

Request to renew Exemption 18b

under the RoHS Directive 2011/65/EU

Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi2O5 :Pb)

Date: January 15, 2015



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1 Name and contact details

Industry association Name:

LightingEurope Attila Morotz

Function: Policy Director

Tel.: +32 2 706 86 07 E-Mail: attila.morotz@lightingeurope.org Address: Diamant Building Boulevard Auguste Reyers 80 1030 Brussels, Belgium

2 Reason for application

Lighting Europe submits this application to:

request for extension of existing exemption **no. 18(b) in Annex III**

Lighting Europe proposes to continue	Lead as activator in the fluorescent
using the existing wording which is:	powder (1 % lead by weight or
	less) of discharge lamps when
	used as sun tanning lamps
	containing phosphors such as BSP
	(BaSi2O5 :Pb)
Lighting Europe requests a duration of	Maximum validity period required.

3 Summary of the exemption request

The validity period of DIRECTIVE 2011/65/EU Article 5(2) will end automatically per 21/10/2016, unless an application for renewal has been made in accordance with Annex V.

With reference to the above, this request concerns the extension of the current Annex III exemption:

18(b) regarding Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP ($BaSi_2O_5$:Pb).

This exemption covers indoor sun tanning discharge lamps containing lead as an activator in the fluorescent powder. These lamps are produced in T12, T8 and T5

diameters and CFL (compact fluorescent lamp) configurations. The phosphors contained in these lamps are manufactured from the same components but can vary in spectral discharge across the UVA and UVB spectrum by the specified proportional phosphor mix. The lamps, and equipment they are installed in, are governed by EU regulations concerning the allowable output of ultraviolet radiation permitted within a determined exposure time. The EU regulates and enforces tanning equipment and the installed lamps which are marked on the lamps by a specific "X, Y" code system for the erythemally-weighed UV radiation in accordance with EN standard 61228 Ed.2 (2008-01). The lamps are installed in various commercial- and residential indoor tanning equipment. This can be in the form of a sun tanning bed or booth or a table top appliance for facial tanning. The abovementioned EN standard forms the basis of lamp marking, and is required. It clearly limits room for substitution by lead-free phosphors. The regulatory demands come from the LVD ADCO group, see below reference.

Ref. website: http://ec.europa.eu/enterprise/electr_equipment/lv/guides/index.htm Declaration of the LVD ADCO Group

At the 18th meeting of the LVD Administrative Co-operation working group (ADCO) in Brussels on the 14th November 2006 the following was unanimously agreed by the Member States present:

- The Scientific Committee on Consumer Products (SCCP) Opinion on: Biological effects of ultraviolet radiation relevant to health with particular reference to sun beds for cosmetic purposes represents the basis for good engineering practice in Europe in relation to the safety matters for such products.

- The recommendations shall be applied with effect six months from the publication of this Declaration.

- The maximum erythemal-weighted irradiance should not exceed 11 SED/h (0.3 W/m2). Published on 22 January 2007

Other UV lamp types are produced for dermatological and phototherapeutic use under medical supervision as in Annex IV of RoHS Directive. These lamps are not used for the production of visible light so general lighting efficacy standards are not relevant and therefore do not apply.

4 Technical description of the exemption request

4.1 Description of the lamps and their applications

4.1.1 Lamps covered by this exemption

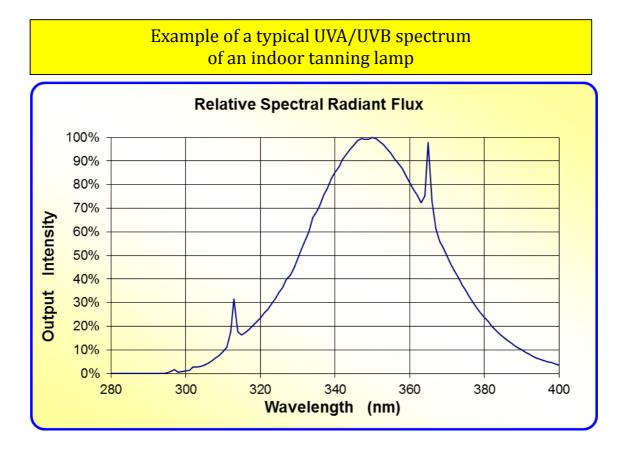
This exemption covers indoor sun tanning discharge lamps containing lead as activator in the fluorescent powder. The lamps produce UVA and UVB in predetermined dosages and ratios for the purpose of producing artificial sunlight. The lamps are installed in tanning equipment which are calibrated for the use of specific lamp types which are marked in accordance with EU regulations for tanning lamps and equipment. Brochures and data about these lamps can be seen in several websites, e.g.:

