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 3 RoHS Exemption Requests (Pack 8)

#1 for lead in thin film electronic sensor elements such as pyroelectric sensors or piezoelectric sensors;

#2 for lead in high voltage cables and cable assemblies (for industrial monitoring and control instruments) for a rated voltage higher than 250kV DC, containing up to 4% lead by weight;

#3 for lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as phototherapy lamps containing phosphors such as BSP ($BaSi_2O_5$:Pb)

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Report for The European Commission

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Disclaimer:

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5.0 Exemption 2015-3: "Lead as Activator in the Fluorescent Powder (1% Lead by Weight or Less) of Discharge Lamps When Used as Phototherapy Lamps Containing Phosphors such as BSP (BaSi2O5:Pb)" (Annex IV)

Abbreviations

BSP	Barium silicate phosphor doped with lead, also known as $BaSi_2O_5$:Pb
EEE	Electrical and Electronic Equipment
Hg	Mercury
InGaN	Indium gallium nitride
LEU	LightingEurope
NMSC	Non-melanoma skin cancer
NB	Narrowband
Pb	Lead
PUVA	Psoralen (P) and ultraviolet A (UVA) therapy
UV	Ultra violet
WEEE	Waste Electrical and Electronic Equipment
YPO	Yttrium phosphate phosphor

5.1 Background

LightingEurope (LEU)[56] explains that UV lamps with lead as activator in the fluorescent material (barium silicate phosphor doped with lead – BSP phosphors) are used for many

[56] LEU (2015a), LightingEurope, Request for an Exemption for phototherapy lamps 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 phototherapy lamps containing phosphors such as BSP (BaSi2O5 :Pb), submitted 16.1.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-3/UV_Medical_LE_RoHS_Exemption_Req_Final.pdf

skin treatment applications e.g. tanning[57]- and photo-therapies. Though such phosphors are used also in non-medical applications, the exemption request is only requested for such lamps when used for medical skin treatment such as psoralen and ultraviolet A (PUVA) phototherapy purposes[58]. PUVA phototherapy is a very specific application, enabling effective skin treatments used in medical applications; for example, a photochemical treatment where a combination of a drug (e.g. psoralen) in combination with UVA radiation is used to treat skin diseases such as psoriasis, vitiligo, atopic dermatitis etc. The lamps are used for dermatological and phototherapeutic use under medical supervision and installed in dedicated phototherapy equipment.

LEU[59] explains that the medical lamp applications have been on the market for many decades and have been shown to be of fundamental value to substantial groups of patients with particular conditions. These patients need the typical spectrum of the light offered by such lamps for a proper and effecting healing process and they are said not to be effectively treated by other technologies. Though a number of new technologies have been taken into consideration, the spectrum of other lamps is different and said to be insufficient for the required effect. LEU states that even if the alternative technologies were comparable, a long approval process would be needed to enable their use in such medical applications. Thus LEU has applied for an exemption for lead in fluorescent powders used in phototherapy discharge lamps, such as BSP ($BaSi_2O_5$:Pb).

Since Ex. 34 which is currently listed in Annex IV of the Directive exempts lead in BSP when used for other medical applications, LEU proposes either:

- To add a new exemption with the following wording formulation:
  "*Lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used for phototherapy lamps containing phosphors such as BSP ($BaSi_2O_5$:Pb)*"

or

- To amend the current exemption with the following wording formulation (amended text in bold):
  "*lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis- **and phototherapy lamps** containing BSP ($BaSi_2O_5$:Pb)*"

In both cases the maximum duration is requested. In their exemption application, LEU specify that both categories 8 (medical devices) and 9 (monitoring and control instruments) are relevant for this request, however the provided information only concerns medical applications, which are understood to fall under the RoHS definition

[57] According to LEU (2015a), although PUVA phototherapy lamps are very similar to tanning lamps in construction and incorporate lead-activated phosphors, they may have small differences in spectral distribution and exposure schedules depending on the application and the patient needs.
[58] Tanning lamp applications are explained to be covered by Ex. 18b of Annex III of the Directive. LEU (2015a)
[59] Op. cit. LEU (2015a)

for devices falling under Cat. 8. When asked about the relevance of Cat. 9 equipment to this request, LEU[60] stated that it "*does not have enough information on applications under Cat. 9, using the same kind of BSP phosphors, as these applications are covered by companies, which are not members of LightingEurope.*"

