals and magazines published interviews about the safety situation of solariums.

The Trade and Market Surveillance Authority organized a Solarium Forum for the stakeholders of the solarium industry in February 2010. The Forum was held under the patronage of the Ministry of National Development and Economy. More than 100 participants took part at the conference and they were given information about the activities during the joint action 1 and the aims of joint action 2, the legislative framework and the legal background. Frequently asked questions were discussed. The experts of the institutions concerned – Hungarian National Public Health and Medical Officer Service (ANTSZ), Hungarian Standards Institution (MSZT), an associate professor from Department of Dermatology, Semmelweis University School of Medicine, – gave lectures on the health, safety, medical and legal aspects of solariums, in Hungary. The secretary and the chairman of the two Hungarian solarium associations (MSZE member of ESA, MSZUE Hungarian Association of Tanning Operators) exposed their opinion and they projected how to solve the bad situation. A press conference was held right after the solarium forum.

¹⁴ ESA: Sun consultant -training manual for tanning facility operators; European Sunlight Association, Brussels, September 2010

The Trade and Market Surveillance Authority issued two Newsletters on its homepage to inform the stakeholders and the clients on the aims and the legal background of the joint action, on the presentations of the Solarium forum and on the safety instructions for the clients. http://www.mkeh.gov.hu/kereskedelmi/EU/piacfelugyelet/hirlevel

Other media exposure included:

Interview in Duna TV, January 6, 2010. http://www.dunatv.hu/musor/videotar?vid=601506

Interview in RTL Klub TV, February 26, 2010. http://www.rtlklub.hu/most/8257_reggeli_10-02-26

RTL Klub TV News, telephone interview, March 31, 2010.

Interview in radio MR1, February 25, 2010

Czech Republic:

There was TV coverage of the risks of artificial tanning multiple times, generally also highlighting the involvement of the Czech Inspection. An example still found on the internet:

http://www.barrandov.tv/53867-test-solaria-jsou-skodliva



Norway

The Sunbed-project was presented at several occasions:

Meeting hosted by and held at NRPA 6-7 May 2010 for the members of Technical Committee No. 61: Safety of household and similar electrical appliances; Maintenance Team 16: Ultra-violet radiation.

Meeting between NRPA and the Norwegian Sunbed Association on the 1 December 2010.

The annual consensus-meeting between scientific experts at the Norwegian Cancer Society in Oslo 7 December 2010.

In addition the NRPA organized 3 courses (1 day each; 17+18 February and 23 March) in 2010 and 1 (23 March) in 2011 for local solarium inspectors. These courses included lectures on health effects, safety and legal aspects of solariums, as well as practical training of inspecting solariums. About 70 inspectors participated. The NRPA aims to publish this course on its web site and the first part is already available (in Norwegian).

Employees of the NRPA also published 2 papers with respect to solariums, both of which attracted media attention¹⁵, ⁵.

Portugal

In 2010 the ASAE gave an internal training for those inspectors who cooperated in this action. The training took place at the premises of the ASAE in Lisbon and Porto.

The practical component of the training was given by a Portuguese notified body, notified under the LVD.

The ASAE also published information on its website regarding the risks associated with artificial tanning aimed at the consumers.

United Kingdom

The Essex Country Council, participant in the action, participated in the Sunbed Association Workshop, Birmingham , the 14th of April 2011 with a presentation on the legal requirements for tanning services and the market surveillance of these services in the United Kingdom.

Probably more participants have been performing similar activities, but these have not been reported.

 ¹⁵ " Sunbeds, vitamin D and skin cancer ", Veierød MB, Nilsen LTN and Robsahm TE. Tidsskr Nor Legefor 2010; 130; 1818-21 (In Norwegian). <u>http://pdf.tidsskriftet.no/tsPdf.php?pdf=pdf2010|1818-21.pdf</u>

5.3.2. Consumer information

The joint action included the development of information material to raise consumer awareness. The assumption here is that consumers who are aware of the risks of artificial tanning will be better able to choose services in compliance with the safety regulations and thus restrict UV exposure to reasonable levels.

During the action the proper communication channel has been extensively discussed. Though it was originally intended to develop leaflets, experiences by some of the participants have shown that the impact of this approach is very limited. Therefore it was decided (and agreed by the EU) to adopt a different approach.

Much of the scientific information on the relation between UV exposure, and UV exposure by indoor tanning has centred on the increased cancer risks in age cohorts up to 35 years and reported a correlation of melanoma incidence with tanning at younger ages. Note however, that though this observation is valid, this does not automatically imply that tanning at later ages is safe⁸. Nevertheless, this observation gave reason to aim the consumer communication effort at the younger ages. Given the interests of the younger age groups in modern media like video, mobile communication by smartphones and the internet, an approach was adopted that tries to employ the popularity these media enjoy under young people.

The package consists of a video (in a short and long version), a web site containing these videos and information on tanning presented in a light hearted way. In addition a mobile phone app was developed, which also gives information on tanning and which refers to the web site.

5.4. Results from Member States' Market Surveillance Activities

5.4.1. Introduction

The main activity that the Member States undertook in the context of the joint action on Sunbeds and Solarium Services at the national level was market surveillance. Over the two year period of the action the participants in the joint action performed inspections at tanning studios, manufacturers and EU-importers. A checklist was provided, which centred on those items in the operation of the studios that assure that customers receive sufficient information and personal advise to allow responsible use of the sunbeds, checks on the age of the customers to prevent youth from using the sunbeds and the intensity of the UV radiation from the sunbeds at the facilities. Where possible a screening measurement of the UV radiation was made using the hand held UV meters supplied.

5.4.2. Characterization of Inspections

During the period from the 1st of January 2010 up till the 14th of December 2011 the participants in this joint action reported a total of 1307 inspections at tanning service providers and manufacturers, EU importers or distributors of sunbeds.

The inspections are summarized by participants and inspection type in Table 2. The inspection type is either a first inspection of a business, or it is a re-inspection, which is generally done when a previous inspection determined shortcomings.

Note that Belgium's participation was restricted to attendance of the meetings in order to stay informed about developments in the other member states and no contribution of inspections was planned. Originally the same held for France, but during the action France decided to perform inspections of indoor tanning services and contribute the results of their inspections to the joint action.

	First inspection	Re-inspection	Total
Cyprus	7	11	18
Czech Republic	64	14	78
Denmark	353		353
France	239	10	249
Germany	32		32
Hungary	128	5	133
Latvia	58		58
Netherlands	204	76	280
Norway	32	1	33
Portugal	17		17
United Kingdom	44	2	46
Total	1178	119	1307

Table 2: inspections by participant and inspection type

5.4.3. Characterization of Inspection Sites

The businesses involved in indoor tanning services include the manufacturers and distributors of the sunbeds used in these services and the businesses that provide the indoor tanning services to the customers. The latter group is varied, but may be distinguished in businesses for which indoor tanning is the main activity and businesses that offer other services, but as a side activity also make sunbeds available to their customers. These include, for example, hotels, fitness and wellness services, swimming pools, beauty parlours, hair dressers, etc.

Table 3 lists the distribution of the inspections according to the type of business inspected.

Only first inspections are taken into account, as these convey an idea about the present situation in the markets. Re-inspections, in which usually checks are made whether

shortcomings have indeed been rectified, are excepted from this analysis, as they would distort the image obtained. Note also that these results refer to the inspected sites, which may well operate multiple sunbeds.

		Manufacturer	Distributive trade		Service	e provider	
participant	total			tanning main activitiy	tanning side activity	staffed?	membership association
Cyprus	7			4	3	100%	0%
Czech Republic	64			32	32	84%	0%
Denmark	353			353		0%	-
France	232		8	16	208	99%	4%
Germany	32		1	23	8	97%	45%
Hungary	128	1		60	67	98%	13%
Latvia	58		1	28	29	100%	8%
Netherlands	204	9	3	58	134	95%	41%
Norway	32			13	19	31%	0%
Portugal	17			13	4	100%	0%
United Kingdom	43			18	25	93%	31%
Total	1170	10	13	618	529		

Table 3: characterization of inspection sites

For the following analyses a word of caution is in order. When the number of inspections for a particular participant is low, the results found are heavily dependent on each specific inspection result and the estimated degree of non-compliance is not very reliable. This is true for example for Cyprus and Portugal and to a lesser extent for Germany, Latvia and Norway.

In the majority of the inspected sites indoor tanning was offered as the main activity. However, this result is heavily influenced by the results from Denmark, which contributed more than 300 inspections exclusively at services where tanning was the main activity. If these inspections are excluded, the situation in the rest of the participating countries appears to be different and a considerable fraction of sunbeds are offered by service providers who offer tanning as a side service. This observation is relevant, because it can reasonably be assumed that businesses that offer tanning as a side service will be harder to reach when trying to convince them of the necessity to comply with the rules. After all, they are unlikely to be a member of a tanning association and most likely will miss information offered by that association.

The ratio between service providers where tanning is the main activity and those who offer service as a side service varies between countries, with a high fraction providers of tanning as a side service in France and the Netherlands. For the Netherlands the high fraction of indoor tanning provided as a side service can be explained, because over the period the joint action's attention has shifted from services with tanning as the main activity to those businesses that offer tanning as a side service. In reality the ratio may therefore be more balanced than found here, probably nearer the half/half ratio.

As can be seen in the last column of the table the percentage of proprietors of tanning facilities that is member of a branch association is low. The percentage shown may even be flattered, because sites that offered tanning as a side service frequently are member of an association, but the association is concerned with their primary activity. The conclusion is that the degree of organization is low in most member states. This is regrettable, because this limits the possibilities for the indoor tanning service associations to influence the standard of service provided directly.

Responsible use of sunbeds by consumers requires that the personnel of the tanning facility informs the customers about the use of sunbed, taking into account skin type, age of the customer, etc. Typically this requires staff. However, there are also 'coin operated self service' sunbeds offered, especially in the Scandinavian countries. Often there is no personnel present to advise customers and preclude that persons under18 years of age and other vulnerable groups use the sunbeds. Table 3 shows the percentage of inspection sites that were staffed. In most countries staff is present at the great majority of service providers. In Denmark staff is almost absent. This is because indoor tanning services are mainly unstaffed sites, where coin operated sunbeds are offered. In Norway the percentage of facilities where staff is present is also low, a fact known to the Authorities and a source of concern. In fact, Norway is passing legislation making staff obligatory for indoor tanning services.