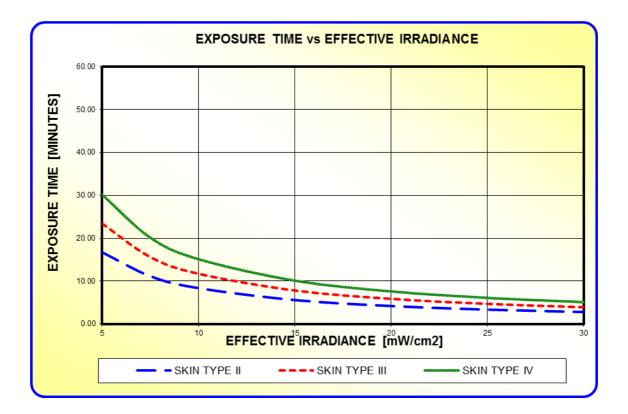
- Lighttech <u>http://www.light-sources.com/tanning/tanning-lamp-products</u>
- Cosmedico http://www.cosmedico.de/en/tubes.html
- Havells-Sylvania: <u>http://www.havells-</u> sylvania.com/media/Downloads/Sylvania%20Lamps%20Brochures/SPG/Suntan ning/SY_Bodycare_Broschuere_2011_2012_ENGL_RZ_FINAL_ANSICHT.pdf

These lamps are produced in T12, T8 and T5 diameters and single capped configurations.



• The phosphors contained in these lamps are manufactured from the same components but can vary in spectral discharge across the UVA and UVB spectrum which provide a variety of erythemal outputs and exposure limits..





The lamps and equipment are governed by EU regulations concerning the allowable output of ultraviolet radiation permitted within a determined exposure time. The EU regulates and enforces tanning equipment and the installed lamps which are marked on the lamps by a specific "X, Y" code system. For example see, IEC 606335-2-27 and EN standard 61228 Ed.2 (2008-01). The lamps are installed in various commercial and residential indoor tanning equipment which can be in the form of a tanning bed or booth or a table top appliance for facial tanning.

The typical lifetime of these lamps ranges from 600 to 1000 hours with a session or usage time that ranges approximately from 5-30 minutes.

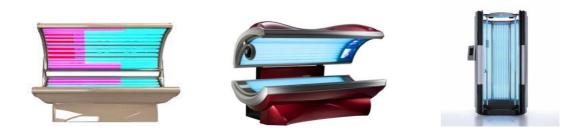
These lamps are not used for the production of visible light so general lighting efficacy standards do not apply. UV output efficacy (UVA radiation out vs electrical power in) is typically between 15% and 25%, but the real measure is with what power the desired effect is reached. This is governed by the equipment, lamp type, lamp power, UV output measured by standardized means, user skin type and other such factors.

The market demand for tanning lamps remains stable for the coming years.

4.1.2 Applications covered by this exemption

Indoor tanning lamps are light sources that produce ultraviolet light in the regions of the UVA and UVB spectrums. Their intent is to produce artificial sunlight to replicate sunlight exposure for the human body (similar to that as produced by the sun) yet applied in calculated doses per European regulations. It is estimated that over 90% of indoor tanning lamps produced and used throughout Europe are manufactured with BSP (BaSi₂O₅ :Pb) phosphors containing 1% or less lead as an activator). There is no feasible alternative for this phosphor that will yield the same or similar results and has undergone the extensive European and US regulatory testing associated with the of the tanning lamps these application usina phosphors. Almost 100% of the tanning lamps using these phosphors are produced in the EU. Below are three examples of typical indoor suntanning equipment.

Left and center photos are tanning beds and right photo is a tanning booth.