5.1.1 Amount of Lead Used under the Exemption

LEU explains that the lead is evenly distributed throughout the phosphor coating of the lamps. The lead content of the phosphors is less than 1% of the total weight of the phosphor. With respect to this exemption, the phosphor coating represents the homogenous material used in the fluorescent lamps. LEU mention that a reduction in the lead content would cause either a loss of output or would not be sufficient to activate the phosphor. Subsequently, the lamp would not meet EU regulations anymore. [61] Detailed information can be found in the evaluation of the Therakos Photopheresis exemption request that led to the approval of Ex. 34 of Annex IV of the Directive[62].

LEU[63] states that the phototherapy application is a small niche market compared to the total lighting market. There is no published data available for the quantity of phototherapy lamps entering the EU. However, based on market estimations of LightingEurope[64] the lead content of phototherapy lamps is limited to 2.5kg of lead in total per year entering into the EU. LEU elaborates that there is no published data available and that it does not collect data in a systematic and regular manner for this small subcategory of phototherapy specialty lamps. LEU has applied the method of expert estimations of the total amount of the sold lamps in the market by LightingEurope members. The amount of 2.5kg is based on the market estimations. The market size for the phototherapy application is said to be relatively stable.

5.2 Description of Requested Exemption

LEU[65] explains that that the exemption covers UV discharge lamps containing lead as an activator in the fluorescent powder. PUVA phototherapy lamps are light sources that produce ultraviolet light in the regions of the UVA and UVB spectrums. Their intent is to produce artificial sunlight (i.e., similar to that as produced by the sun) to replicate sunlight exposure for the human body, yet applied in calculated doses as regulated by European regulations.

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[60] LEU (2015b), LightingEurope, Answers to 1st Clarification Questions, submitted 27.03.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-3/Oko_Ex_Re_2015_3_Answers_2_Clarification_Questions_20150327_final.pdf
[61] Op. cit. LEU (2015a)
[62] See application details 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
[63] Op. cit. LEU (2015a)
[64] Op. cit. LEU (2015b)
[65] Op. cit. LEU (2015a)

According to LEU[66], a fluorescent lamp uses phosphors which, when activated, will produce light in different wavelengths. The lead activator is required to allow the barium silicate phosphor to fluoresce. When excited by the radiation produced in the lamp, it transforms the 254 nm radiation [emitted from the discharge within the lamp – consultants' comment] to the requested UV (290nm-400nm) radiation [emitted from the lamp – consultants' comment]. The primary wavelengths of "light" produced by these lamps are in the UVA and UVB regions or 290-400nm. Lead is used as the primary activator for the barium silicate phosphors in over 95% of the indoor low pressure mercury vapour fluorescent lamp[67]s used for tanning and certain medical applications, such as PUVA phototherapy.

LEU[68] claim that there is no feasible alternative for this phosphor that will yield the same or similar results and that has undergone the extensive European and US regulatory testing associated with the application of UVA phototherapy lamps using these phosphors. Over 80% of phototherapy lamps do not use BSP. These are so-called (narrowband) UVB lamps. However a substantial group of patients cannot be effectively treated by (NB–)UVB phototherapy. For this group, PUVA phototherapy is the only effective treatment therapy available[69]. Almost 100% of the medical skin treatment lamps using these phosphors are produced in the EU.

