Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance Restrictions in Electrical and Electronic Equipment:

Study to assess renewal requests for 29 RoHS 2 Annex III exemptions [no. I(a to e -lighting purpose), no. I(f - special purpose), no. 2(a), no. 2(b)(3), no. 2(b)(4), no. 3, no. 4(a), no. 4(b), no. 4(c), no. 4(e), no. 4(f), no. 5(b), no. 6(a), no. 6(b), no. 6(c), no. 7(a), no. 7(c) - I, no. 7(c) - II, no. 7(c) - IV, no. 8(b), no. 9, no. 15, no. 18b, no. 21, no. 24, no. 29, no. 32, no. 34, no. 37]

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Report for The European Commission

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Disclaimer:

Eunomia Research & Consulting, Oeko-Institut and Fraunhofer Institute IZM have taken due care in the preparation of this report to ensure that all facts and analysis presented are as accurate as possible within the scope of the project. However no guarantee is provided in respect of the information presented, and Eunomia Research & Consulting, Oeko-Institut and Fraunhofer Institute IZM are not responsible for decisions or actions taken on the basis of the content of this report.

28.0 Exemption 18b: "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)"

Declaration

In the sections that precede the "Critical Review" the phrasings and wordings of stakeholders' explanations and arguments have been adopted from the documents provided by the stakeholders as far as required and reasonable in the context of the evaluation at hand. Formulations have been altered in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and Definitions

BSP	Barium silicate phosphor doped with lead, also known as $BaSi_2O_5$:Pb
CFL	Compact fluorescent lamp
EEE	Electrical and Electronic Equipment
Hg	Mercury
HID	High intensity discharge lamps
InGaN	Indium gallium nitride
LED	Light emitting diode
OLED	Organic LED
LEU	LightingEurope
NARVA	NARVA Lichtquellen GmbH + Co. KG
NMSC	Non-melanoma skin cancer
Pb	Lead
PUVA	Psoralen (P) and ultraviolet A (UVA) therapy

UV	Ultra violet
UVB	Ultra violet radiation in the range of 280-315 nm
UVC	Ultra violet radiation in the range of 100-280 nm
WEEE	Waste Electrical and Electronic Equipment
WPE	Wall plug efficiency
YPO	Yttrium phosphate phosphor

Declaration

The phrasings and wordings of stakeholders' explanations and arguments have been adopted from the documents provided by the stakeholders as far as required and reasonable in the context of the evaluation at hand. Formulations have been altered in cases where it was necessary to maintain the readability and comprehensibility of the text.

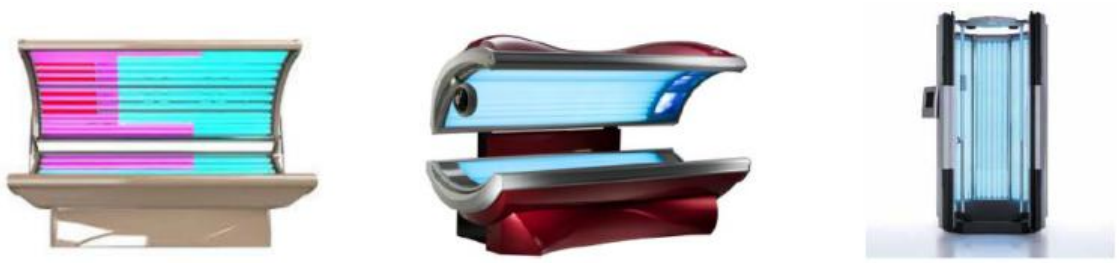
28.1 Background

NARVA Lichtquellen GmbH + Co. KG (NARVA) and LightingEurope (LEU) have applied for a renewal of exemption 18b of Annex III of the RoHS Directive.

According to LEU[1610], 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 (e.g., similar to that as emitted by the sun) for the human body, yet applied in calculated doses in line with European regulations. 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. 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).

[1610] LEU (2015a), LightingEurope, 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), submitted 15.1.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_9/Exemption_18_b_/Lighting_EUrope/18b_LE_RoHS_Exemption__Req_Final_draft.pdf

Figure 28-1: Examples of indoor tanning equipment



Source: LEU (2015a)

NARVA[1611] explain that fluorescent lamps using barium silicate phosphor doped with lead (BSP lamps) are used in tanning equipment. Since the lamps contain lead, an exemption from the RoHS Directive is needed to allow further use in tanning equipment.

Both applicants request the renewal of the exemption for applications of category 5, with the current wording and for the maximum duration:

> "*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)*"

28.1.1 Amount of Lead Used under the Exemption

LEU[1612] explains that 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 in total entering the EU per annum[1613].