Examples of Indoor tanning equipment

4.1.3 Annex I category covered by this exemption

List of relevant Annex I categories for this exemption

1	2	3	4	5 🛛	
6	7	8	9	□ 10	□ 11

Application in other categories, which the exemption request does not refer to: N/A

Equipment of category 8 and 9: N/A

The requested exemption will be applied in

monitoring and control instruments in industry

- in-vitro diagnostics
- ☑ other medical devices or other monitoring and control instruments than those in industry

LightingEurope is of the opinion that lamps in general are category 5 products, but having a character of a component, a consumable as well as a spare-part.

There are numerous applications where lamps can also be regarded as component of a product belonging to any of the other categories 1 - 11 e.g. lamps/lighting in ovens, refrigerators [1],

clocks [2], copy machines, projectors [3] TV sets [4], background lighting of tools [6], video games [7], UV lamps in medical equipment [8], control panels for industrial installations [9], UV in automatic dispensers [10] or lamps fixed installed in furniture [11].

LightingEurope believes that lamps covered by exemption 4f might not belong to category 5 equipment only if it is specifically designed as part or component of only one specific other category and there is no intended possibility to use it in others. Examples for the latter case are specific lamps for medical equipment, which have a certain special function in such equipment only, e.g. lamps for vitreoretinal surgical systems Please note that exempted applications for categories 8 and 9 will be reviewed in 2021 at earliest, and are not covered in the current review for other categories, although these applications will continue to need these lamps after July 2016.

LightingEurope is aware of the difficulty to unambiguously classify certain lamps in the category set out by RoHS legislation. For lamp producers it is essential to have legal certainty regarding the possibility to put the products on the market irrespective of the planned application as we are not able to control the use of the lamps in products. While for general lighting it is easier comprehensible that they cannot be considered as "spare parts of a luminaire" application specific special purpose lamps indeed can be considered also as a spare part (or consumable) in certain applications such as sun-tanning cabins.

4.2 Description of the substance

4.2.1 Substance covered by this exemption

Lighting Europe is asking for exempting

 Pb
 Cd
 Hg
 Cr-VI
 PBB
 PBDE

4.2.2 Function of lead

Lead is used in the phosphor for UV radiation in tanning lamps. The lead activator is required to allow the barium silicate phosphor to fluoresce. It transforms the 254 nm radiation to the designed UV (290nm-400nm) radiation. A fluorescent lamp uses phosphors which, when activated, will produce light in different wavelengths. The primary wavelengths of "light" produced by indoor tanning lamps are in the UVA and UVB regions or 290-400nm. Lead is the primary activator for the barium silicate phosphors to fluoresce and is used in over 95% of the indoor low pressure mercury vapour fluorescent lamps used for tanning and certain medical applications which are not covered by this exemption.

4.2.3 Location of lead in lamps

The lead is evenly distributed throughout the phosphor coating of the lamps to radiate in the range of 290-400nm when excited by radiation at 254nm. The lead content of the phosphors is less than 1% of the total weight of the phosphor.

4.2.4 Amount of lead

The phosphor coating represents the homogenous material used in the fluorescent lamps with respect to this exemption. The lead content of the phosphor is less than 1% of the total phosphor weight.

There is no published data available for the quantity of tanning lamps entering the EU.

However, based on market estimations of LightingEurope the lead content of tanning lamps is limited to 250 kg of lead total per year entering into the EU.

Lead is also used in similar lamp types for medical and phototherapy applications such as PUVA light therapy for skin conditions such as psoriasis. This mentioned figures do not include estimated usage as these lamps will be subject to Annex IV exemption.

4.2.5 Environmental assessments, LCAs

Additional information is not available as no alternate phosphor types are available that will yield the same result nor has undergone the regulatory testing of the EU or US. There are no statistical data available specific to the Life Cycle Analysis of the tanning and medical lamps represented in this exemption request, however due to the relatively low market quantities for special lighting, the total environmental impact is expected to be limited. Research conducted about fluorescent lamps for general lighting applications does not specifically equate to these specialty lamps as they are not designed to produce visible light. Efficacies, expressing the amount of visible light in Lumen per Watt, are normally related to e.g. fluorescent lamps for general lighting do not apply to tanning lamps. Cradle to grave estimates for the production of the components and the finished lamps in this exemption request are similar to those of general lighting fluorescent lamps.