5.4.4. Safety information, tanning advise, handling of age limit and the availability of goggles

Minimizing the adverse effects of the use of sunbeds requires that consumers visiting the solarium service are informed about the risks of sunbed use and that they are advised about a suitable tanning scheme, taking into account their skin type, the presence of freckles or moles, medical history, etc. Also, the sites should have procedures in place to prohibit the use of sunbeds by people under the age of 18. Such policies should be part of the way in which the tanning facility is run.

These aspects were addressed in the joint action, where inspections checked the way in which safety information and individual tanning advise were given, how the age limit was upheld and if sufficient goggles were available. Table 4 shows the results for indoor tanning service providers at first inspection.

Table 4: risk information, personal advise, handling of age limit (18 year+) and availability of goggles; all service providers (n=1147)

	Risk information	Personal advise	18 year +	Sufficient goggles
	No/insufficient	No/insufficient	No/insufficient	No
Cyprus	29%	71%	29%	0%
Czech Republic	11%	13%	22%	3%
Denmark	100%	100%	100%	25%
France	17%	30%	41%	3%
Germany	10%	6%	3%	7%
Hungary	9 <mark>2%</mark>	71%	9 <mark>1%</mark>	2%
Latvia	33%	21%	24%	8%
Netherlands	44%	47%	9%	12%
Norway	100%	100%	100%	75%
Portugal	82%	0%	0%	35%
United Kingdom	7%	14%	33%	5%,

From the table it can be concluded that great differences exist between the participating countries, but that generally the way customers are informed about the risks of sunbed use and the way they are given personal advice leaves much to be desired. The same holds true for the enforcement of the 18+ years of age limit, which is often absent or insufficient. Remarkable are the results for Norway. In Norway tanning services are required to show a wall poster, easily seen in the room, with precautionary text, warnings against the use of solariums and advise against the use by persons under the age of 18 years. This information is generally present, but because personal advise is frequently lacking there is no guarantee that these warnings are actually read. For that reason the single observation that such posters were present did not qualify for the NRPA as sufficient. This is of course connected with the fact that in Norway most services are presently not staffed, which also explains why personal advise and enforcement of the age limit is judged insufficient.

Norway also reports that goggles are frequently not available to the customers. The reason for that is that Norwegian regulations did not require goggles to be made available until the 1st of January 2011.

The results shown above refer to all service providers, including those providers that offer tanning only as a side service. Those businesses may not be informed about the regulations as well as those who offer tanning as their main activity. The latter are more likely to be member of tanning business associations as tanning service is their main concern. It is interesting therefore to see if services whose main activity is offering indoor tanning comply better than average.

	Risk information		Personal advice		18 years +		sufficient goggles		
	no/insu	no/insufficient		no/insufficient		no/insufficient		No	
	main		main		main		main		
	activtity	side service	activtity	side service	activtity	side service	activtity	side service	
Cyprus	50%	0%	75%	67%	25%	33%	0%	0%	
Denmark	100%	-	100%	-	100%	-	0%	-	
Czech Republic	6%	16%	9%	16%	16%	28%	0%	5%	
France	6%	17%	44%	29%	25%	41%	6%	3%	
Germany	9%	13%	4%	13%	4%	0%	9%	0%	
Hungary	95%	90%	63%	78%	92%	90%	0%	3%	
Latvia	14%	52%	11%	31%	4%	45%	7%	3%	
Netherlands	38%	47%	40%	51%	7%	10%	5%	15%	
Norway	100%	100%	100%	100%	100%	100%	77%	74%	
Portugal	77%	100%	0%	0%	0%	0%	46%	0%	
United Kingdom	6%	8%	17%	12%	33%	32%	6%	4%	

Table 5: risk information, personal advise, handling of age limit and availability of goggles; tanning as the main activity (n=618) vs. tanning as a side service (n=529)

Table 5 gives this information for service providers whose primary activity is providing indoor tanning services (blue columns) against the same information for providers who do tanning as a side service (reddish columns).

The differences vary by participant, but from this table compliance on the whole seems better for those businesses that have tanning as their main activity.

5.4.5. Re-inspections

The joint action on sunbeds and solarium devices is primarily a market surveillance action, which means that when non compliances are found corrective measures are taken. The severity of the measures taken depends on the enforcement policies of the participants. In general measures can vary from unofficial warnings to imposing fines or starting official prosecution. At first offense the measures taken are usually not very strict and may be confined to a warning when the violation does not directly constitute an immediate safety hazard. The measures taken during the joint action will be discussed later (because they frequently involve non compliance of the sunbeds offered, which is discussed in section 5.4.6).

Once measures are taken the usual best practice is to re-inspect the business at a later time to check if the violations were indeed corrected. The results with respect to the same parameters discussed before is listed in Table 6. The percentages listed have been calculated from a limited number of re-inspections (n= 119), so the significance of the results, especially for the individual participants, should not be overestimated. For example, for Norway the improvement in personal advise of 100% is based on the result of a single re-inspection.

	Risk information	personal advise	18 year +	sufficient goggles
	no/insufficient	no/insufficient	No/insufficient	No
Cyprus	18%	64%	18%	0%
Czech Republic	21%	29%	29%	0%
France	11%	0%	22%	0%
Hungary	80%	60%	80%	0%
Netherlands	17%	22%	10%	25%
Norway	100%	0%	100%	0%
United Kingdom	0%	0%	0%	0%

Table 6: risk information, personal advise, handling of age limit and availability of goggles; all service providers; re-inspections (n= 119)

On the whole it appears that compliance is somewhat improved after re-inspection compared with the average compliance levels at first inspection.

5.4.6. Inspected sunbeds

Sunbeds used in solarium services must be electrically safe and at the same time comply with the requirements of the GPSD. Electrical safety implies that they comply with the requirements of the Low Voltage Directive, which also requires the level of radiation from the sunbeds to be safe. The LVD requirements apply when the sunbed is brought on the European market. However, when used in the context of providing solarium services, both maintenance (replacing of worn out UV tubes by proper replacements, etc) and the way it is used determine the level of UV irradiance the customers are exposed to. Operating a tanning salon responsibly therefore also depends on the way customers are informed of the dangers and how they are advised about suitable tanning schemes. Both of these have been discussed in the previous section.

Besides, the sunbeds themselves have to comply with a number of other requirements, both with respect to labelling (prescribed warnings, administrative labelling requirements, etc) as well as electrical safety requirements and limitations to the level of UV radiation emitted. The most important aspects have been inspected during the joint action on sunbeds 2 and results follow.

Until the 14th of December 2011 inspection results for a total of 1798 sunbeds were (sometimes partially) submitted by the participants in the joint action. This number exceeds the number of inspections performed, because many inspected sites operate more than one sunbed. For many of the inspected sunbeds screening measurements of the UV irradiances have been made using hand held meters distributed in the joint action. In some cases sunbeds were also measured with radio-spectrometer equipment.

5.4.6.1. Characterization of inspected sunbeds

Sunbeds can be roughly divided in single and double solariums. The latter also have UV emitters in the bench upon which the customer lies, so that the whole body is irradiated at the same time. Both can be fitted with special emitters to irradiate the face, i.e. they also comprise a facial solarium.

There are also vertical sunbeds. In this case the customer stands while being irradiated. One may assume that, because standing is less comfortable, there is a strong incentive to limit the exposure time and, in order to get good results in this short time, increase the UV level. Market surveillance authorities therefore categorize these as more likely to exceed the UV radiation limit, though presently this assumption has not been substantiated.

An overview of the types of sunbeds seen by the participants is given in Table 7.

	Double solarium	Single solarium	Vertical solarium	Not classified	Total
Cyprus	14		12		26
Czech Rep	124	33	4	3	164
Denmark	353				353
France	233	85	14	2	334
Germany	71	3	1		75
Hungary	159		89		248
Latvia	62		27		89
Netherlands	307		15	1	323
Norway	54		1		55
Portugal	27		5		32
United Kingdom	49		50		99
Total	1453	121	218	6	1798

Table 7: inspected sunbeds by type of sunbed

The great majority of the sunbeds seen during the inspections were double solariums (1453 sunbeds, 81% of the sunbeds classified) and most of those were equipped with facial emitters (90% of the sunbeds for which data were available). Single solariums are relatively rare in the sites inspected; 121 single solaria were checked (6,7% of the sunbeds classified), 80% of which were also facial solaria.

Finally, 11,7 % of the sunbeds encountered were vertical sunbeds. These seem to be especially common in Hungary, the United Kingdom and Cyprus.

5.4.6.2. Coin operated sunbeds

Though in many European countries solarium services are typically offered by tanning salons and similar businesses, which are generally staffed, in some of the member states coin operated sunbeds are frequently encountered. Especially the Scandinavian countries have indicated that such coin operated systems are common.

When coin operated sunbeds are offered in an environment where no staff is present to advise consumers about their tanning habits, passing the safety information required for safe tanning effectively is more difficult and more likely to be absent.

The checklist for the action therefore asked to indicate if the sunbed investigated was a coin operated machine. Results are given in Table 8 as the percentage coin operated machines of the total number of sunbeds inspected (last column).

	coin operated %	unclassified	total
Cyprus	50%		26
Czech Rep	10%	24%	164
Denmark	100%		353
France	7%		334
Germany	15%		75
Hungary	6%		248
Latvia	0%		89
Netherlands	21%		323
Norway	98 <mark>%</mark>		55
Portugal	0%		32
United Kingdom	3%		99
total			1798

Table 8: Percentage coin operated machines by participant

In Denmark (100%) and Norway (98%) the sunbeds investigated were almost exclusively coin operated. The sites where these coin operated sunbeds are offered are generally unattended. In Denmark the inspections were specifically aimed at such unattended sunbed services, but such services are the main operators of indoor tanning services in Denmark. There are businesses who offer tanning as a side service, but these are relatively rare (at most 5% of the sunbeds offered). Coin operated sunbeds are also common in Cyprus and to a minor extent in the Czech Republic, Germany and the Netherlands.

The common opinion of market surveillance officers in the Netherland is that coin operated machines are less frequent than it appears in this investigation. An explanation is found in the fact that the Netherlands have been inspecting tanning services for a number of years, starting with inspections of tanning salons but now gradually shifting to providers who offer tanning as a side service and with special attention to coin operated machines. Also premises with coin operated sunbeds were inspected during complaint investigations. Possibly this also holds true for other participants, who have been inspecting indoor tanning services for a longer time.