28.2 Description of Requested Exemption

According to LEU[1614] the 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 is calibrated for the use of specific lamp

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[1611] NARVA (2014), NARVA Lichtquellen GmbH + Co. KG, exemption Request for Using Lead in fluorescent Lamps for Tanning, submitted 19.12.2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_9/Exemption_18_b_/NARVA/18b.pdf

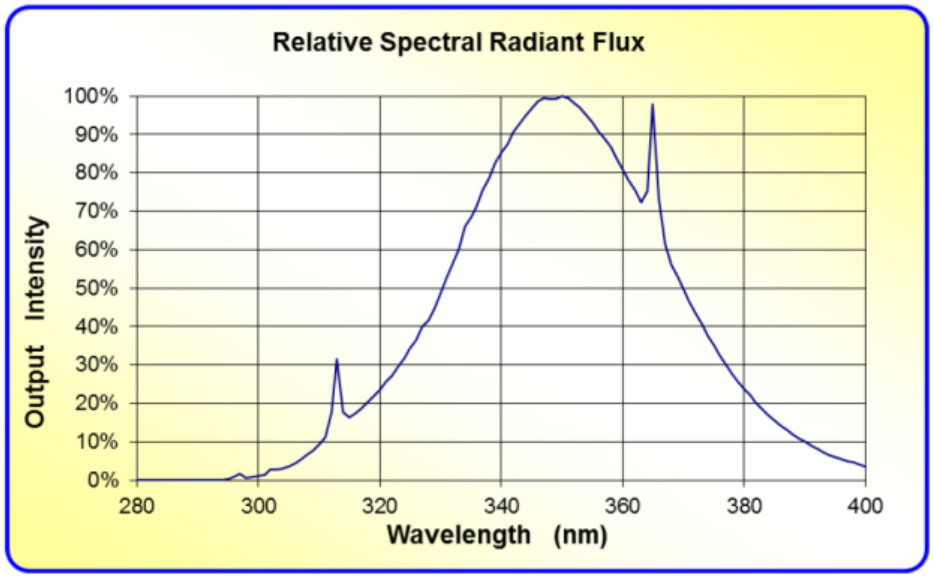
[1612] Op. cit. LEU (2015a)

[1613] According to LEU, lead is also used in similar lamp types for medical and phototherapy applications such as PUVA light therapy for skin conditions such as psoriasis. The mentioned figures are explained not to include estimated usage of lamps used in medical therapy, for which a separate exemption has been requested.

[1614] Op. cit. LEU (2015a)

types, marked in accordance with EU regulations for tanning lamps and equipment[1615]. Lamps are produced in T12, T8 and T5 diameters and compact fluorescent lamp (CFL) 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 as a result of the specified proportional phosphor mix (see typical example in Figure 28-2).

Figure 28-2: Example of a typical UVA/UVB spectrum



Source: LEU (2015a)

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.[1616]

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 is an international standard that deals with the safety of electrical equipment on exposing the skin to

[1615] LEU (2015a) reference brochures and data about such lamps as follows:

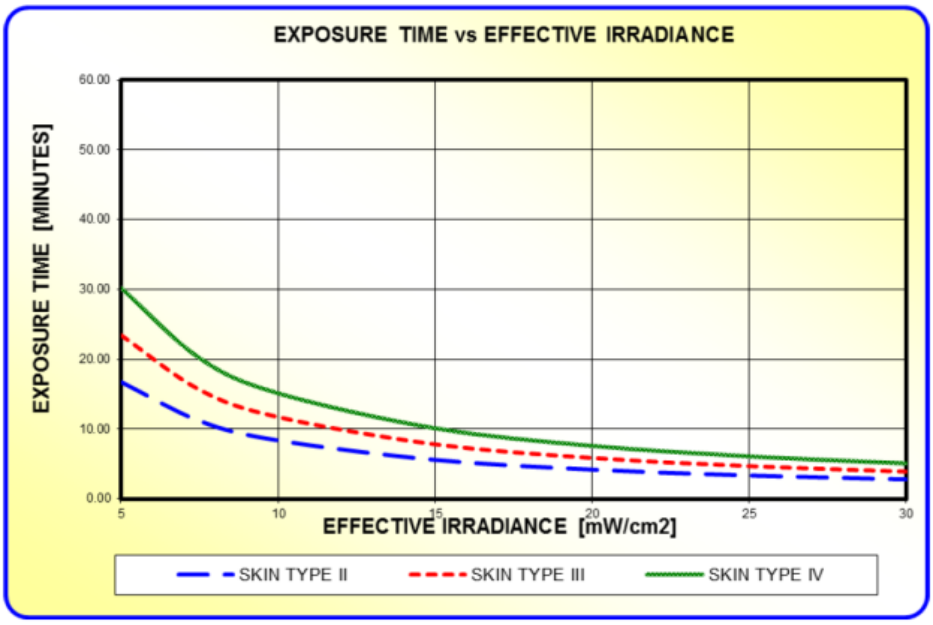
- Lighttech http://www.light-sources.com/tanning/tanning-lamp-products
- Cosmedico http://www.cosmedico.de/en/tubes.html
- Havells-Sylvania: http://www.havells-sylvania.com/media/Downloads/Sylvania%20Lamps%20Brochures/SPG/Suntanning/SY_Bodycare_Broschuere_2011_2012_ENGL_RZ_FINAL_ANSICHT.pdf

[1616] Op. cit. LEU (2015a)

ultraviolet or infrared radiation, for household and similar use in tanning salons, beauty parlours and similar buildings. EN 61228 includes requirements for measurement and details specification methods. 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 non-equivalent lamps is restricted.