We refer to the fact however that the use of lead as an activator of the phosphor in these lamps allows the transmission of the specific wavelengths of light to be emitted in such a fashion to be the most effective form for its purpose, which is not achievable with other phosphor types or other technologies. Therefore efficacies of any alternate product types would not be an adequate comparison. The potential substitution or replacement to other wavelengths or ultraviolet dosages would require revalidation of all existing equipment in the EU market or could cause the elimination of such equipment causing great hardship to the small business owners of tanning salons throughout the EU. These current lamp types have been tested, studied and regulated in the EU and changes to these products would require a duplication of the clinical testing which has been compiled over years of study and regulation. It is further noted that the overall lead content of such lamps, as in general lighting, has been reduced in the past five years with the less than 0.1% lead content to allow for recycled glass in the glass envelop of the lamp.

5 Waste management

5.1 Waste streams

- Article is collected and sent without dismantling for recycling
- Article is collected and completely refurbished for reuse
- Article is collected and dismantled:

The following parts are refurbished for use as spare parts:

The following parts are subsequently recycled:

Article cannot be recycled and is therefore:

Sent for energy return

Landfilled

Sun tanning lamps are in the scope of EU Directives 2002/96/EC - WEEE and 2012/19/EU– WEEE Recast. Take back systems are installed in all EU Member States: end users and most commercial customers can bring back the lamps free of charge. Sun tanning lamps are collected separately from general household waste and separately from other WEEE waste. Also a dedicated recycling process exists for lamps.

European legislation on Waste Electrical and Electronic Equipment makes producers responsible for end of life products within this category as from August 13th, 2005. Target setting as consequence of the present legislation is 4kg per inhabitant per year for all categories.

European Lamp Companies have founded Collection & Recycling Organizations in the EU Member-States, with the objective to organize the collection and recycling of gas

discharge lamps. Goal is to comply with present and probable future EU legislation and meet or exceed national targets.

In general the following channels have been established in the respective memberstates providing countrywide coverage:

• Direct collection from large end users and professional installers:

Containers have been made available, ad hoc or permanently, and will be collected upon notification by the end user that the container is full.

• Collection through distribution:

Wholesalers and Retailers place collection means at their premises respectively in their shops. Collection is done upon notification.

• Collection through municipalities:

Where infrastructure allows collection means are placed at municipality depots.

5.2 Amount of lead in WEEE

Phosphor coating represents the homogenous material used in the fluorescent lamps with respect to this exemption. The lead content is less than 1% of the total phosphor weight.

There is no published data available for the quantity of tanning lamps entering the EU.

However, based on market estimations of LightingEurope the lead content of tanning lamps is limited to 250 kg of lead total per year entering into the EU.

In articles which	are refurbished
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 $\ensuremath{\boxtimes}$ In articles which are recycled

In articles which are sent for energy return

☐ In articles which are landfilled

6 Substitution

Can the substance of this exemption be substituted?

Yes, by

Design changes:

Other materials:

Other substance:

🖂 No

Justification: see in below chapters

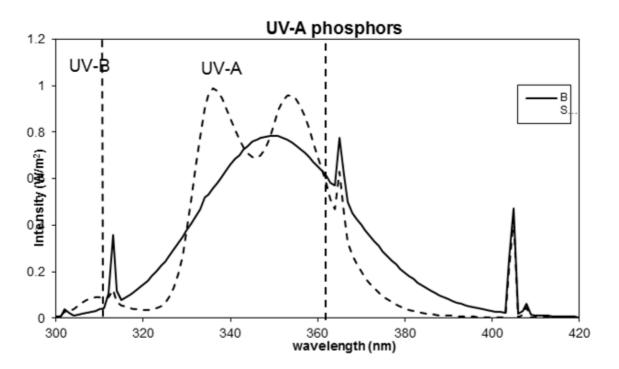
6.1 Substituting lead in the fluorescent powder of discharge lamps when used as sun tanning lamps