Despite the fact that it is mandatory in Norway to provide posters with warnings and information, it is recognized by the Norwegian Authorities that the high percentage of coin operated machines, often employed without supervision, may lead to inadequate guidance of the customers.

In December 2011 the Norwegian Ministry of Health and Care Services announced that regulations have passed requiring no solarium to be offered to persons under the age of 18 years and that every tanning studio must have trained staff to guide the customers.

The age limit is valid from 1 July 2012, while requirements for trained staff is valid from 1 January 2014. (see also Annexe 1 for legal situation in Norway).

5.4.6.3. Compliance with the requirements

Labelling

The LVD requires that electrical products carry specific labelling. This includes the requirement to carry the CE mark. Warnings are required where necessary for the user to make responsible use of the appliance. Specifically Standard EN 60335-2-27, which applies to sunbeds, requires a warning that "Ultraviolet radiation can cause injury". Though there are more labelling requirements, these are the most important and the joint action has restricted the checks on these labelling requirements.

An overview of the results for labelling of sunbeds is given in Table 9, which lists the non compliances with the main labelling requirements investigated.

			1 47		descent to stife
		CE -marking	warning is lacking	passport	a oes not testily
		absent	15 lacking	lacking	<0,5 w/ 112
Cyprus	26	8%	23%	85%	100%
Czech Rep	164	. 9%	3%	81%	74%
Denmark	353	no data	29%	no data	no data
France	334	12%	0%	19%	52%
Germany	75	1%		44%	21%
Hungary	248	46%	45%	57%	89%
Latvia	89	12%	30%	43%	27%
Netherlands	323	18%	15%	35%	17%
Norway	55	82%	18%	*	*
Portugal	32	6%	0%	100%	-
United Kingdom	99	29%	34%	100%	-
Total	1798				

Table 9: compliance with labelling requirements and presence of 'passport"

* For Norway: see text

Note that the warning "Ultraviolet radiation may cause injury" is regularly found not to be present in some of the participants Member States. Remarkable is also that a substantial fraction of the sunbeds does not carry the obligatory CE marking. Especially in Hungary, the United Kingdom and Norway the percentages non compliance are high.

The checklist for the joint action also asked if name and address of the manufacturer/EUimporter was listed on the sunbed. Regrettably the data submitted by some of the participants did not allow a precise estimate of the fraction non compliances with this requirement. For those participants that submitted accurate data the percentage non compliance with the obligation was low: generally less than 5 %.

Passport and/or technical file

Each sunbed should be accompanied by a technical file or 'passport'. The technical file is a requirement from the LVD, which refers to all technical information about the product necessary to demonstrate its compliance before the product can be introduced into the European market. The "passport" is a document that summarizes the main specification and properties of the sunbed, which is promoted by the industry organizations as a way of certifying the compliance of the sunbed with the regulations, in particular with respect to the UV radiation emitted.

In principle this type of document could facilitate the market surveillance of tanning services, because it allows to check that the sunbed complies with the radiation limit by document checks only. That way expensive on site UV measurements can be avoided. Of course this is based on the assumption that the passport reflects the actual situation and performance of the sunbed it refers to, an assumption that may not always be justified. For the time being the usefulness of these documents for market surveillance authorities remains limited. Table 9 shows that in the majority of cases such a documents could not be shown by the proprietor of the solarium service, or that, when the document can be shown, it frequently does not specify the UV radiation emitted by the sunbed.

For proper interpretation it should be noted that in Norway a different situation occurs. All solariums that can be used in Norway must be listed on NRPA's web-pages and in order to be listed the UV-type 3 classification must be documented to NRPA. Solariums are then listed with lamps that can be used in each specific solarium. Also user instructions must be documented to the NRPA. In that way, passports are more or less publically available. In the context of this joint action it is relevant that the NRPA did not have the inspection mandate to check either the passports or the CE-marking, which explains why no data are given (Responsible for these aspects is DSB - Directorate for Civil Protection and Emergency Planning). In fact, many of the tested solariums did comply with the "passports" requirements, and the data are available on the NRPA's internet pages.

UV measurements

Though responsible use of indoor tanning services depends on the factors discussed before, the level of UV radiation emitted from the sunbed itself also determines the amount of UV radiation the consumer is exposed to.

For sunbeds the requirement is that the EWI does not exceed $0,3W/m^2$. The EWI (erythemally weighted irradiance) describes the ability of a particular dose of UV light to induce erythema and serves as an indicator for the adverse effect of UV radiation.

In this joint action the EWI value from the UV radiation emitted was measured by using handheld meters, type Solarmeter® model 7,5 (Solartech), one of which was made available to each of the participants. Before handing over the meters these were checked using a radiospectrometer (Spectroradiometer: OL756; Integrating Sphere: IS670; Dual Calibration Check Source: OL756-150; Irradiation; lamp standard Model 220 and Programmable Current Source OL65A).

Hand held meters are not very accurate, so the results cannot yet be used to determine unequivocally that a sunbed violates the limit. In fact measurements with the Solarmeter® should be seen as screening measurements. To obtain results that can stand up in court measurement with the far more expensive UV Spectroradiometer/monochromator system are required. These were also performed during the action, but because these are complicated and lengthy measurements and therefore expensive, only a limited number of sunbeds were measured with this equipment.

Hand held meters may not be as accurate as the spectroradiometer/monochromator, they do allow to measure a large number of sunbeds quickly, giving useful indicative information on the UV levels of the sunbeds currently in use.

The participants were asked to measure the sunbeds they were inspecting where possible. The method used for these measurements was instructed during the training and is described in Annex III. Measurements were to made of the bench emitters of the sunbed, of the canopy emitters on double solariums and also facial emitters when these were part of the sunbed. In all the participants made measurements on a total 1072 sunbeds. The results of these measurements are summarized in Figure 2.

Figure 2 shows normalized bar graphs for the measured emissions from the bench and the canopy of the sunbed, as well as for the facial area. The number of measurements in each range is denoted in the corresponding sections of the bars. The percentage of measurements below the UV radiation limit of EWI < 0.3 W/m^2 is denoted in the green part of the bar, while higher EWI values are denoted progressively more reddish.

Striking in Figure 2 are the scores for Norway and the Netherlands, which show relatively high percentages of measurements below the $0,3 \text{ W/m}^2$ limit, while violations of this limit remain limited. A possible reason is that both Norway and the Netherlands have inspected indoor tanning services and have measured sunbeds for some years and that these efforts are showing effect. Notable is also that the scores for the bench, the canopy and the facial

emitters run highly parallel for these countries; compliance behaviour appears to address all UV emitters of the sunbed. To a greater or lesser extent this also holds the other way round: a substantial share of large violations of the limit is frequently seen for bench, canopy and facial UV emissions.





Results for the Solarmeter measurements of the top emission, bottom emission and facial emission by participants. The numbers of beds measured for each source are indicated in the bars.

Though Figure 2 conveys the notion that many sunbeds violate the 0,3 W/m2 limit for UV radiation, it is not possible to see which fraction is actually not complying. For a sunbed to comply the UV radiation emitted from each of the top side, bottom side and facial emitter must remain below 0,3 W/m²; when one of the values exceeds the limit the sunbed does not comply.

Figure 3 gives a bar graph which shows the numbers of sunbeds where the value of the worst UV radiation value measured (of either bench, canopy or face area) are within the designated ranges. The figure gives a fair indication of the fractions of sunbed complying with the limit (green part of the bar) and the distribution of violations over progressively higher EWI ranges.



In fact, for a total number of 1072 sunbeds (of 1798 inspected) one or more measurement values were reported. In 688 (64%) sunbeds measured at least one of the EWI values exceeded 0,3 W/m², sometimes considerably. In 138 sunbeds (13%) the EWI exceeded 0,9 W/m², 34 (3,2%) of which read even higher than 1,2 W/m².

An overview of the overall distribution of the highest EWI values measured for each sunbed, as reported by all the participants, is shown in Figure 4.



Figure 4: Histogram of highest measured EWI values (n=1072)

Positive about this figure is that it shows the largest bar in the $< 0.3 \text{ W/m}^2$ range, indicating that many proprietors of tanning services operate sunbeds which comply with the safety limit (36%). Sobering is the observation that a considerable fraction (64%) of the sunbeds in use in indoor tanning services still exceed the limit, frequently by double or thrice the EWI value allowed.

Reliability of the results

Results of EWI measurements with the handheld meters, including the Solarmeter®, are known to deviate from the results obtained with the more sophisticated Spectroradiometer. The doubts are such, that in most Member States measurement with a Spectroradiometer is necessary to substantiate court cases against violation of the UV limit. It is therefore reasonable to question the significance of these results.

In this joint action a number of sunbeds were also measured with Spectroradiometer equipment. These measurements are discussed in section 5.4.7. Because the sunbeds measured with the Spectroradiometer were also measured with the Solarmeter[®] the results of the Solarmeter[®] measurements can be compared with those of the Spectroradiometer, giving an impression of the precision of the Solarmeter[®] . In section 5.4.8 the precision of the Solarmeter[®] with regard to the Spectroradiometer measurements is discussed, taking the latter as the reference method. From that analysis it is concluded that the deviation between the instrument's readings remains within 20% in 90% of the measured cases. The deviations of the Solarmeter[®] are both positive and negative, but positive deviations occur slightly more frequent (55% against 45%).

This raises the question what influence the deviations of the Solarmeter[®] may have on the results previously discussed. An impression is obtained when it is (incorrectly) assumed

that all Solarmeter® results are 20% high. For the sunbed operator this would mean that he is allowed a 20% increase in UV radiation before the sunbed is classified as 'over the limit'. This is a worst case approach, because in reality the deviations are less in 90% of the cases and many of them (45%) underestimate the value given by the Spectroradiometer (taken again as the reference).

Recalculation for the results of all sunbeds measured then gives the results shown in Figure 5. This figure compares the results without 'correction' as previously given (n) with those after recalculation of the data for limits 20% higher (nw).





Indeed there is a shift in the direction of more compliance, but the fraction of sunbeds in violation of the UV limit remains more than 50% and the conclusion that an unacceptable percentage of the sunbeds investigated violates the UV limit remains unaffected .

5.4.7. UV Spectroradiometer measurements

To avoid the expensive necessity of buying UV spectroradiometers by all participants, this joint action, like the previous joint action on sunbeds, used a single UV spectroradiometer¹⁶ with double monochromator, co-funded by the European Commission within the scope of the grant agreement. 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

¹⁶ Spectroradiometer: OL756; Integrating Sphere: IS670; Dual Calibration Check Source: OL756-150; Irradiation; lamp standard Model 220 and Programmable Current Source OL65A

equipment. The use of this equipment is required to obtain accurate measurements of the EWI values of the sunbeds, suitable to serve as proof when cases come to court.