EU regulations govern the allowable output of ultraviolet radiation permitted within a determined exposure time (see Figure 28-3). The EU regulates and enforces tanning equipment and the installed lamps, which are marked on the lamps with a specific "X, Y" code system for the erythemally-weighed UV radiation in accordance with EN standard 61228 Ed.2 (2008-01). This EN standard forms the basis of lamp marking, and needs to be complied with. LEU claims that this limits the possibility of substitution with lead-free phosphors. The regulatory demands come from the LVD Administrative Co-operation working group (ADCO)[1617], which at its 18th meeting on the 14th of November 2006 decided among others that the maximum erythemal-weighted irradiance should not exceed 11 SED/h (0.3 W/m2).[1618]

Figure 28-3: Exposure time vs. effective irradiance



Source: LEU (2015a)

[1617] LEU (2015a) references the declaration of the LVD ADCO Group on the following website: http://ec.europa.eu/enterprise/electr_equipment/lv/guides/index.htm

[1618] Op. cit. LEU (2015a)

28.3 Applicant's Justification for Exemption

LEU[1619] explains that 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%[1620] of the indoor low pressure mercury vapour fluorescent lamps used for tanning and certain medical applications, which are not covered by this exemption. The lead is evenly distributed throughout the phosphor coating of the lamps to radiate in the range of 290-400 nm when excited by radiation at 254 nm.

LEU[1621] further explains that UV intensity at the wavelength of 350 nm is crucial in order to get skin pigmentation (tanning result). The UV output of the lamps with narrow band UVA phosphor is negligible at that important wavelength so that they are insufficient for use for a wider range of tanning applications.

Tanning equipment is strictly regulated in the EU, and thus LEU[1622] explains that any possible alternative to lead in BSP type of phosphor would need to fulfil following criteria:

- "*Lamp specification must be the same with regard to:*
  - *UVA and UVB output, and with that Erythema[1623];*
  - *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.*

[1619] Op. cit. LEU (2015a)

[1620] LEU (2015b) explains that these non-BSP lamps emit only a narrow bandwidth of the UVA spectrum and no- UVB and do not produce the required action spectrum required for tanning response. As evidenced by the market size there is limited use of such lamps and when used it is always in conjunction with BSP phosphor lamps to generate the total UVA and UVB spectrums needed to initiate a tanning response.

[1621] LEU (2015b), LightingEurope, Answers to 1st Questionnaire Exemption No. 18b (renewal request), submitted 28.8.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_9/Exemption_18_b_/Lighting_EUrope/Ex_18b_LightingEurope_1st_round_Clarification_LE_Answers_20150828.pdf

[1622] Op. cit. LEU (2015a)

[1623] In this respect LEU explains that the EU regulates tanning equipment (including lamps) with a specific "X, Y" code system for the erythemally-weighed UV radiation in accordance with EN standard 61228 Ed.2 (2008-01).

- *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*."

28.3.1 Possible Alternatives for Substituting RoHS Substances

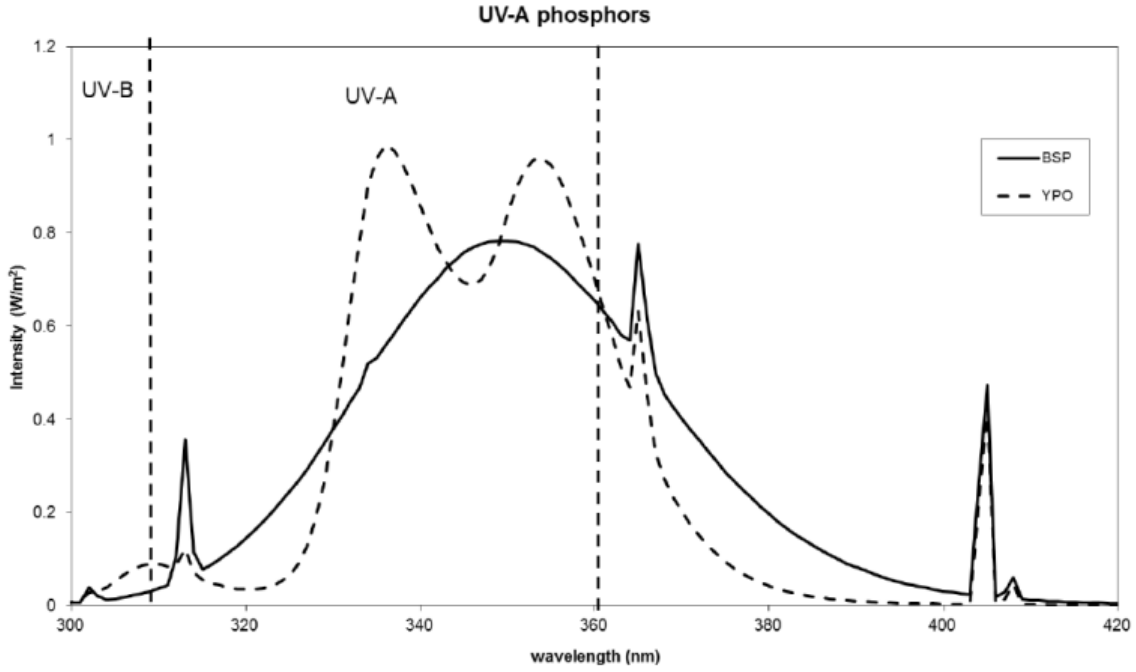
According to LEU[1624], only one alternative substance comes close to the performance of BSP phosphors - cerium (Ce) doped yttrium phosphate phosphor (YPO) phosphor. LEU explains that tanning lamp output is measured on a weighted distribution of UVA and UVB output measured by the output depending on the wavelength (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. Such phosphors would not be able to comply with CE regulations for tanning lamps (due to spectral incompatibility) and are thus not allowed for this application.