6.1.1 Spectrum incompatibility

The application for tanning equipment is strictly regulated in the EU. Any possible alternative to lead in BSP type of phosphor would need to fulfil following criteria:

- Lamp specification must be same w.r.t.
 - UVA and UVB output, and with that Erythema
 - Spectral power distribution
 - Compatibility (electrical/mechanical spec) must be OK
 - Reliability must be OK
 - Safety must be OK
 - Lamp operation must be the same in the different equipment in the market
 - Lamp start-up and time to peak intensity must be the same.
 - Lamp intensity must be the same.
 - Lamp maintenance/depreciation must be the same,
- Tanning result on patients
- Compliance with CE regulations (X/Y coding system for tanning lamps according to EN 60335-2-27)
- No (negative) side effects
- Economically feasible. Equipment in use today is calibrated and requires lamps to meet output limits using X/Y coding system. Different lamps would need revalidation.

Only one alternative material comes close: Ce doped YPO phosphor. Please see below spectrum of Ce doped YPO phosphor in comparison to BSP. Phosphor coating represents the homogenous material used in the fluorescent lamps with respect to this exemption. The lead content is less than 1% of the total phosphor weight.



Graph: Emission spectrum of a Cerium-doped phosphor – UV lamp

Based on above measurement results, it can be concluded that:

- 1. The spectral power distribution shows differences in the UVA and UVB range.
- 2. The ratio for UVA and UVB output is different which is an important factor for tanning applications and is governed by EU regulations.
- 3. Therefore the Cerium based material has a lower expected treatment effectiveness, w.r.t. Erythema and NMSC (non-melanoma skin cancer).

Tanning lamp output is measured on a weighted distribution of UVA and UVB output measured by the output by nanometer. The lamps are coded using the X/Y system by lamp type which is then applied for use in each specific piece of equipment. Tests have been done using these phosphors for tanning lamps showing that the spread in UVA and UVB output is too high to be viable as a practically feasible alternative. It would not be able to comply with CE regulations for tanning lamps (due to spectral incompatibility).

Therefore, this Ce-based material is not allowed for this application.

6.1.2 UV output variations of Cerium phosphors in UV lamps

A second problem for the Ce doped phosphors is the variations of the UV output over the lamp length due to coating thickness. When fluorescent lamps are coated with a phosphor the thickness of the coating varies over the length of the lamp. For current UV-fluorescent coatings used, like BSP, the thickness variations do not lead to a severe inhomogeneous output. However, for Cerium doped phosphor this thickness difference leads to unacceptable UV output variations which will affect the skin treatment effectiveness (see table below).

	thin coated side		thick coated side	
	UVB		UVB	
1 P	594		325	
2 P	567		313	
3 P	614		322	
4 P	614		322	
5 P	604		350	
6 P	600		325	
7 P	595		301	
8 P	615		265	
9 P	599		283	
10 P	622		409	
AVG	602,4		321,5	
STDV	14,87	2%	36,96	11%
MAX	622,00		409,00	
MIN	567,00		265,00	
Range	55,00	9%	144,00	45%

Table: Thickness variations of Ce-doped coatings and the impact on UV output

6.2 Substituting fluorescent technology by lead free technology

In principle other technologies can be evaluated for replacing fluorescent technology for tanning applications. One could think of e.g. LED, OLED, HID, and incandescent or halogen technology.

However, for any new technology one needs to address the replacement market (replacing lamps in existing fixtures) and the market for new equipment using the new technology.

The criteria to determine whether a new technology can replace existing fluorescent technology using BSP (and Hg) in existing equipment are:

- Lamp specification must be same w.r.t.
 - UVA and UVB output
 - Spectral power distribution
- Safety must be OK
- Compatibility must be OK (Electrical and mechanical specification)
- o Reliability must be OK
- Tanning result
- Compliance with CE regulations (X/Y coding system for tanning lamps according to EN 60335-2-27)
- No (negative) side effects
- Economically feasible (cost of replacement technology)

For new equipment the similar criteria hold:

- o UVA and UVB output must be similar
- o Spectral power distribution must be similar
- Safety must be certain
- o Compatibility must be OK (Electrical and mechanical specification)
- o Reliability must be equivalent
- o Tanning result on patients
- Compliance with CE regulations
- No (negative) side effects
- Economically feasible (cost of replacement technology)

6.2.1 Feasibility of the alternatives

In this paragraph we only discuss LED as an alternative radiation technology as Incandescent, halogen and OLED simply do not emit radiation in the UVA/UVB range.