During the joint action a trained operator took along the equipment to perform measurement in most of the participants member states. 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. These measurements were performed during the period May - December 2010.

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.

Measurements were performed in: the United Kingdom, Norway, Portugal , Denmark, Cyprus, Latvia, the Netherlands and Germany. Measurements started in July 2010 and ended in November 2010. In the Czech Republic and Hungary the main purpose of the use of the measurement train was to compare and fine tune the results with those obtained by similar equipment that those participants have meanwhile purchased. Having their own equipment extends the possibilities of the Czech Republic and Hungary to effectively enforce the 0,3W/m² regulation for tanning studios.

5.4.7.1. Results

In all 128 sunbeds were measured with the spectroradiometer in the United Kingdom, Norway, Portugal, Denmark, Cyprus, Latvia, Germany and the Netherlands. Depending on the type of sunbed the UV emission of the bottom part of the sun bed, the top part of the sunbed and the facial emitters were measured.

The results of the measurements with the spectroradiometer are summarized in the following table, which gives the maximum EWI values measured in 128 sunbeds.

EWI	<0,3	>0,3 - 0,6	>0,6 - 0,9	>0,9 - 1,2	>1,2
n	12	55	39	13	9
%	14%	63%	44%	15%	10%

Table 10: maximum EWI values of 128 sunbeds measured by spectroradiometer

It should be realized that the results of these measurements, though more accurate than the results obtained with the Solarmeter®, are not representative of the situation in the market. The investigated sunbeds are a biased sample, selected for measurement on the suspicion that they might not comply with the radiation limit.

5.4.8. Accuracy and precision of Solarmeter® measurements

Since the sunbeds measured by the spectroradiometer were also measured with the Solarmeter®, an impression of the precision of the Solarmeter® measurements in comparison with the spectroradiometer measurements can be obtained. Though the spectroradiometer readings (like all analytical methods) will be subject to systematic error, for the purpose of this analysis it is taken as the reference method. The measurements used have been made on the 128 sunbeds referred to above, which included double solaria, single solaria and vertical solaria. Depending on type of sunbed, both measurements were made on the bench and canopy sections of the bed. In all, 171 measurements were taken on the canopy and bench sections with both instruments. In addition 13 measurements were taken on vertical sunbeds. Note that more than one measurement can be taken on each sunbed (canopy, bench or facial emitters); hence the number of measurements exceeds the number of sunbeds.

Figure 6 shows a plot of the Solarmeter® measurement results against the corresponding results obtained by the spectroradiometer. Linear regression gives the regression coefficient as 0,993 (Standard Error = 0,017) and the regression constant as 0,017 (SE=0,010), with a correlation coefficient of 0,975.

Because for higher Spectroradiometer values the data seem to be consistently below the predicted values regression on a quadratic model was performed to assess whether the deviation from linearity was significant. Indeed the quadratic coefficient was statistically significant, leading to:



EWI_{Solarmeter} = -0,038 + 1,194EWI_{Spectroradiometer} - 0,148 EWI²_{Spectroradiometer}

Figure 6: plot measurement results Solarmeter® against spectroradiometer

The quadratic model is also shown in Figure 6. The differences between the models are small and only serve to show that there is indeed a minor deviation from linearity. The Solarmeter[®] appears to slightly underestimate high EWI values.

Regression models fit the data by minimizing the squares between the distances of estimate and data points. For the data set analyzed, the distances between estimate and data point seem to slightly increase with increasing EWI values. However, for the purpose of market surveillance the absolute values of the deviations between both measuring instruments are less interesting than the relative differences.

Figure 7 plots the relative differences between the results of the measurement with the spectroradiometer and the hand held meters ((EWI_{Solarmeter®} - EWI_{Spectraradiometer})/ EWI_{Spectraradiometer})) against the value measured with the spectroradiometer. These are plotted against the value measured with the spectroradiometer (X-axis). Positive values for the relative difference signify an overestimate of the EWI value measured with the Solarmeter® when compared to the spectroradiometer reading; negative differences the opposite. As can be seen from the plot, the Solarmeter[®] has a slight tendency to overestimate more at lower EWI values and underestimate for higher values.



Figure 7: plot of relative differences between Solarmeter® and Spectroradiometer for the bench tubes, the canopy tubes of the sunbed and for vertical sunbeds

Casual inspection of the figure indicates that most deviations of the Solarmeter® values remain within an absolute value of 20% and many within 10%. In fact a plot of the

percentiles of these relative deviations shows that app. 90% of the measurements with the Solarmeter® remain within 20% of the Spectroradiometer results and app. 65% within 10%.



It should be noted that the above refers to absolute deviations (signs disregarded). In practice the deviations are both positive and negative. The distribution is a bit skewed, though. Approximately 55% of the deviations are positive, 45% zero or negative.

Facial emitters

During the action measurements of the UV radiation of the facial emitters present in many sunbeds were also made. It is known that the uncertainty of measurements with the Solarmeter[®] of the UV emitted by high pressure lamps, which are frequently used in the integrated facial tanner, can be very high. The results of the measurements of the facial emitters in this action confirm this. Figure 9 shows the plot for the relative deviations between the Solarmeter[®] readings of facial emitters and the spectroradiometer readings.

Clearly the relative differences are much higher than was the case for the bench and canopy tubes measured in the sunbeds. Interesting is, however, that here the Solarmeter[®] underestimates quite substantially at lower levels. On average actual UV levels are therefore (much) higher than the values obtained with the Solarmeter[®].



Figure 9: plot of relative differences between Solarmeter[®] and Spectroradiometer readings for the facial emitters in sunbeds measured

5.4.9. Sanctions

Market surveillance authorities can impose sanctions when violation of the regulations are determined. The severity of the sanction depends on the gravity of the violation. Because the legal systems in the Member States differ the measures taken by market surveillance authorities may also vary. For example, some authorities are authorized to directly impose fines, while others have to submit official reports to the public prosecution.

For the purpose of this action the participants were asked to categorize the sanctions they imposed in the following categories:

- None: no legal measure was taken
- Official warning: official warnings are not really sanctions, but formally inform the inspected business that it violates the rules. Warnings are usually given when the violations are not a very serious risk for health or injury and are often given for violation of labelling requirements. Common (best) practice is that after a short period of time the business will be inspected again to check if the shortcomings have been corrected. On repeat violation generally more severe sanctions are imposed.
- *Fine, Official report, Protocol*: these are different forms a real sanctions imposed for violations of the rules. The procedures differ between the member states and

participants, but the intended results are real fines or even stricter punishment. Fines, reports and protocols are generally imposed for more severe violation of the rules, generally when the violation subjects the customer to an unacceptable health or safety risk.

The sanctions imposed during the joint action are summarized in Table 11. In interpreting this table it is important to realize that the majority of inspections were 'first inspections'. This means the inspected indoor tanning provider was visited for the first

	None	Warning	Fine/official report
Cyprus	71%	0%	29%
Czech Republic	20%	55%	25%
Denmark	19%	12%	69%
France	76%	20%	4%
Germany	77%	0%	23%
Hungary	17%	3%	80%
Latvia	97%	3%	0%
Netherlands	38%	54%	8%
Norway	22%	41%	38%
Portugal			*
United Kingdom	7%	93%	0%

Table 11: Summary of sanctions imposed during the action as percentage of the number of inspected tanning service providers

* For Portugal: see text

time by the market surveillance organization. Moreover, these inspection were made in a branch where many businesses are not yet accustomed to these regulations. Though varying between the Member States, first inspections often serve to check the business and to inform the proprietor about the shortcoming found. This may either be informal, or formal via a written 'warning'. Measures taken in first inspections are generally not severe, unless immediate remedy of a health or injury risk is at stake.

As can be seen from Table 11 the sanctions given vary by participant, but a considerable fraction of the inspected indoor tanning services was sanctioned. Hungary sanctioned most frequently, 80% of inspections led to sanctions classified fine or official report. In a number of other Member States this sanction was imposed in between 20 - 30% of the cases.

The table does not give results for Portugal, although Portugal did take legal measures. In all cases the ASAE fined the operators and sealed and closed the tanning equipment, the closure only to be cancelled when the economic operator has brought the equipment incompliance. This requires that the tanning equipment is inspected by a notified body under the LVD with test accreditation.

5.4.10. Comparison with the first joint action on sunbeds

Have compliance levels been raised since the first joint action? Did the first joint action effect any change? A comparison between the results found in this investigation and those of the first joint action on sunbeds might give insight in whether the present situation has improved over the last two years.

For a number of reasons this comparison is not easy to make. The participants in this joint action are only partially the same as those who participated in the previous action, making overall results difficult to compare. The items checked in the previous action were not exactly the same as during the present action, which sharpened the inspected parameters to zoom in on safety . The reason for this is that in the meantime the regulations have become clearer for everybody, both because of the publishing of the updated standard for sunbeds and the publication of the training manual by ESA. Finally, in the first action it was not really possible to obtain a view of the UV radiation emitted from the inspected sunbeds. Only few sunbeds were measured, and then only those already suspected to violate the limit were actually measured.

Comparing results between the actions is therefore hazardous. For example, when looking at the compliance levels with respect to the obligation to provide the customer with sufficient information and personal advice the results differ between the participants. Part of those participating in both actions show minor improvements, but others report compliance levels much worse than before. Probably this is not a real effect and it is likely to be caused by clearer formulation of the items to inspect in the current action. Things like the fraction of tanning sites where staff is present and the availability of goggles in the sites remain high, with only few exceptions.

The obligatory warning on the sunbeds offered by service providers, that UV radiation can damage the health of the users was reported to be lacking in about 50% of the cases in the previous action. Now most participants report lower and sometimes much lower levels of non compliance. The availability of technical documentation was and remains low.

No comparison can be made for the UV radiation emitted. The first joint action did not have the means to collect sufficient data to make such a comparison useful. Only with the results from this action a good idea has become available on the present situation in the market.

Overall the conclusion must be that it is not really possible to make a definite statement about the progress made by the action in terms of improved compliance levels.

Interesting is that Hungary reports in its status report (Annex I) improvement in the compliance with the UV limit since the first joint action.