Figure 28-4 below shows the spectrum of Ce doped YPO phosphor in comparison to BSP. Based on the comparison, LEU concludes that:

- The spectral power distribution shows differences in the UVA and UVB range.
- The ratio for UVA and UVB output is different, which is an important factor for tanning applications and is governed by EU regulations due to the health risks.
- Therefore the cerium-based material has a lower expected treatment effectiveness, with regard to Erythema and NMSC (non-melanoma skin cancer).

[1624] Op. cit. LEU (2015a)

Figure 28-4: Emission spectrum of a cerium-doped phosphor – UV lamp



Source: LEU (2015a)

LEU[1625] raises a second point of relevance, with relation to the variations of the UV output along the lamp length [i.e. its surface area – consultants comment] 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 cause 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 (for further details see Appendix A.5.0).

LEU[1626] also explains why the BSP phosphor cannot be replaced in order to eliminate the need for lead as an activator: besides $BaSi_2O_5$:Pb, below lead doped phosphors are known as UV emitting phosphor.

- $SrBaMgSi_2O_7$:Pb 370nm
- $BaZn_2Si_2O_7$:Pb 303nm
- $BaMg_2Si_2O_7$:Pb 290nm

All above phosphors are doped with lead, but the emission wavelength depends on the chemical composition of the base substance. To get an efficient emission at 350nm, which is effective for sun tanning purpose, only $BaSi_2O_5$ can be used as a base substance. In parallel, though both lead (Pb) and europium can be used as a doper for BSP, barium

[1625] Op. cit. LEU (2015a)
[1626] Op. cit. LEU (2015b)

silicate emits 520nm when it is activated by europium, making $BaSi_2O_5$:Pb the only compound that achieves the 350nm output.

28.3.2 Possible Alternatives for Eliminating RoHS Substances

In relation to different designs of equipment (i.e. alternative technologies that could enable the elimination of lead in this application), LEU[1627] explains that other technologies could be evaluated for replacing fluorescent technology in tanning applications. These could be for example e.g. LED, OLED, HID, and incandescent or halogen technology. However, for any new technology there will be a need 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 related to the discharge technology of the lamps) in existing equipment are detailed in Section 28.3 above. Since incandescent, halogen and OLED do not emit radiation in the UVA/UVB range, LEU only provides additional information as to the potential of LED technology as an alternative. The following obstacles are detailed in this regard:

- **Wall Plug Efficiency** - 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 indium gallium nitride (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. There are other materials available from which LEDs can be made that generate UV light (like AlGaN), however the efficiency (radiated power out / electrical power in) of LEDs with those materials is still very low. In the UVC (100-280 nm) and UVB (280-315 nm), the wall plug efficiency (WPE) of LEDs is below 1%, where the WPE of fluorescent lamps is close to 20% or even higher. There is currently no comparable WPE for LEDs with a spectral output below 380 nm. Therefore, LED lamps are not suitable at present as a practical alternative for tanning applications.
- **Effectiveness (i.e. same tanning effect)** - No tests results, from a comparative study of equipment using fluorescent lamps and equipment using LEDs, are available at present with regard to the effectiveness of alternative lamps to reach the desired effect in terms of tanning results. This is explained to be related to the lacking availability of LED candidates. Thus concluding as to possible effectiveness is not possible at present.
- **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)) are

[1627] Op. cit. LEU (2015a)

based on fluorescent discharge lamps (with respect to safety and system responsibility). No CE conformity is available for other lamp technologies.

28.3.3 Environmental Arguments

According to LEU[1628], there are no statistical data available specific to the Life Cycle Analysis of tanning 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.

Sun tanning lamps are further explained to be 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 (see application for additional detail).[1629]

The limited wall-plug efficiency of LEDs currently available that produce light in the non-visible region is also understood to be of environmental relevance. Please see Section 28.3.2 and in 28.5.3 in this respect.

28.3.4 Socio-economic Impact of Substitution

LEU[1630] claims 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 alternative product types would not be an adequate comparison. The potential substitution or replacement with 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. LEU further explains that the 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 an alternative technology, effects on health and safety will have to be investigated once candidates are developed.

According to LEU[1631], it can be 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 may have significant impact on the application. The possibility for lead-free technology for these lamps is not feasible

[1628] Op. cit. LEU (2015a)
[1629] Op. cit. LEU (2015a)
[1630] Op. cit. LEU (2015a)
[1631] Op. cit. LEU (2015a)

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. The 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.

In a later communication, LEU[1632] however explains that the substitute candidate should have exactly the same spectral distribution curve and power effectiveness like BSP phosphor, because this is the only way to avoid needing to clinically retest all the tanning devices on the EU market.