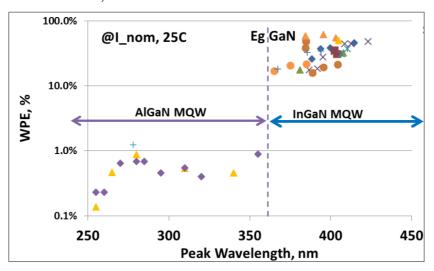
LEDs in principle could be chosen as radiation technology for special purposes, provided following criteria are fulfilled.

- Wall Plug Efficiency is comparable to fluorescent lamps
- Effectiveness is comparable to fluorescent lamps (i.e. same tanning effect)
- Regulation/approbation is passed

In the following paragraphs each of these 3 criteria is discussed.

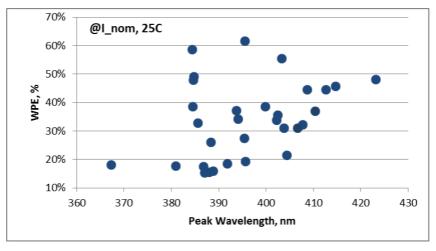
6.2.1.1 Wall Plug Efficiency

- a. In contrast to general lighting lamps, (compact) fluorescent lamps for special purposes emit radiation in UV or blue wavelength bands. LEDs for general lighting purposes are made of InGaN, a material that emits blue light which with the help of phosphors is converted into the desired visible wavelengths. Theory says you can only convert from shorter wavelengths to longer. It is therefore impossible to create UV light with LED material as used for visible light LEDs.
- b. There are other materials available from which LEDs can be made that generate UV light (like AIGaN), however the efficiency (radiated power out / electrical power in) of LEDs with those materials is still very low. In the UVC (100-280nm) and UVB (280-315nm), the WPE (wall plug efficiency of LEDs are below 1%), where the wall plug efficiency of fluorescent lamps are close to 20% or even higher. See below pictures in which public data from several manufacturers are put together in one graph.



Graph: LEDs (UVC-Blue): WPE vs. wavelength (data of several manufacturers)

Graph: UVA-LEDs: WPE vs wavelength (data of several manufacturers)



Conclusion:

There is no comparable WPE for LEDs below 380 nm. Therefore, LED lamps are not suitable soon as a practical alternative for tanning applications.

6.2.1.2 Effectiveness data

For tanning no tests results are available yet w.r.t. effectiveness to reach the desired effect in a comparison study between equipment using fluorescent lamps and equipment using LEDs. For most of these applications that is not done yet as no LEDs were available. So effectiveness data are not available.

6.2.1.3 Regulation/approbation

CE conformity and other European directives for special purpose applications (like for instance approbation of medical devices for phototherapy and CE regulations on tanning lamps (CE 60335-2-27)) is based on fluorescent discharge lamps (with respect to safety and system responsibility). No CE conformity is available for other lamp technologies.

6.2.2 Availability of substitutes

UVA LEDs are available from several suppliers. However, as is clear from above efficiency is very low. No public roadmaps exist that predict when UVA LEDs with acceptable output and efficiency are available. Only after that design and development of LED based equipment can start and after that customer/patient tests could start.

6.2.3 Impacts of substitution

Apart from feasibility and availability also the potential impacts of substitution must be considered.

Amongst the impacts are:

- Environmental impact
- Health & Safety impact
- Socio-economic impacts
- Impact on innovation

6.2.3.1 Environmental impact of substitutes

Though LED technology is developing at a rapid pace for general lighting, however there is today no viable LED alternative available for phototherapy applications. Therefore, this paragraph is not applicable.