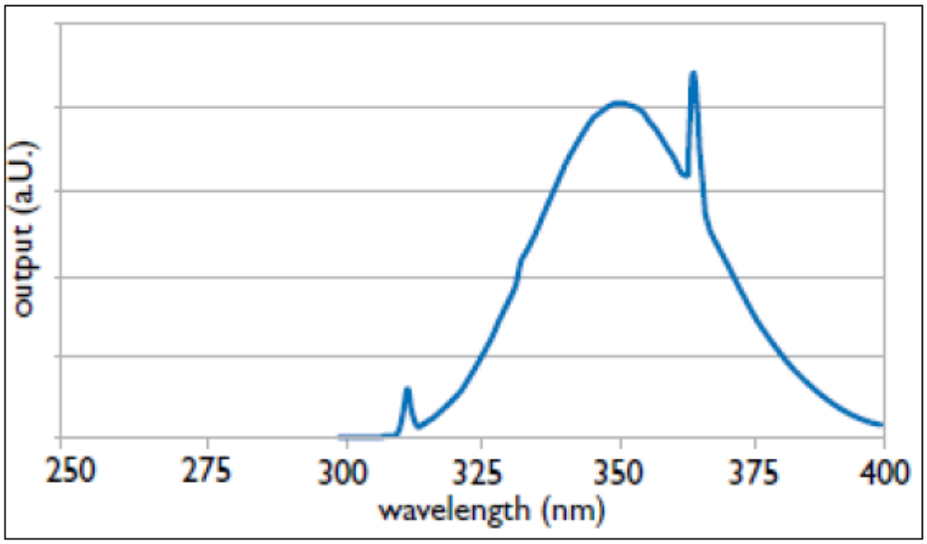
Figure 5-1: Examples of Phototherapy Equipment

Source: Op. cit. LEU (2015a)

[66] Op. cit. LEU (2015a)
[67] It should be noted that the mercury used in such lamps is understood to be regulated through under exemptions, for example, if BSP lamps exist in compact fluorescent lamp form, it would be expected that they are regulated under Ex. 1 which covers the use of Hg in CFLs.
[68] Op. cit. LEU (2015a)
[69] LUE (2015a) provide the following references in this regard: http://psoriasis-cure-now.org/uvb-puva/ and Sami S. Yones; Roy A. Palmer; Trish T. Garibaldinos; John L. M. Hawk. "Randomized Double-blind Trial of the Treatment of Chronic Plaque Psoriasis: Efficacy of Psoralen-UV-A Therapy vs Narrowband UV-B Therapy." Arch Dermatol 2006 142: 836-842.)

These lamps are produced in many shapes e.g. T12, T8 and T5 diameters and single capped configurations. The fluorescent materials contained in these lamps are manufactured from the same compounds, but can vary in spectral discharge across the UVA and UVB spectrum. The typical spectrum is demonstrated in Figure 5-2 below. The EU regulates and enforces equipment for UV treatment. Such regulations determine the allowable output of ultraviolet radiation permitted within a determined exposure time in the equipment relevant for this exemption request. [70]

Figure 5-2: Example of a Typical UVA/UVB Spectrum of Phototherapy-Photopheresis and Tanning Lamps



Source: Op. cit. LEU (2015a)

The typical lifetime of these lamps ranges from 600 to 1000 hours with a typical session 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 (e.g. clearance rate for PUVA phototherapy lamps). [71]

5.3 Applicant's Justification for Exemption

LEU[72] names a few alternatives that have been considered, but their application suggests that the research of such alternatives does not allow concluding as to their comparable effectiveness. Extensive literature is available on the effectiveness of PUVA phototherapy with BSP containing lamps, however no studies with effective results have

[70] Op. cit. LEU (2015a)
[71] Op. cit. LEU (2015a)
[72] Op. cit. LEU (2015a)

been done with either fluorescent lamps with other phosphors, or with other technologies (LED) with UVA/UVB spectra. PUVA equipment release and approbation has always been based on extensive patient tests with lamps containing BSP. Any possible alternative to would need to fulfil the following criteria:

- "*Lamp specification must be same with regard to:*
  - *UVA and UVB output, and with that Erythema;*[73]
  - *Spectral power distribution;*
  - *Compatibility (electrical/mechanical spec) must be OK;*
  - *Reliability must be OK*
  - *Safety must be OK*
- *(Psoriasis) Clearance rate on phototherapy patients;*
- *No (negative) side effects;*
- *Economically feasible (cost of replacement technology)*."