In terms of social impacts, LEU[1633] explains that as there are no reliable substitutes if the renewal of the exemption is denied it would shut down the indoor tanning industry in Europe. LEU estimates that:

- Almost 100% of the BSP tanning lamps used in Europe are manufactured in Europe by fluorescent lamp companies;
- Almost 100% of the indoor tanning equipment sold in Europe is manufactured in Europe. Almost 100% of the tanning lamps sold as aftermarket lamps are sold by manufacturers or distributors located in Europe;
- Over 90% of the tanning lamps used in the US are manufactured in Europe;
- Over 75% of the tanning equipment sold in the United States is made in Europe.

28.3.5 Road Map to Substitution

LEU[1634] expects that given the market size in combination with strict regulations, efforts to substitute BSP containing lamps are extremely limited (to non-existent). There are no plans to replace Pb with Ce as earlier tests were unsuccessful. With regard to LEDs, other UVA applications are available in LEDs but tanning application development has been limited. At this moment it is impossible to predict if and when UVA LED based equipment will become feasible.

[1632] Op. cit. LEU (2015b)
[1633] Op. cit. LEU (2015a)
[1634] Op. cit. LEU (2015a)

28.4 Stakeholder Contributions

A single contribution was made in relation to Ex. 18b during the stakeholder consultation. The Test and Measurement Coalition (TMC)[1635] includes the seven leading companies in the sector representing roughly 60% of the global production of industrial test and measurement products. It is TMC's understanding that, according to the RoHS Directive, the exemptions listed in Annex III and Annex IV for which no expiry date has been specified, apply to sub-category 9 industrial with a validity period of 7 years, starting from 22 July 2017. This is also said to be explained in the RoHS FAQ, p. 26 http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf. TMC, thus does not interpret the current exemption evaluation related to package 9 to concern category 9 industrial equipment and has not provided exemption specific information.

28.5 Critical Review

28.5.1 REACH Compliance - Relation to the REACH Regulation

Appendix A.1.0 of this report lists entry 28 and entry 30 in Annex XVII of the REACH Regulation, stipulating that lead and its compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public. A prerequisite to granting the requested exemption would therefore be to establish whether the intended use of lead in this exemption request might weaken the environmental and health protection afforded by the REACH regulation.

In the consultants' understanding, the restriction for substances under entry 28 and entry 30 of Annex XVII does not apply to the use of lead in this application. Pb used as an activator of BSP phosphors applied in discharge lamps used for tanning, in the consultants' point of view is not a supply of lead and its compounds as a substance, mixture or constituent of other mixtures to the general public. Pb is part of an article and as such, entry 28 and entry 30 of Annex XVII of the REACH Regulation would not apply.

In general, BSP, or silicic acid ($H_2Si_2O_5$), barium salt (1:1), lead-doped (CAS number 68784-75-8) has been addressed in an Annex XV dossier[1636] prepared by the European Chemicals Agency (ECHA), proposing its classification as a substance of very high concern (SVHC). The substance has been proposed to be identified as a substance meeting the criteria of Article 57 (c) of REACH, owing to its classification as toxic for reproduction category 1 A. Furthermore BSP is a registered substance[1637]. Nonetheless, at present,

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[1635] TMC (2015), Test & Measurement Coalition, General comments related to RoHS exemption package 9, submitted 16.10.2015, available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_9/Exemption_1_a-e_/General_Contribution_Test___Measurement_Coalition_package_9_exemptions_20151016.pdf

[1636] Available here: http://echa.europa.eu/documents/10162/13638/SVHC_AXVREP_EC_272-271-5_SilicicAcidBariumSaltLead-doped_en.pdf

[1637] Available information from REACH registration dossiers can be found under the following link:

there are no listings of this substance under Annexes XIV and XVII of REACH that restrict its use in products to be placed on the EU market. There are also currently no processes underway to evaluate the need for such listings (restriction / authorisation). Even if further processes should be embarked on, it is currently not possible to assume if this would result in legislation that would restrict the use of BSP in lamps used for tanning (or medical) applications. Though such proceedings should be observed in future evaluations of the RoHS exemption for lead in BSP lamps, the consultants do not think it would be appropriate at present to limit the current exemption or its duration in anticipation of results of such processes.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status January 2016).

Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

28.5.2 Scientific and Technical Practicability of Substitution

NARVA and LEU explain that lead in BSP lamp types used for tanning applications currently cannot be substituted or eliminated. Though a few candidate alternatives are elaborated on, it can be understood that none of these have reached a stage of maturity in terms of being used in articles to be placed on the market. In this sense, at least at present, it can be understood that substitutes are not available on the market for a number of reasons.