6. Conclusions

6.1. Aims and time schedule

The second joint action on sunbeds and solarium services was scheduled to run from January 2010 till the end of December 2011. Goals of the action were to raise awareness of regulations in the indoor tanning branch, to inform the public of the safety risks of indoor tanning and to raise compliance with regulations in indoor tanning services by performing market surveillance.

During the period from the 1st of January 2010 up till the 14th of December 2011 a total of 1307 inspections at tanning service providers and manufacturers, EU importers or distributors of sunbeds were performed by the participating market surveillance authorities.

6.2. Tanning as the main activity versus tanning as a side activity

In a small majority of the sites inspected indoor tanning was offered as the main activity of the inspected business, but indoor tanning was often also offered as a side service in businesses whose first activity concerned other something else. That so often indoor tanning is not the main occupation is an important observation, because awareness raising activities and enforcement communication has largely been aimed at services where tanning is the primary activity via the associations for the tanning branch. The finding that an appreciable fraction of sunbeds is offered as a side service suggests more attention should be paid to service providers offering tanning as a side service.

6.3.Associations

Tanning associations play a valuable role in the development of service standards for indoor tanning services and promoting compliance of the service providers with these standards and with the rules via initiatives to make this information available to their members and other indoor tanning services. This investigation found the percentage of proprietors of tanning facilities that is member of a indoor tanning branch association to be low, an observation which was already made in the report of the previous action on sunbeds. Where so many tanning service providers are not members of the tanning associations it seems wise to investigate if alternative channels to reach the providers of tanning services who are not members can be used. Such channels could for example include industry associations for the wellness, beauty and hotel branches, which can be approached both by ESA and the Market Surveillance Authorities.

6.4. Risk information and personal tanning advice

Customers of indoor tanning services must be informed about the risks of indoor tanning and must given personal advice and proper tanning schedules, taking into account their individual skin type and medical history. Youngsters till the age of 18 and other vulnerable groups should be prohibited to use the service. Though there are great differences between the participating countries this investigation shows that the way customers are informed about the risks of sunbed use and the way they are given personal advice still leaves much to be desired. The same holds true for the enforcement of the 18+ years of age limit, which is often absent or insufficient.

6.5.Staffed/not staffed

In Cyprus, Denmark and Norway coin operated sunbeds are widespread. To a lesser extent this is also the case in the Czech Republic, Germany and the Netherlands. Since the sites where coin operated sunbeds are offered are frequently not staffed, safety information and personal advised is usually not given and checks on the users age are absent. In Norway it is recognized by the national authorities that the high percentage of coin operated machines without supervision may lead to inadequate guidance of the customers and legislation is being passed where mandatory attendance with relevant training to guide the customers will be required.

6.6.Compliance of sunbeds

The risks of indoor tanning are also determined by the properties of the sunbeds used. To limit this risk the amount of UV radiation emitted by sunbeds in indoor tanning services is restricted to $0,3W/m^2$, measured as EWI and sunbeds must carry a warning about the risks of UV radiation.

During the inspection performed in this joint action 1798 sunbeds were checked on compliance with labelling requirements and, where possible, compliance with the 0,3 W/m^2 limit.

6.6.1. Labelling

The warning "Ultraviolet radiation can cause injury" is found to be absent in 16% of all the sunbeds checked at first inspection. The percentage varies between the participants and was much higher in some of the participants' Member States. Remarkable is also that a substantial fraction of the sunbeds (22%) does not carry the obligatory CE marking. The technical information required, technical file or 'passport' for the sunbed, was absent or insufficient for 50% of the sunbeds.

6.6.2. Radiation limit

For a total number of 1072 sunbeds one or more measurement values were reported. In 688 (64%) sunbeds measured the EWI value exceeded 0,3 W/m², sometimes considerably. In 138 sunbeds (13%) the EWI exceeded 0,9 W/m², 34 (3,5%) of which read even higher than 1,2 W/m².

The overall conclusions from the results of the inspections are that:

- 1. For many businesses indoor tanning is offered as a side activity;
- 2. Many providers of indoor tanning services are not member of branch organization for the tanning branch;
- 3. Consumer guidance in tanning studios is frequently not given;
- 4. In some member states indoor tanning is offered with coin operates sunbeds in facilities without staff. Where no supervision is present the probability that the guidance given is inadequate increases;
- 5. The labelling of the sunbeds fails to comply in at least 20% of the cases and technical documentation is frequently absent;
- 6. 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 less than 40%. Overall far too many sunbeds offered in indoor tanning services still exceed the limit for UV radiation.

7. Recommendations

The data presented in this report 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.

Considering the fact that, according to this investigation, a considerable fraction of the indoor tanning services are offered by providers who offer indoor tanning as a side service and who are not a member of a tanning association, it seems wise to investigate if additional channels can be used to reach the providers of tanning services who are not members. Such channels could for example include industry associations for the wellness, beauty and hotel branches, which can be approached both by ESA and the Market Surveillance Authorities.

Following an initiative from ESA a standard for *services in indoor tanning facilities* is under development within CEN. Potentially such a standard can contribute significantly to establishing clear and harmonized requirements in tanning services, which benefits both the industry and the market surveillance authorities. To maximize the effect of this standard it should be assured that not only the tanning branch, but also providers who offer tanning as a side service are also made familiar with this standard.

Annex I: Status reports of participants

Hungary

Hungarian Trade Licensing Office

December 6, 2010

Status report on the inspection of solariums in 2010

The Market Surveillance Department of the Hungarian Trade Licensing Office has inspected 123 sunbeds of which 81were double and 42 were vertical tanning equipment. We inspected 58 locations (32 tanning studios, 12 beauty shops, 12 fitness centres, 1 hotel, 1 importer and manufacturer).

The following Table 1. shows the distribution of the measured UV-radiation from January till the end of November in 2010 for the vertical and double solariums.

Table 1.

EWI 2	Vertical	Double, %			
W/m ⁻	%	Тор	Bottom	Face	
0 - 0,3	11,6	16,0	13,6	65,8	
0,3-0,6	7,0	21,0	17,3	31,6	
0,6-0,9	34,9	43,2	43,6	1,3	
0,9-1,2	34,9	13,6	27,2	1,3	
1,2-1,4	11,6	6,2	7,4	0	

Table. 2

EWI W/m ²	We a 2009	ighted to verage* 2010	otal % Δ	
0 - 0,3	0	14,2	+14,2	
0,3-0,6	5	16,7	+11,7	
0,6-0,9	45	37,7	-7,3	
0,9-1,2	35	23,5	-11,5	
1,2-1,4	15	7,8	- 7,2	
* Without face tanner				

Comparing the results of this year to the data measured in the last year, an increase can be seen in the corresponding lower ranges as it is illustrated in Table 2. Last year there was no sunbed in the correct 0-0,3 W/m^2 EWI range, while this year the ratio of the appropriate appliances went up to 12-16 % (Table 1.).

At the beginning of the year we translated and published the press releases issued by the European Commission and PROSAFE, furthermore a summary of the Report on the joint action in 2009. The Ministry of National Development and Economy (NFGM) issued a communication on the joint action and on the results of the Hungarian surveillance. These publications induced a large press interest about the joint solarium action. Many of TV channels, radio stations broadcasted reports on the joint action and its results. Also several journals and magazines published interviews about the safety situation of solariums.

Our authority organized a Solarium Forum for the stakeholders of the solarium industry in February. The Forum was held under the patronage of the Ministry of National Development and Economy. More than 100 participants took part at the conference and we gave them information about the experiments of the joint action 1 and the aims of joint action 2, the legislative framework, the legal background and the frequently asked questions were discussed. The experts of the institutions concerned – Hungarian National Public Health and Medical Officer Service (ANTSZ), Hungarian Standards Institution (MSZT), an associate professor from Department of Dermatology, Semmelweis University School of Medicine, – gave lectures on the health, safety, medical and legal aspects of solariums, in Hungary.

The secretary and the chairman of the two Hungarian solarium associations (MSZE member of ESA, MSZUE Hungarian Association of Tanning Operators) exposed their opinion and they

projected how to solve the bad situation. At last a direct consultation and disputation started with the stakeholders.

A press conference was held right after the solarium forum.

We issued two Newsletters in the homepage of our Authority this year to inform the stakeholders and the clients on the aims and the legal background of the joint action, on the presentations of the Solarium forum and on the safety instructions for the clients.

Between 9 and 13 of August a joint measurement was made with the Dutch colleague to check our spectro radiometer. The comparison of the results measured by own spectro radiometer to the other instrument showed a good accuracy. This mutual work was very useful for us, our colleagues learnt a lot from Mr. Hans Feijen.

Our Authority was invited to some meetings and conferences held by the Hungarian solarium associations. At these events the leader of the Market Surveillance Department presented the results of the UV-measurement, the legal status of solariums, the requirements and very useful consultations were held with the stakeholders every time.

Together with PROSAFE, ESA and the MSZE Hungarian Solarium Association, the leader of the Market Surveillance Department also gave a presentation at the National Stakeholder Meeting in March and answered many questions.

MSZUE solarium association organized training for the solarium owners and operators. About 200 participants were trained this time in order to well acquire the regulation. We were asked to inform the stakeholders on the requirement of the market surveillance authority.

Most tanning studios have consumer guidance in the tanning studios and the clients are provided with information verbally by the staff and by the written posters. When the information is false or incomplete we order to revise it. Our Newsletter helps the stakeholders and the clients to learn the correct tanning. The solarium associations started spreading their information posters, too.

From this year our Authority practices the Regulation 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance.

In the coming year we will continue the inspections using the hand UV-meter and our spectro radiometer, too. The estimated number of the solarium equipment is 6-8000 in Hungary, all of these are staff guided and operated. Besides measuring of UV-radiation we will emphasise checking the information provided for the clients.

We consider as a success that this year every checked stakeholder has known the requirements and the very bad last year result is getting better.

The address of the newsletters: http://www.mkeh.gov.hu/kereskedelmi/EU/piacfelugyelet/hirlevel

Interview in Duna TV, January 6, 2010. http://www.dunatv.hu/musor/videotar?vid=601506 Interview in RTL Klub TV, February 26, 2010. http://www.rtlklub.hu/most/8257_reggeli_10-02-26 RTL Klub TV News, telephone interview, March 31, 2010. Interview in radio MR1, February 25, 2010.

Hungarian Trade Licensing Office (HTLO)

October 5, 2011

Status report

on the activity within the joint action on sunbeds 2

UV-measurements:

The estimated number of the solarium equipment is 6-8000 in Hungary, most of them are staff guided and operated. Besides measuring of UV-radiation we emphasised checking the information provided for the clients.