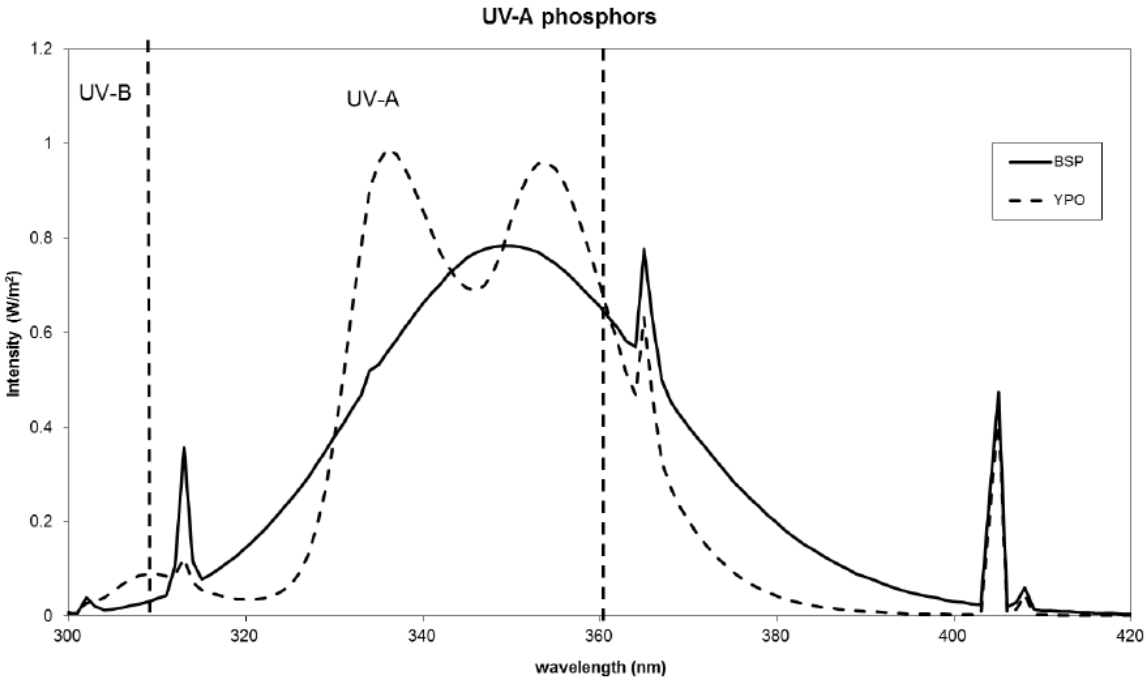
In this respect, it should be noted that erythema and possibly non-melanoma skin cancer (NMSC) are side effects of phototherapy. Treating skin diseases (like psoriasis) with phototherapy can lead to unwanted erythema (skin reddening) and a risk of creating NMSC. In this sense, alternatives need to be observed in relation to changes in the risks for such side effects. [74]

5.3.1 Possible Alternatives for Substituting RoHS Substances

Where substance substitutes are concerned, LEU[75] contend that studies on alternative materials show that the only alternative material, which comes close to the specifications mentioned above, is cerium-doped yttrium phosphate (YPO) phosphor. The spectrum of Ce doped YPO phosphor as compared to BSP phosphor is presented in Figure 5-3 below.

[73] In this respect LEU explains in its application for the renewal of Annex III Ex. 18b (see here) 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). The consultants understand that medical equipment and thus also medical lamps are also regulated and that the reference to UVA and UVB output and erythema is related to regulation of erythemally-weighed UV radiation.
[74] Op. cit. LEU (2015b)
[75] Op. cit. LEU (2015a)

Figure 5-3: Emission Spectrum of a Cerium-doped Phosphor UV Lamp as Compared to a BSP Phosphor UV Lamp Spectrum



Source: Op. cit. LEU (2015a)

Based on the above measurement results, LEU[76] 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 effective phototherapy and is governed by EU regulations.*
- *Therefore the Cerium based material has a lower expected treatment effectiveness, w.r.t. Erythema and NMSC (non-melanoma skin cancer)."*

LEU[77] further explains that the spectral incompatibility has resulted in a lack of interest of the medical community. Subsequently meaning that adequate tests and clinical studies of patients to prove the effectiveness from Ce doped YPO phosphor for PUVA phototherapy have not been performed and no approbations for such equipment exists. Therefore, this Ce-based material is not allowed for this application. This is also elaborated on in a later communication[78]. Based on a theoretical comparison, it can be concluded that Ce doped YPO phosphor will lead to more (unwanted) effects of NMSC for the same erythema dose, which is a measure for the therapeutic effect. For this reason no clinical trials have been started because it is known beforehand that the patients would run the risk on non-melanoma skin cancer.