To begin with, an alternative light source providing the same function as BSP lamps using lead is yet to be found. Using an alternative activator to dope BSP instead of lead, such as europium, would not result in a comparable spectral output. Though the option of using YPO phosphors is elaborated on as a substance substitute, it can be understood that such lamps do not provide the same spectral output as BSP lamps either. The change of spectral output is explained to possibly result in larger negative health impacts such as erythema. It can be understood that the spectral output of BSP lamps may also cause such health impacts, however at a lower rate and thus holding lower risks for health effects on patients. From an earlier exemption request evaluation[1638] that led to Ex. 34 of Annex IV, it is also understood that other phosphor compositions that have

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http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdc6c5f-6d4c-29d1-e044-00144f67d031/AGGR-ec42affe-9178-4b25-911c-415860a9699a_DISS-9fdc6c5f-6d4c-29d1-e044-00144f67d031.html#section_3_5

[1638] Exemption request from Therakos Photopheresis to exempt BSP lamps in extracorporeal photopheresis applications. Application documents can be viewed here: http://rohs.exemptions.oeko.info/index.php?id=146 and final evaluation report here: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/20130412_RoHS2_Evaluation_Proj2_Pack1_Ex_Requests_1-11_Final.pdf

been investigated in the past, would either lead to similar risks or to an ineffective treatment. In parallel, developing alternative light sources with technologies such as LED have also yet to mature. Though first UVA LED lamps may have started to become available, their efficiency (radiated power out ÷ electrical power in) is said to be very low in comparison with BSP lamps, and information predicting when UVA LEDs with acceptable output and efficiency shall become available is not publicly available. Though such lamps are currently not available for use in tanning equipment, it should be noted that differences in efficiency could have relevance to the environmental comparison of alternatives.

To conclude, as an alternative light source is a precondition for developing equipment which would be compatible with such new technologies, further evaluating the performance of such possible equipment is not yet possible, making substitution and elimination not practical at this time.

28.5.3 Environmental Arguments

LEU provides some information regarding environmental aspects of BSP lamps, mainly related to the treatment of waste. As the information does not allow a comparison with possible alternatives (which are in any case understood to not be applicable at present), the information is not further discussed.

As shortly explained above, though first UVA LED lamps may have started to become available, their efficiency is said to be very low in comparison with BSP lamps. This is understood to mean that even if their spectral output would be comparable to that of BSP lamps, their limited efficiency would result in a significantly higher energy consumption than that of BSP lamps.

28.5.4 Socio-Economic Arguments

LEU mentions a number of aspects related to socio-economic aspects.

Among others, information is provided regarding possible differences in health impacts of BSP lamps and of the current candidate alternatives; these have been discussed above in Section 28.5.2.

Furthermore, LEU claims that once an alternative is to be found, the development and implementation of such alternatives in equipment can be expected to result in heavier costs for business (tanning salons). In this respect LEU[1639] mentions that:

- **Even if UVA LEDs become available with feasible specifications, tanning equipment may become much more expensive** – in the consultants' view it is difficult to estimate what costs substitution could lead to. Alternatives may not necessarily be more expensive, especially if they are to be developed after most discharge lamp applications have been replaced with Hg-free

[1639] Op. cit. LEU (2015a)

alternatives. In the transformation of the lighting sector from Hg-based (discharge lamps) to Hg-free applications (other technologies), it can be expected that at some point the burden of manufacturing last Hg-based articles in relatively small quantities shall become an incentive for developing alternatives. In such a case, emerging alternatives could be viewed by businesses more as a blessing than as a burden. As the spectral function of alternative light sources cannot be anticipated at present, it cannot be predicted if in the long run the alternatives may have lower negative impacts on health and thus provide benefits for patients, regardless of the costs of a transformation.

- **Development of replacement lamps for existing equipment shall not to be feasible** as the recertification would need to be performed for every type of fixture or appliance, resulting in an economic burden for small business owners (e.g. tanning salons). The consultants are aware that different technologies may use different fixtures or require rewiring or changes to the interface of the lamp with equipment, however cannot follow that this is always the case. If the spectral out-put of alternatives is the same as well as its directionality and other characteristic properties of the light source, the consultants cannot follow that a change in light source would require extensive recertification of each type of equipment. In this sense, here too, it is difficult to say how costs of development, clinical studies and recertification shall add up. Though it can be expected that such processes for replacement lamps may be time consuming and less practical, it needs to be kept in mind that all equipment has a certain service life and is gradually replaced with new equipment, which has undergone at least some degree of redesign. In this sense, though ensuring replacement lamps for existing equipment with new technologies could justify keeping BSP lamps on the market in some cases, predicting this at present is not straightforward.

28.5.5 Stakeholder Contributions

The contribution submitted by TMC raises a legal question as to the availability of the current exemption to category 9 equipment. Regardless of TMCs claims as to the availability of Annex III exemptions to sub-category 9 industrial for 7 years starting in 22.7.2017, in the case of Ex. 18b the wording formulation limits its applicability to tanning applications. As tanning equipment is understood not to fall under Cat. 9, in the consultants' opinion, sub-category 9 industrial equipment would not benefit from the exemption. Should BSP lamps be in use in Cat. 9 equipment (general and industrial), relevant stakeholders would have been expected to come forward with such information, either in the past evaluations related to medical equipment or in the current one.

28.5.6 The Scope of the Exemption

LEU[1640] explains that technically there is no difference between BSP phosphors used for medical purposes and BSP phosphors used for tanning purposes. Both lamp categories may have the same diameter and same wattage range in principle. Medical lamps may also be used in smaller lengths, diameters and wattages for partial body or spot treatment. The phosphor types may use the same components with a very similar or different blend to produce a specific UV output. In medical applications these would be called PUVA[1641] lamps and produce broad band UVA output. These lamps would be marked accordingly. The differences are in the field of application, in marking of the lamps and in the way to market. The sizes and wattages of certain tanning lamps can be the same as PUVA type of medical lamps for which LightingEurope has submitted a separate application for the use of BSP phosphors in those medical lamps. The manufacturers of tanning lamps do not market tanning lamps for use in medical equipment and therefore do not request an exemption for the use of tanning lamps in medical equipment.