The Market Surveillance Department of the HTLO has inspected 247 sunbeds of which 160 were double and 87 were vertical tanning equipment within the framework of the second joint action on sunbeds. We inspected 132 locations (68 tanning studios, 34 beauty shops, 30 fitness centres, hotel, importer and manufacturer). The coin operated appliances are not wide-spread in Hungary, during the whole project only in one case had to be taken action regarding this types of products.

The following diagram below shows the distribution of the UV-radiation measured in the course of the project in 2010 and 2011 in comparison with the results of the first joint action.



Comparing the results of this year to the data measured in the last year, a significant increase can be seen in the corresponding lower ranges as it is illustrated in the diagram above. In the first year of our inspections, during the first action in 2009 there were no sunbeds found in the correct 0-0,3 W/m^2 EWI range, in practice, while the year 2010 the ratio of the appropriate appliances went up to 16 %, and in this year increased up to 45 %. In parallel the number of appliances having EWI above 0,6 W/m^2 decreased accordingly.

Measures taken:

As it can be seen, the significant no. of products inspected during the Sunbeds II project was still not compliant in Hungary. When non-compliant product was found applying the principles of proportionality at first step we ordered to bring the product into compliance whit the essential health and safety requirements of implementing legislation of the Low Voltage Directive giving time to the economic operators to do so (about 200 cases). The time given to take action was established taking into account the nature of the failure and

the measured volume of the UV radiation. When the economic operator did not fulfill its obligation within the given time frame decision on restricting measures were taken regarding the marketing of the product (22%). Only in cases, when the possibility to bring the product compliant was not possible, were issued decision on immediate action. **Information activity:**

At the beginning of the year 2010 we translated and published the press releases issued by the European Commission and PROSAFE, furthermore a summary of the Report on the first joint action finished in 2009. The Ministry of National Development and Economy (NFGM) issued a communication on the joint action and on the results of the Hungarian surveillance. These publications induced a large press interest about the joint solarium action. Many of TV channels, radio stations broadcasted reports on the joint action and its results. Also several journals and magazines published interviews about the safety situation of solariums.

Our authority organized a Solarium Forum for the stakeholders of the solarium sector in February 2010. The Forum was held under the patronage of the Ministry of National Development and Economy. More than 100 participants took part at the conference and we gave them information about the experiments of the joint action 1 and the aims of joint action 2, furthermore, the legislative framework, the legal background and the frequently asked questions were discussed, too. The experts of Hungarian institutions concerned like - the Hungarian National Public Health and Medical Officer Service (ANTSZ), the Hungarian Standards Institution (MSZT), an associate professor from Department of Dermatology, Semmelweis University of Medicine, – gave lectures on the health and safety, medical and legal aspects of solariums, in Hungary.

The secretary and the chairman of the two Hungarian solarium associations (Hungarian Solarium Association, MSZE member of ESA, Hungarian Association of Tanning Operators, MSZUE) exposed their opinion and they projected how they are thinking to solve the bad situation. At last a direct consultation and disputation started with the stakeholders. A press conference was held right after the solarium forum.

Two Newsletters in 2010 and one in 2011 were issued and published in the homepage of HTLO to inform the stakeholders and the clients on the aims and the legal background of the joint actions, on the presentations of the Solarium Forum and on the safety instructions for the clients.

Joint measurement:

Between 9 and 13 of August 2010 a joint measurement was made with the Dutch colleague to check our spectro radiometer. The comparison of the results measured by our own spectro radiometer to the other instrument showed a good accuracy. This mutual work was very useful for us; our colleagues learnt a lot from Mr. Hans Feijen regarding the measurement practice.

Cooperation with the Hungarian solarium associations:

Together with PROSAFE, ESA and the MSZE Hungarian Solarium Association, the leader of the Market Surveillance Department also gave a presentation at the National Stakeholder Meeting in March 2010 and answered many questions.

Our Authority was invited to some training, meetings and conferences held by the Hungarian solarium associations. At these events the leader of the Market Surveillance Department presented the results of the UV-measurement, the legal status of solariums, the requirements and very useful consultations were held with the stakeholders every time.

MSZUE solarium association organized training for the solarium owners and operators in 9th October 2010. Stakeholders were informed about the most important issues related the artificial tanning. About 200 participants were trained this time in order to well acquire the regulation. The association held a press conference in 19 of May 2011. We were asked

to inform the stakeholders and the media on the surveillance issues of the sunbed campaign.

About 100 stakeholders and operators participated on the event organised by MSZE about the healthy solarium tanning in 28th of September 2011. A representative of our authority informed the audiences on the legal basis of the market surveillance of solariums and on the experiences of the joint action 2 in the last two years. The most important aspects were discussed with the stakeholders. Furthermore the audiences were informed on the effect of cosmetics while sun tanning and on the nature of the different type UV-lamps, the so called "EU 0.3 UV-tubes" that meet the safety requirements. At last some case studies about how to serve the guests, how to define the different skin types and how to inform the guests on the proper tanning were presented.

We thing that the relationship of our authority with the above associations resulted very good. We believe they are convinced that we are going to the right direction and that the task is common for us.

Consumer information:

Concerning the consumer information our results shows that most tanning studios have consumer guidance in the tanning studios and the clients are provided with information verbally by the staff and by the written posters. When the information is false or incomplete we order to revise it. Our Newsletters help the stakeholders and the clients to learn the correct tanning. The solarium associations started spreading their information posters on the correct tanning, too.

Summary:

We consider as a success that at this time every checked stakeholder has known the requirements and the very bad previous results are getting better. Although the results achieved are considerable we might not be contented because there are lots of non complying sunbeds available for users amongst them for young people, in Hungary

Next steps:

HTLO will inform the stakeholders and throughout the media the users of solariums on the out-comings of the joint action on sunbeds 2 by press conference or forum.

In the coming years we will continue the inspections using the handheld UV-meters and our spectro radiometer, too.

We are considering a "zero" tolerance action (details of it to be determined later on) for further inspections and/or initiating a national legislation aiming the studio owners and operators at the goal of achieving that almost all sunbeds comply with the legislation and users, first of all young people, are provided with appropriate information about tanning.

Publications:

The address of the newsletters: http://www.mkeh.gov.hu/kereskedelmi/EU/piacfelugyelet/hirlevel

Interview in Duna TV, January 6, 2010 and June 3, 2011. http://www.dunatv.hu/musor/videotar?vid=601506 Interview in RTL Klub TV, February 26, 2010. http://www.rtlklub.hu/most/8257_reggeli_10-02-26 RTL Klub TV News, telephone interview, March 31, 2010.

Annex II

Legal situation in the participating member states

Belgium:

Belgium has specific legislation on the use of tanning salons and similar services: the Royal Decree of 20th June 2002 regharding the operation of tanning saloons (*Koninklijk besluit van 20 juni 2002 houdende voorwaarden betreffende de exploitatie van zonnecentra; Arrêté royal du 20 juin 2002 relatif à l'exploitation des centres de bronzage*). 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). (See also:

http://economie.fgov.be/en/entreprises/Safety_of_products_and_services/Safety_of_tanning_salons/)

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 of Enforcement and Mediation

Cyprus:

In Cyprus new sunbeds are inspected under the LVD. Existing sunbeds are inspected under the GPSD. The national legislation applied is the legislation transposing LVD and GPSD into national law. Applicable is also EN 60335-2-27:2009. In all cases, including sunbeds already in service, the limit of irradiance is 0,3W/m2 and responsible operation of the tanning service is checked.

Enforcement of the legislation on sunbed is the responsibility of the **Competition and Consumer Protection Service**, which is part of the Ministry of Commerce, Industry and **Tourism**.

http://www.mcit.gov.cy/mcit/mcit.nsf/dmlprotection_en/dmlprotection_en?OpenDocume nt

Czech Republic:

In the Czech Republic the 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 Coll., on electrical equipment, implements the LVD. Furthermore, ČSN EN 60335-2-27:2009 provides the framework for sunbeds with respect to the requirements for responsible use and radiation levels. Sunbeds in service for consumers above 0,3W/m2 are considered as dangerous.

The Czech Republic has no other national specific legislation for sunbeds.

Market surveillance of indoor tanning services is based on this legislation and is under responsibility of the Czech Trade Inspection Authority (website in English: <<u>http://www.coi.cz/en/</u>>).

If more than 0,3 W/m2 is measured usually one month time-limit is allowed for a provider to bring the sunbed into conformity with the limit. If the sunbed is above 0,5 W/m2 a penalty is imposed as well. After the elapse of this period for the fail correction the next penalty could be given if sunbed is still above the limit.

Denmark

Sunbeds as an appliance is covered by LVD and the Danish Heavy Current Law, and for commercial use MD. It is still under negotiation which Danish authority should be responsible for those sunbeds intended for commercial use.

Sunbeds provided as a service in tanning salons etc. is covered by the GPSD and the Danish Product Safety Law.

Sunbeds must be used in accordance with the intentions in EN 60335-2-27:2003 + A1:2008 + A2:2008, in respect with the definitions in IEC 60335-2-27 § 6.101. This means that only

UV-type 3 may be used in unmanned tanning salons etc., and none of the solariums may exceed $0.3W/m^2$ in total effective irradiance irrespective of their UV-types. Approximately 95% tanning salons in Denmark are unmanned.

An interdepartmental working group has been organized to evaluate if Denmark needs a specific legislation covering tanning salons and other places where artificial sun tanning is provided. The considerations are ongoing.

www.sik.dk

Germany:

In Germany a law on the protection from non-ionising radiation (Gesetz zum Schutz vor nichtionisierender Strahlung bei der Anwendung am Menschen vom 29. Juli 2009 (BGBl. I S. 2433)) came into force on the 4th of August 2009 (see attachment). Paragraph 4 of this law contained a ban on commercial indoor tanning services to persons under 18 years.

During the period in which the joint action took place specific legislation regarding the safety of sunbeds and the safety of indoor tanning services came into force in Germany

(Verordnung zum Schutz vor schädlichen Wirkungen künstlicher ultravioletter Strahlung (UV-Schutz-Verordnung - UVSV).