6.2.3.2 Health and safety impact of substitutes

The fluorescent tanning lamps in use today have undergone extensive testing and calibration in the equipment. Effect of Ce doped phosphor may have considerable impact on health and safety of customers as the manufacturing tolerance in output and spectrum cannot be controlled to the extent required by EU regulations. For LED as alternative technology effects on health and safety will have to be investigated.

6.2.3.3 Socio-economic impact of substitution

Economic effects related to substitution:

- \square Increase in direct production costs
- \boxtimes Increase in fixed costs
- \boxtimes Increase in overhead
- \boxtimes Possible social impacts within the EU
- \boxtimes Possible social impacts external to the EU
- Other:

It is expected that even if UVA LEDs become available with feasible specifications tanning equipment may become much more expensive. It will become therefore an economically unattractive solution and that can have significant impact on the application.

The possibility for lead free technology for these lamps is not feasible for replacements lamps in existing equipment due to the scientific and clinical evaluations that would need to be done on every type of fixture or appliance that is in the field. This economic burden this would impose on the small business owners such as tanning salons and dermatologists would cause the closing of many businesses. It can be imagined that new equipment could be changed to non-lead phosphors. However over 90%, and it is estimated that it may be as much as 99%, of the tanning phosphors are lead activated. There are no alternative non-lead activated phosphors available today that provide the same or equivalent spectral radiation.

Social impacts

As there are no reliable substitutes if the renewal of the exemption is not allowed it would shut down the indoor tanning industry in Europe. It is estimated that almost 100% of these lamps used in Europe are manufactured in Europe by fluorescent lamp companies. It is estimated that almost 100% of the indoor tanning equipment sold in Europe is manufactured in Europe. It is estimated that almost 100% of the tanning lamps sold as aftermarket lamps are sold by manufacturers or distributors located in Europe. It is estimated that over 90% of the tanning lamps used in the US are manufactured in Europe. It is estimated that over 75% of the tanning equipment sold in the United States is made in Europe.

Other impact

Economic impact due to the loss of the entire tanning application in Europe.

6.2.3.4 Impact of substitution on innovation

If UVA LEDs will become available new equipment will have to be developed.

6.2.4 Future trends of substitution

Given the market size in combination with strict regulations efforts to substitute BSP containing lamps are extremely limited (to non-existent).

No plans are made to replace Pb with Ce as earlier tests were unsuccessful and no new insights have been created.

W.r.t. LEDs: other UVA applications are available in LEDs but tanning development has been limited. At this moment it is impossible to predict if and when UVA LED based equipment will become feasible.

6.3 Links to REACH, according to RoHS Directive Article 5(1)(a)

Do any of the following provisions apply	to the application described?	
	no	
 Authorisation SVHC Candidate list Proposal inclusion Annex XIV 	 Restriction Annex XIV Annex XVII Registry of intentions 	Registration
Provide REACH-relevant information red	ceived through the supply chai	n.

Not Applicable

. . .

Removal of lead from lamps 7

Can lead be eliminated?

	Yes.
\square	No.

It is not practical to remove the lead from these lamp types as the lead is required as an activator for the phosphors that produce the specific wavelengths of light necessary to provide the necessary spectrum and meet the clinical and regulated requirements imposed by the EU regulatory agencies.

Reduction of lead content of lamps 8

The less than 1% lead content of these lamps as a percentage of the weight of the homogenous phosphor material is needed to activate the phosphor. A reduction in the lead content would cause either a loss of output or not be sufficient to activate the phosphor.

9 Other relevant information

The tanning industry is closely monitored and regulated by European authorities under regulations such as EN 60335-2-27 and EN 61228.

EN 60335-2-27

This International Standard deals with the safety of electrical equipment on exposing the skin to ultraviolet or infrared radiation, for household and similar use in tanning salons, beauty parlours and similar buildings.

Tanning and medical equipment in Europe is subject to unscheduled auditing and measurement of the lamps and equipment which has been certified for use with lamps that are equivalent or the same as the lamps originally installed by the OEM. This equipment has undergone extensive testing to assure compliance with ultraviolet exposure schedules and the use of any other lamps than those substantially equivalents are restricted. It would be a significant financial burden if not impossible to the independent salon owners to try to retrofit their equipment and have each unit certified by the regulating bodies.

10 Information that should be regarded as proprietary