In the consultants view, in relation to the scope of the exemption, the question here is whether a distinction can be made between similar BSP lamps used in different types of equipment. If the same lamp can be used in equipment falling into different categories, there would be a justification to merge all applications to a single exemption with a single validity date, regardless of category. The aim of this would be, on the one side, to ensure that the need to renew exemptions for BSP lamps be evaluated in the future for all applications during the same review, i.e. for a single merged exemption. On the other hand, should all BSP lamps which are interchangeable be addressed by a single exemption, this would simplify the legislation.

LEU was thus asked to clarify the aspect of exclusivity related to the use of BSP lamps in tanning and medical equipment. LEU[1642] explains that differentiation between tanning and medical lamps is done via the following protocol: On each and every sunlamp there is a mandatory warning text which describes clearly that the lamp is made for tanning purposes. This applies for medical lamps as well where the warning text shows that the lamp is intended for use in medical applications. All lamps manufactured for tanning purposes are marked with a so-called ‘equivalency code’ which refers to the UV strength of the lamp. This code ensures that in the application the user applies the correct lamps to avoid over exposure. Such code (i.e. its significance - consultants comment) is well known and widely used by people who replace the lamps in the sunbeds. On each and every sunbed there is a sticker, which specifies what lamp with what ‘equivalency code’ should be used in the device. Such ‘equivalency codes’ are not etched on medical lamps.

[1640] Op. cit. LEU (2015b)

[1641] The name PUVA comes from a group of medical treatment practices that combine intake of a psoralen drug with exposure to UVA radiation.

[1642] LEU (2016a), LightingEurope, Answers to 2nd Questionnaire Exemption No. 18b (renewal request), submitted 19.01.2016 per email.

Each and every tanning lamp is marked accordingly and each and every medical lamp is marked according to legal and safety requirements for its intended use. LEU contends that this sufficiently prevents misuse of the lamps.

Figure 28-5: Warning text, equivalency code and marking examples for lamps

Tanning Lamps	Medical Lamps
Warning text	**Warning text**
Sunlamp - **DANGER**.Ultraviolet radiation. Follow instructions. Use **ONLY** in fixture equipped with a timer.	**WARNING: Medical UV lamp. Use only in certified medical devices! Use protective eyewear.**
Equivalency code	
180-R-36/2,4	
Marking	**Marking**
R 180W 2m Sunlamp - **DANGER**.Ultraviolet radiation. Follow instructions. Use **ONLY** in fixture equipped with a timer. USA Technology. 180-R-36/2,4 CE	**WIDE BAND PUVA 100W** **WARNING: Medical UV lamp. Use only in certified medical devices! Use protective eyewear.** CE

Source: Op. cit. LEU (2016a)

Nonetheless, when asked whether some BSP lamps were sold on the open market (i.e. accessible to private consumers, LEU[1643] answered positively, explaining that they are sold through professional distribution networks. Regarding the possibility of using medical lamps in tanning applications and vice versa, LEU explained that as some medical lamps and tanning lamps are made to lighting industry standard dimensions and electrical characteristics (e.g. length, diameter, wattage, end fitting) it is mechanically possible that a lamp intended for medical use or tanning use or general lighting use can fit in the same luminaire or equipment. However, these lamps are absolutely not intended to be interchangeable for medical or tanning or general lighting applications and any such misuse could cause harm to the user. All tanning lamps are marked for sun tanning purposes and all medical lamps are marked for medical use in accordance with safety regulations and as demonstrated in our previous responses".

According to the above information, though the consultants can follow that BSP lamps of different types are manufactured for use in specific equipment, it cannot be concluded that tanning lamps and medical lamps would not be interchangeable. It is understood that lamps for other medical applications and lamps for tanning applications are sold as individual lamps. Though they are sold through professional distribution networks, LEU confirms that private consumers could have access to some lamps as is also apparent from searching the internet in this respect[1644]. This can also be followed as it is

[1643] LEU (2016b), LightingEurope, Answers to 3rd Questionnaire Exemption No. 18b (renewal request), submitted 27.01.2016 per email.
[1644] See for example: http://www.uvee.be/puva-uvb-lamps

understood that equipment both for tanning and for medical phototherapy can be purchased by private consumers. In this respect, even if this is not the intended use, lamps manufactured for one application could be implemented by users in the other application type.

The consultants, thus, cannot follow why there should be separate exemptions for sun-tanning lamps and for medical applications as this would mean double regulation of the same product, possibly leading to uncertainties in the future.

In this respect, it is also clear that should substitutes become available, that their applicability would need to be evaluated for all applications, further supporting formulating a single exemption for all BSP applications.