This 'Verordnung' defines the legal requirements that tanning services have to fulfil, including:

- A limit on the emission of UV-radiation of $0,3W/m^2$
- The obligation for the service provider to provide for UV goggles
- Several other technical requirements to the UV emitter and the setting in which it may be used
- Obligation for the service provider to make sure the requirements are fulfilled and to demonstrate this to the authorities by means of prescribed documentation
- Requirements with respect to the presence of personnel, the tasks they have to fulfil and the competences required. (including the requirement to inform the customers, determine their skin type and to make up a tanning scheme appropriate for their skin type.
- Requirements for the training of personnel.
- Requirements to make available suitable information for the responsible use of the equipment and safe tanning in general, as well as where this information has to be shown

The UV Schutz Verordnung was published 25.7.2011 and gets into Force 1.1.2012 except § 4 (1) (concerning the qualification of Personnel), which gets in Force 1.11.2012 and § 10 Connections Passage says: § 3 (1) the Radiation Limit 0,3 W/m**2 and § 3 (2) 2-5 (technical measures) must be fulfilled 1.8.2012

The responsible Authorities to supervise the UVSV will be nominated by the Ministries of the Bundesländer (Countries) until 1.1.2012.

When the studio owners change the original emitters (lamps) into (not equivalent) emitters with higher radiation the studio owners change the safety properties of the sunbed and they are to be seen as manufacturers. They are then subject to market surveillance by the market Surveillance Authorities responsible for the enforcement of the legislation transposing the LVD (low voltage directive)

France:

France has specific legislation on sun beds. It is the decree n° 97-617 dated 30 May 1997 related to the sale and marketing of some sun devices using UV radiation.

This decree describes 4 categories of devices.

Two categories (UV 2 and 4) can only be used for a therapeutic purpose and must answer to a medical prescription. They cannot be sold or put at the disposal of the public.

Appliances classified into the UV 1 category can only be used by professionals. They can't be sold to the public.

UV 3 devices can be put on the market for adults only.

It is forbidden to sell UV 3 to minors less than 18, and to authorise the use of UV 1 devices for those minors.

It is compulsory to have qualified professionals assuming the supervision of the use of sun beds. These professionals must have a special skill to undertake this supervision. A specific decree of 10 September 1997 describes the training and makes compulsory an update of their knowledge every 5 years.

In order to use UV 1 and 3 (dedicated to the public), the operators must provide to the users goggles to protect their eyes.

According to the regulation, every user must be delivered a leaflet giving information on the use of UV 1 and 3. It is compulsory to deliver information with special warnings on the risks related to the use of sun beds.

Every operator must register and make an official declaration to the administrative public authority. This notification will mention the technical description of the device, together with the training of the professionals.

It is compulsory for the appliances to be checked every two years by a technical organisation, accredited by the Ministry of Health. A specific decree dated 9 December 1997 describes the conditions to be fulfilled to get the accreditation (application form, qualified staff, technical inspection..).

The market surveillance authority responsible for the market surveillance of the sun beds in France is the DGCCRF (General Directorate of Competition Policy, Consumer Affairs and Fraud Control).

http://www.economie.gouv.fr/dgccrf.

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. Market surveillance in the area of indoor tanning services is performed by the *Magyar Kereskedelmi Engedélyezési Hivatal*, the Hungarian Trade Licensing Office:

http://www.mkeh.gov.hu/kereskedelmi/piacfelugyelet

The principal requirement is that essential safety requirements in the Directives have to be fulfilled. To evaluate the conformity use is made of European Standard EN 60335-2-27: 2009, but already before this (revised) standard was applicable the 0.3 W/m^2 radiation limit was enforced, based on the opinion of the SCCP that higher radiation values violate the essential requirements.

Latvia:

Since the 7th of September, 2010 in Latvia a new Regulation was issued by the Cabinet, No. 834 "Terms of the acquisition of a cosmetic tanning service, hygiene and safety requirements and the requirements for monitoring". Since that date the new act on sunbeds is in force, which regulates safety requirements related to sunbeds and also designates the competent authority responsible for market surveillance in this field. In accordance with the above mentioned regulation Health Inspectorate has legal power to do market surveillance on sunbeds.

The Regulation prescribes:

- Service restrictions and consumer information on UV radiation health risks:
 - Services are prohibited to consumers under the age of 18 years, except when the person presents a certificate from a physician or dermatologist
 - To verify the consumer's age solarium staff requests that the consumer show an identity card or driving license.
 - The service provider is obliged to inform the consumer of the health risks associated with UV radiation prior to receiving the service, and he has to be made aware of the service conditions.
 - Etc.
- Requirements for tanning facilities, machinery and equipment
 - The service provider must establish a cleaning and disinfection plan, ensuring that the UV equipment is cleaned and disinfected after each use.
 - $\circ~$ UV equipment does not exceed a maximum effective UV radiation levels of 0.3 $W/m^2.$
 - UV equipment complies with the maximum effective UV radiation levels allowed and will have available the UV equipment technical documentation. The manufacturer's declaration of conformity and or the results of measurements will be available.
 - At least once months are recorded (electronic or paper form) for the UV lamp any change in equipment, the rate of utilization, as well as any technical checks. These data are available on request to consumers and the Health Inspectorate.
 - \circ The service provider shall provide to each customer:
 - UV protective goggles;
 - Swabs or other means of makeup remover.
 - UV protective glasses are cleaned and disinfected with appropriate cleaning and disinfecting after each use.

• Requirements for solarium staff:

 The service provider is responsible for a service that is safe and harmless to human health. Solarium staff have adequate theoretical and practical knowledge of skin structure and physiology, physical characteristics of the UV radiation, UV radiation of the physiological and therapeutic effects in humans, indications, contraindications, use of facilities, equipment, safety and first aid to UV radiation induced health disorders.

These Regulations contain legal norms arising from:
1) The European Parliament and Council Directive 98/34/EC of 22 June 1998 laying down a procedure for technical standards and regulations;
2) The European Parliament and Council Directive 98/48/EC of 20 July 1998, amending Directive 98/34/EC laying down a procedure for technical standards and regulations.

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.

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. The publication of EN 60335-2-27:2010 (consolidated version of IEC 60335-2-27 :2002, MOD; IEC 60335-2-27:2002/A1:2004, MOD; IEC 60335-2-27:2002/A2:2007, MOD) provided a new version of the standard for sun beds. It is presumed that that standard is in line with the report of the SCCP and the commitment to that report by the Commission and the mandate for a change of the relevant previous standard. Therefore that new standard is also likely to fulfil the obligations of the LVD. Levels higher than 0,3 W/m2 for the sun beds are not acceptable with regard to the Directives and the national legislation. There is no additional national regulation for sunbeds in the Netherlands because such a provision would be superfluous.

Norway

Since 2000 the Act on Radiation Protection and Use of Radiation (No. 36 of 12 May 2000) has been in force in Norway. The act applies to ionizing and non-ionizing radiation.

The Act on Radiation Protection and Use of Radiation lays out general provisions for the use of radiation and requires justification of its use. General provisions include the possibilities to issue regulations that require notification and approval prior to the marketing and or use, training requirements for personnel handling the radiation, protective measures as well environmental requirements. Pursuant to the Act, Regulations on Radiation Protection and Use of Radiation (Radiation Protection Regulations) were laid

down by Royal decree in 2010 (No. 1380 of 29 October 2010). This replaced the 2003 Radiation Protection Regulation (No. 1362 of 21 November 2003).

Specifically relevant for indoor tanning, the present Regulations (No. 1380, valid from 1 January 2011) contain administrative requirements (Chapter I and II), a section on technical requirements for tanning appliances (Section 36) and administrative provisions (Chapter VII):

- Undertakings which offer tanning appliances for cosmetic purposes for sale, rent or use shall notify the Norwegian Radiation Protection Authority.
- Only tanning appliances belonging to UV type 3 are permitted for sale, lease or use for cosmetic purposes, and they shall be in conformity with the harmonised standard EN 60335-2-27.
- Anyone who imports/sells a tanning appliance is responsible for ensuring that the requirements are met, that necessary measurements have been performed and that the appliance is notified the Norwegian Radiation Protection Authority. No solarium model can be offered for use, sale or rent before included in the list of permitted models listed in "The Norwegian Radiation Protection Authority's overview of tanning appliances" (<u>http://www.nrpa.no/solarieliste/default_en.aspx</u>).
- The importer and distributor are responsible for ensuring that the appliances are equipped with instructions for use and labelling in Norwegian in conformity with EN 60335-2-27.
- The undertaking offering indoor tanning has a duty:
 - o to ensure that appliances and marking meet applicable requirements,
 - \circ to inform the customer of the recommended schedule of exposure,
 - \circ to have protection glasses available for the customer,
 - to see that specification of permitted radiation sources is physically available next to each model,
 - to see that the settings of the tanning appliance's timer are compatible with the times specified in the recommended schedule of exposure,
 - to post a notice with a warning text and safety rules in conformity with EN 60335-2-27 in an easily visible position on the premises.
- Inspection mandate regarding tanning appliances is delegated to the municipal authorities.

These Regulations followed specific regulations for indoor tanning and tanning appliances from 1983, so in Norway regulation of tanning appliances and their use has a longer history

than in most of the EU member states. Also these regulations have been subject to market surveillance⁵,¹⁷.

In December 2011 the Norwegian Ministry of Health and Care Services announced that regulations have passed requiring no solarium to be offered to persons under the age of 18 years and that every tanning studio must have trained staff to guide the customers.

The age limit is valid from 1 July 2012, while requirements for trained staff is valid from 1 January 2014.

Portugal

Portugal has specific legislation on the service of artificial tanning by means of the use of tanning equipment that emits ultraviolet (UV) rays in any form — the Decree-Law 205/2005 of 28 November 2005.

This Law has been subject to the procedure of the Directive 98/34/CE of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, amended by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 and Council Directive 2006/96/EC of 20 November 2006.

With the transpose of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, by means of Decree-Law No 69/2005 of 17 March 2005, the general safety obligation established therein whereby only safe products can be launched on the market (Article 3 of the Directive and Article 4 of the Decree-Law) applies, *mutatis mutandis*, to the provision of services.

This obligation is of a general kind, covering all services including those that are not covered by special regulations and those that are, however the regulations do not cover all risks or risk categories.

The activities of tanning centres is subject to this general safety obligation and the tanning equipment used is covered by the terms of Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, amended by Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits approach to be the terms of the laws of Member States relating to electrical equipment designed for use within certain voltage limits transposed into Portuguese Law by Decree-Law No 6/2008 of 10 January 2008.