[76] Op. cit. LEU (2015a)
[77] Op. cit. LEU (2015a)
[78] Op. cit. LEU (2015b)

LEU[79] 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.2.0).

5.3.2 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[80] explains that other technologies could be evaluated for replacing fluorescent technology for applications in PUVA phototherapy. 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 5.3 above. Since incandescent, halogen and OLED do not emit radiation in the UVA/UVB range, LEU only provide 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 (100-280nm) and UVB (280-315nm), the wall plug efficiency of LEDs is below 1%, whereas the wall plug efficiency of fluorescent lamps is close to 20% or even higher. In other words, the wall plug efficiency of current LED phosphors is not comparable.
- **Effectiveness in terms of photo-therapeutic effect**: Currently, for PUVA phototherapy applications, there are no test results available related to the effectiveness of equipment using LEDs to reach the desired effect in patients.

[79] Op. cit. LEU (2015a)
[80] Op. cit. LEU (2015a)

Once an LED alternative candidate is to be identified, such research would need to be performed to establish comparability.

- **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 at present for other lamp technologies.

Though LEU[81] admits that UVA LEDs are available from several suppliers, it is further explained that their efficiency is very low and that no publicly available roadmaps exist that predict when UVA LEDs with acceptable output and efficiency shall become available. Nonetheless, this is said to be a precondition for design and development of LED based equipment and subsequently for the beginning of customer/patient clinical studies.

5.3.3 Environmental Arguments

According to LEU[82], there are no statistical data available specific to the Life Cycle Analysis of UVA phototherapy 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.

UVA phototherapy 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). [83]

LEU[84] later explained that the lamps are mainly installed and replaced by professional installers and thus should not end up in medical waste streams. The installers are instructed to recycle the spent lamps according to the WEEE Directives. The lamps are collected separately from general household waste stream and in this sense should not end up in the household waste stream. The lamps are expected to be recycled as normal low pressure fluorescent lamps and are labelled accordingly for recycling.

5.3.4 Socio-economic Impact of Substitution

LEU[85] explains the function of lead as an activator of the phosphor in these lamps to allow the transmission of the specific wavelengths of light to be emitted in the most effective form for its purpose, which is not achievable with other phosphor types or

[81] Op. cit. LEU (2015a)
[82] Op. cit. LEU (2015a)
[83] Op. cit. LEU (2015a)
[84] Op. cit. LEU (2015a)
[85] Op. cit. LEU (2015a)

other technologies. 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 phototherapy patients that rely on this treatment and do not benefit from other forms of phototherapy products which do not contain lead activators in the specific phosphors. 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[86] claims that there are certain socio-economic impacts that could result from the substitution of lead in this application. Among others it is expected that even if UVA LEDs become available with feasible specifications, PUVA phototherapy equipment shall become much more expensive. It will become therefore an economically unattractive solution that will have significant impact on patients' lives. Furthermore the possibility for lead free technology for these lamps is said not to be feasible for replacement 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 and PUVA phototherapy phosphors are lead activated.

5.3.5 Road Map to Substitution

Summarising the information in the sections above, though information has been provided as to possible candidate alternatives to be developed in the future, at present LEU explains these technologies to require both further development and sufficient clinical studies with patients to evaluate comparability. This is said to require in the first stage development of alternative light sources and as a second stage the possible development of new PUVA equipment. LEU did not provide information as to the possible stages of such developments, neither as to their possible timelines.

5.4 Stakeholder Contributions

Contributions were not submitted to the stakeholder consultation concerning this request for exemption.

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

5.5 Critical Review

5.5.1 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 medical therapy, 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[87] 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[88]. Nonetheless, at present, 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.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status December 2015).

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.