28.5.7 Exemption Wording Formulation

The aspect of lamp exclusivity has been discussed in the evaluation of Ex. 2015-3, evaluated in the course of an earlier project[1645]. In this earlier evaluation, a recommendation was made to merge the exemption for tanning applications and for medical applications (excluding at present applications covered under Ex. 34 of Annex VI, which is due to expire only on 22 July 2021). In this sense the wording recommended in this earlier exemption evaluation is also proposed below, as a means of merging the applications under one exemption.

28.5.8 Conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria is fulfilled:

- their **elimination or substitution** via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

In the consultants' opinion, in the case of BSP lamps it can be followed that there are currently no alternatives that would allow either a substance substitution in the existing technology or an elimination of the need for lead through the implementation of new technologies. In this sense, elimination and substitution are considered to be impractical at present.

Furthermore, though it can be understood that none of the named candidate alternatives have matured to the point of being subjected to clinical trials and testing, for some of these candidates negative health risks have been identified due to spectral

[1645] See Report for Pack 8, available under http://rohs.exemptions.oeko.info/index.php?id=164

output differences. Though in theory YPO alternatives could be used in lamps, the first research suggests that their spectrum would raise the risk for Erythema and non-melanoma skin cancer. In this sense such substitutes are understood to also have higher negative impacts on health in comparison with BSP lamps. Though the conclusion that the first criterion is fulfilled would suffice to justify an exemption, this aspect (if true) further strengthens the justification.

As there is currently no information to suggest that alternatives should become market ready in the next few years, setting a short duration for an exemption does not seem practical. As Ex. 34 currently has an expiration date in mid-2021, and addresses BSP lamps used for a different application, and as a positive evaluation of Ex. Request 2015-3 could result in the same expiration date, the consultants would recommend that should an exemption be approved for tanning applications, that its validity be aligned with this date, even if the date of the EU COMs decision would in theory allow extending the duration of the exemption beyond this point in time.

28.6 Recommendation

It is recommended to grant the requested exemption extending its applicability from tanning applications to medical applications. In the consultants' view an amendment of Ex. 34, which also covers a certain type of medical application, should be avoided at present though it should be consider in future reviews. It is thus recommended to amend exemption 18(B) of Annex III as follows:

Exemption 18b	Duration*
Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5 :Pb), when used:	
I. ***in tanning equipment; or***	*For Cat. 5: 21 July 2021*
II. ***in Annex I category 8 medical phototherapy equipment - excluding applications falling under point 34 of Annex IV***	

The consultants' do not see a need to grant the exemption to Cat. 9 equipment, or to applications in the scope of Cat. 8 equipment not specifically addressed in the formulation above and in Ex. 34 of annex IV. The current Ex. 18b is restricted to tanning equipment, understood not to fall under Cat. 8 or Cat. 9. Furthermore, in the evaluation of the current request, the recent evaluation of Ex. Re. 2015-3 also applied for by LEU and the evaluation of the Therakos request, information has not become available to suggest that BSP lamps are used in Cat. 9 equipment or in other Cat. 8 equipment.

Nonetheless, as for exemptions listed in Annex III, for which an expiration date is not specified, it is understood that from a legal point of view, they shall be valid for applications of Cat. 8 and Cat. 9 for up to 7 years. This validity period is understood to start from the dates specified in Article 4(3), for when these categories come into the scope of the Directive. Thus if from a formal-legal point of view the original formulation of the exemption needs to remain valid for these categories for the specified duration, the following formulation would be recommended:

Exemption 18b	Duration*
(1) Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5 :Pb), when used: ***I. in tanning equipment; or*** ***II. in Annex I category 8 medical phototherapy equipment - excluding applications falling under point 34 of Annex IV***	For Cat. 5: 21 July 2021
(2) 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)	For Cat. 8 and 9: 21 July 2021; For Sub-Cat. 8 in-vitro: 21 July 2023; For Sub-Cat 9 industrial: 21 July 2024

The consultants recommend the next review to be performed along with the review of all other exemptions for BSP applications (e.g. Annex IV Ex. 34), assuming applicants request the renewal of these exemptions.

28.7 References Exemption 18b

LEU (2015a) LightingEurope, 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), submitted 15.1.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_9/Exemption_18_b_/Lighting_EUrope/18b_LE_RoHS_Exemption__Req_Final_draft.pdf

LEU (2015b) LightingEurope, Answers to 1st Questionnaire Exemption No. 18b (renewal request), submitted 28.8.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_9/Exemption_18_b_/Lighting_EUrope/Ex_18b_LightingEurope_1st_round_Clarification_LE_Answers_20150828.pdf

LEU (2016a) LightingEurope, Answers to 2nd Questionnaire Exemption No. 18b (renewal request), submitted 19.01.2016 per email.

LEU (2016b) LightingEurope, Answers to 3rd Questionnaire Exemption No. 18b (renewal request), submitted 27.01.2016 per email.

NARVA (2014) NARVA Lichtquellen GmbH + Co. KG, exemption Request for Using Lead in fluorescent Lamps for Tanning, submitted 19.12.2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_9/Exemption_18_b_/NARVA/18b.pdf

TMC (2015) Test & Measurement Coalition, General comments related to RoHS exemption package 9, submitted 16.10.2015, available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_9/Exemption_1_a-e_/General_Contribution_Test__Measurement_Coalition_package_9_exemptions_20151016.pdf