However, in view of its specific nature and the risks to the health and safety of consumers, it is necessary to proceed with the regulation of the activities of artificial tanning centres

¹⁷ "Indoor Tanning in Norway. Regulations and inspections", Nilsen LTN, Aalerud TN, Johnsen B, Friberg EG Hannevik M. StrålevernRapport 2008:9. Østerås: Norwegian Radiation Protection Authority, 2008. http://www.nrpa.no/dav/87fc659b70.pdf

by means of an independent law with the aim of better prevention and the minimization of those risks.

The desire to have tanned skin, now considered as a standard for beauty in contemporary societies, has attracted many consumers to tanning centres, even in countries like Portugal where exposure to the sun and access to beaches is possible during most of the year.

The right to health and safety is a fundamental consumer right established in the Constitution of the Portuguese Republic and in Law No 24/96 of July 31 1996. In order to safeguard these rights, the creation of specific regulations has been imposed for the provision of tanning services.

This law therefore lays down the system for installation and operation as well as the safety requirements with which all establishments must comply, including hotels, beauty parlours or establishments of a similar nature for fitness that provide consumers with artificial tanning services by means of the use of equipment that emits ultraviolet rays. The categories of equipment used within the scope of these services are laid down, as well as the specification of the conditions for the handling and maintenance of the equipment and the compulsory provision of consumers with protective glasses. It is prohibited to provide artificial tanning services to persons under 18 and pregnant women as well as those showing signs of sunstroke, in response to the concerns expressed by the WHO. It is anticipated that the consumer will have to sign a consent form when first being subjected to radiation from the equipment. Each consumer will have a personal file on which is recorded the skin type and exposure programme recommended.

The compulsory nature of specific training is stipulated for personal that work in tanning centres. The training programme is specified. It is laid down that there must be a complaint book as well as the provision of information in the form of a notice displayed in a place that is immediately accessible to the user. It is envisaged that such information must be included in advertising relating to the provision of the artificial tanning service.

This Decree-Law defines the legal requirements to the tanning salons and its services, including:

- **Presence of the member of staff responsible** the member of staff responsible must be present at the tanning salon when it is operating;
- **Safety instructions** technical staff trained to handle tanning equipment must comply strictly with the manufacturer's instructions;
- Maintenance tanning equipment must be subject to an annual technical inspection by the notified bodies under LVD and the evidence of such inspections must be available to the users using the equipment and may be requested at any time by the competent inspection body;
- **Maintenance book** each item of equipment must have a maintenance book containing the following information: details and description of the equipment;

name of the owner and of the installer; date on which the consumables were changed; evidence of maintenance and repairs carried out; evidence of complaints and accidents. Evidence of annual inspections carried out by the nominated body; complete name of the company that installed the equipment and of manufacturer and of the bodies responsible for maintaining and repairing the equipment.

- **Protective equipment** the tanning salon must provide consumers with protective glasses suitable for the level of radiation emitted during the tanning session, as well as genital protectors for male users;
- **Conditions of hygiene** protective glasses and genital protectors, as well as sun beds and all materials with which the consumer comes into direct contact, must be disinfected and sterilized after each session.
- Notice (Advertise) the rays from UV tanning equipment may affect the skin and eyes. These effects depend on the nature and the intensity of the rays as well as the sensitivity of the skin;
- **Compulsory information** i. e. "Ultraviolet radiation may seriously affect the skin and eyes and intense and frequent exposure of the skin causes ageing of the skin and increases the risk of the emergence of skin cancer The damage caused to the skin is irreversible"; "It is forbidden to provide artificial tanning services to under eighteens and pregnant women and those showing signs of sunstroke".

The providers of artificial tanning services cannot subject consumers to ultraviolet radiation that has:

- a) Effective radiation greater than 0.30 W/m², measured in accordance with Standard EN 60335-2-27;
- b) A wavelength less than 295 nm.

According to article 17 of the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of product the market surveillance authority responsible for the LVD and GPSD is ASAE — Autoridade de Segurança Alimentar e Económica (Food and Economic Safety Authority), which is part of Ministry of Economy.

During the enforcement actions in tanning centres the economic operator needs to evidence the an annual technical inspection performed by a notified body under LVD and the evidence of such inspections must be made available to users using the equipment and may be requested at any time by the competent market surveillance authority (ASAE). The absence of an inspection is enough to close the sun beds because ASAE is organ of criminal police.

United Kingdom

In the UK the requirements for sunbeds and indoor tanning services rest on the national implementation of the Low Voltage Directive (The Electrical Equipment (Safety) Regulations 1994 No. 3260)

http://www.legislation.gov.uk/uksi/1994/3260/introduction/made and the General Product Safety Directive (The General Product Safety Regulations 2005 No. 1803) http://www.legislation.gov.uk/uksi/2005/1803/pdfs/uksi_20051803_en.pdf

Specific requirements for sunbeds are given in harmonized standard BS EN 60335-2-27: 2010 (Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation), which provides the framework for sunbeds with respect to the requirements for responsible use and radiation levels.

A duty on sunbed business owners to prevent access to persons under 18 years old became law in England and Wales in April 2011 as a result of new domestic legislation, the Sunbeds (Regulation) Act 2010

http://www.legislation.gov.uk/ukpga/2010/20/pdfs/ukpga_20100020_en.pdf This legislation only addresses age-restriction of indoor tanning services. There is similar legislation in Scotland that pre-dates the rules on age-restriction in England and Wales http://www.legislation.gov.uk/asp/2008/5/pdfs/asp_20080005_en.pdf , namely Part 8 of the Public Health etc. (Scotland) Act 2008. In Northern Ireland there is new legislation to prevent access to sunbeds by under-18s, but the Sunbeds Act (Northern Ireland) 2011 is not expected to come into force until May 2012

http://www.legislation.gov.uk/nia/2011/19/pdfs/nia_20110019_en.pdf

Corrective measures against sunbed businesses failing to act on advice to convert older sunbeds to 0.3 W/m2 can include the issue of a Suspension Notice under regulation 11 of the General Product Safety Regulations 2005, which prohibits the use of the sunbed for a period specified by the market surveillance authority (MSA), being a period necessary to organise appropriate safety evaluations, checks and controls. The suspension period would for example allow the MSA to arrange formal testing using a double monochromator. If compliance is not achieved by this means then the remaining option is action against the salon business in the UK criminal court system, resulting in a financial penalty.

In the United Kingdom there is a fragmentation of responsibilities for official control of sunbeds and UV tanning services. This is in part due to the devolved administrations that exist in Scotland, Wales and in Northern Ireland, but is also due to the way in which the relevant enforcement functions are delegated by Ministers to local council regulatory services officers.

For transactions in sunbeds controlled by the Low Voltage Directive (LVD), business-tobusiness supplies are the responsibility of the Health & Safety Executive (a national agency sponsored by the Ministry of Work & Pensions). Supplies of UV tanning equipment to consumers for their personal use at home are controlled under the LVD by local council Trading Standards services, except in Northern Ireland where enforcement is the responsibility of local council Environmental Health officers. Regulation of tanning services under the General Product Safety Directive (GPSD) is the responsibility of local Trading Standards officers, except in Northern Ireland where it falls to local Environmental Health services.

To complete the enforcement picture, responsibility for the 18+ rules lies with Environmental Health officers throughout the UK. Whereas at Ministerial level national policy responsibility for LVD and GPSD sits with the Department for Business (BIS), the agerestriction of indoor tanning services is the responsibility of government Ministers in the Department of Health (DoH).

Annex III : Measurement protocol

INSTRUCTION FOR THE INDICATIVE MEASUREMENT OF SUNBED RADIATION

Background:

Cheap and fast measurement of the radiation of sunbeds are not possible if accuracy is required. An accurate measurement requires a double monochromator, costing over 20.000 euros, and takes several hours.

The reason that a double monochromator is required, is that the spectrum has to be weighted by the erythema curve. This weighting is necessary because the contribution/impact of UVB is to be about 1000 times stronger than of UVA.

A simple manner to **indicatively** measure the same quantity is a handheld radiometer with a filter that resembles the erythema curve. This device measures the total energy of the radiation which passes through the filter. The response of such a radiometer is shown in the figure below.



Med/hr Meter Spectral Response

surface of the sensor. In practice, this kind of sensor will be much more sensitive to light perpendicular to the surface.

Instruction

Most sun beds are of the sandwich type, consisting of

- a bottom panel with tubes
- a top panel with tubes
- a face tanner integrated in the top panel, often containing high pressure lamps

The indicative instrument only measures while the button is pressed. Very often this makes it impossible to perform a measurement when the sun bed is closed. Most of the times a sun bed can also be measured when the top panel is up. Some effort can be necessary to estimate the distance at which to measure.

For the bottom panel, the distance is zero. The radiometer can be placed at the acryl plate with the sensor down.

For the top panel and the face tanner, the required distance is the distance between the bottom and top panel minus 30 cm. Measuring this distance can be done in the following manner:



• Use a flexible steel rule with the brake knob adjusted so that the rule can be moved with a little force

• Protect the tip of the rule with some tape to avoid scratching

• Estimate the distance between the panels

• Pull out the flexible steel rule a few centimetres more than this estimation

• Place the flexible steel rule vertically at the bottom panel and support it if necessary

• Carefully move the top panel down so that the steel rule is pressed in

• Move up the top panel and read the distance of the rule

Measure the radiation by holding the radiometer with the sensor at the prescribed distance and pressing the button simultaneously. Before switching on the sun bed, inform if it operates at maximum power. Modern sun beds can be regulated at lower levels, e.g. by means of skin analysis.

- Switch on the sun bed and set the timer at 15 minutes
- Close the sun bed and let it heat up for 5 minutes
- Measure the radiation of the separate parts of the sun bed at the prescribed distance
 - Search for the worst case spot, usually this is right before a tube or lamp
 - Protect your eyes and skin against the UV radiation

• Note down the maximum value and describe the spot of measurement

<u>Remarks</u>

- Keep in mind that the uncertainty of measurements on high pressure lamps can be very high.
- The standard EN 60335-2-27 prescribes to measure after half the maximum exposure time. In practice, heating up the sun bed for 5 minutes gives almost the same results.

From the standard EN 60335-2-27

The appliance is supplied at **rated voltage** and operated for approximately half the maximum exposure time allowed by the timer.

The irradiance is then measured at the shortest recommended exposure distance, the measuring instrument being positioned so that the highest radiation is recorded.....

The exposure distance of **UV emitters** that are located over a person is the distance between the emitter and the supporting surface, reduced by 0,3 m.