5.5.2 Scientific and Technical Practicability of Substitution

LEU explains that lead in BSP lamp types used for phototherapy applications currently cannot be substituted or eliminated. In general, it is understood that there are different types of phototherapy technologies (e.g., PUVA, narrowband UVB), however for a

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

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

substantial group of patients PUVA phototherapy is the only effective treatment therapy available. 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. 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 such as the BSP lamps. The change of spectral output is explained to possibly result in larger negative health impacts such as erythema and NMSC (non-melanoma skin cancer), considered to be side effects of Phototherapy. 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. This is also explained to be the reason why clinical trials were not performed for YPO lamp based equipment. From the original evaluation of the Therakos request that led to Ex. 34, it is also understood that other phosphor compositions that have 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 available. Though such lamps are currently not available for use in phototherapy 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.

5.5.3 Environmental Arguments

LEU provide 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.

5.5.4 Socio-Economic Arguments

LEU mention 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 5.5.2. A further aspect raised in this regard is that BSP lamp types have been tested, studied and regulated in the EU for many years and changes to these products would be very time consuming as clinical testing and recertification processes would

need to be repeated for various lamps and fixtures. It can also be understood that the fact that EU regulation specifically addresses BSP lamp types, whereas alternatives are not addressed, would not allow placing such alternatives on the market in relevant applications. Though the consultants' can follow that until such regulation is updated, approbation of new lamps and equipment would not be possible, this can only be viewed as an obstacle that would require updating of standards and regulation. This could delay the coming of equipment using alternatives on the market, but cannot be considered an argument as to why alternatives could not become available in the future.

Furthermore, LEU claim 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 and subsequently for consumers (medical facilities) and patients. In this respect LEU[89] mentions that:

- **PUVA phototherapy equipment shall become much more expensive having a significant impact on patients' lives** – in the consultants' view it is difficult to estimate what costs this 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 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. In parallel, 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 scientific and clinical evaluations would need to be performed for every type of fixture or appliance, resulting in an economic burden for small business owners (e.g., dermatologists). 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

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

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.

5.5.5 Stakeholder Contributions

Contributions were not submitted to the stakeholder consultation concerning this request for exemption. However, since one of the proposals of LEU is to amend the current Ex. 34 of Annex IV of the Directive, an effort was made to contact Therakos Photopheresis, who had originally requested that the exemption be granted to allow the use of Pb in BSP lamps used in their extracorporeal photopheresis equipment. Therakos were asked to clarify whether the suggested formulation "*Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis- and phototherapy lamps containing BSP (BaSi2O5 :Pb)*" was suitable in the sense that it would continue to benefit their equipment. Therakos[90] has responded, proposing that, should an amendment be considered, that the exemption be reformulated as follows:

"*Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal Photopheresis and Photopheresis lamps containing BSP (BaSi2O5:Pb)*"

5.5.6 The Scope and Duration of the Exemption

LEU have requested the exemption for medical equipment and propose to either amend the current exemption 34 of Annex IV or to add a new exemption to this annex in light of the affinity to Cat. 8 equipment. Nonetheless, if an exemption is to be approved, in the consultants' view, it should be taken into consideration, whether a single exemption could be formulated to cover all medical equipment applications, as well as tanning equipment applications. There are a few aspects that should be kept in mind in this regard.

- The first relates to the general discussion, whether lamps are to be considered to fall under Cat. 5, regardless of the equipment in which they are used. The consultants' are not aware of any legal interpretation for this aspect. However, it can be followed that if a product is used exclusively in a specific type of equipment, that there would at least be a relation between the design cycles of such equipment and the time needed to implement alternatives into such equipment, i.e. the time needed for redesign where alternatives are not drop-in and for completing reliability testing and recertification where it is required.
- In this respect, a key aspect is whether a distinction can be made between similar applications (in this case BSP lamps) used for different types of

[90] Therakos (2015), Answers to clarification question concerning Ex. 34 wording formulation, sent per e-mail 11.12.2015

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. Otherwise, the article could be manufactured for equipment of a specific category (e.g. Cat. 8) and could continue to be applied in equipment of other categories (e.g. Cat. 6), even should the parallel exemption (e.g. for Cat 5 EEE) expire. In this respect, LEU[91] explains some of the differences between BSP lamps used for medical applications and for tanning applications as follows: "*The tanning lamps and the medical lamps use similar lead activated BSP type phosphors, with small differences in the spectrum (a small amount of other phosphors) but clearly different in lamp wattage meaning different lengths of the tube and designed for instance with a different glass type. The equipment for phototherapy is designed and approved and certified for specifically designed lamps with a dedicated spectrum (based on BSP type phosphors) and it is not allowed to use other lamp types / phosphors in this equipment. A lamp designed and labelled for sun tanning use shall not be used for medical use. Vice versa, a lamp designed and labelled for medical use shall not be used for sun tanning*". In contrast however, from a LEU document submitted by LEU in relation to the Ex. 18b evaluation which is still in progress, the opposite is stated. LEU[92] contends 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 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".*

- Finally the last issue relates to the prospect of future evaluations. As Article 5 requires that exemptions be granted for a finite time, setting maximum validity periods for various categories, it is understood that as long as substitutes are not developed, that exemptions concerning a certain application would be evaluated from time to time. Where the maximum validity periods of equipment (categories) may differ, in the consultants' view, it would still be recommended to specify the validity periods granted to different categories, so that mutual evaluations could be performed in the

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

[92] LEU (2015c), LightingEurope, Answers to 1st Questionnaire Exemption No. 18b (renewal request), submitted 28.08.2015 and 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

future. This would save the Commission resources, but more importantly, should a substitute become available to applications of one kind, it would be relevant to directly investigate their compatibility with other equipment and possible influences on further renewals of exemptions.

To further clarify the exclusivity aspect, both LEU and Therakos Photopheresis were asked to provide further information.

LEU[93] 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. 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 5-4: Warning text, equivalency code and marking examples for lamps

Warning text on tanning lamps	Equivalency code on tanning lamps	Warning text on medical lamps
Sunlamp - **DANGER**.Ultraviolet radiation. Follow instructions. Use **ONLY** in fixture equipped with a timer.	180-R-36/2,4	**WARNING: Medical UV lamp. Use only in certified medical devices! Use protective eyewear.**

Tanning lamp marking	Medical lamp 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	**WIDE BAND PUVA 100W** **WARNING: Medical UV lamp. Use only in certified medical devices! Use protective eyewear.**

Source: Op. cit. LEU (2016a)

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

Nonetheless, when asked whether some BSP lamps were sold on the open market (i.e. accessible to private consumers, LEU[94] 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".

Mallinckrodt Pharmaceuticals (formerly Therakos, Inc.) provided the following response: Lamps used for the Therakos Extracorpereal Photopheresis may fit into other fixtures that would have the same lamp configuration in terms of lamp length, bi-pin configuration. However, depending on the power supply furnished and how the circuit is configured, they may not be able to be lit. A total of 18 lamps are used in the Therakos Extracorpereal Photopheresis finished UV device. In the device, the lamps are configured to custom ballasts to deliver the required output. [95]

Mallinckrodt[96] further explained that the UV bulbs made specifically for Therakos (per Therakos specifications) are permanently soldered together into an assembly (light box assembly) for specific use in Therakos instruments. These bulbs are not available individually (only available in the unique assembly) and are stamped with Therakos' "UVAR" registered trademark. UVAR® lamps are not available to anyone but Therakos and are never sold individually (see Figure 5-5 below). However, if an individual UVAR® bulb were to get illegally into the market, it is perceivable that the lamp could be placed into a piece of equipment (with the correct power requirements) to produce UV light or be used in other Photopheresis equipment. In order for Photopheresis to be effective, human white cells must be exposed to a specific amount of UV energy. Too much energy and too little energy applied to the cells will result in ineffective therapy. Therakos developed a proprietary algorithm to control this energy effectively.

[94] LEU (2016b), LightingEurope, Answers to 3rd Questionnaire Exemption No. 18b (renewal request), submitted 27.01.2016 per e-mail.

[95] Mallinckrodt (2015), Mallinckrodt Pharmaceuticals, Answer to 1st Questionnaire Regarding Exclusivity of Therakos Extracorpereal Photopheresis Lamps, submitted 14.12.2015 per e-mail

[96] Mallinckrodt (2016), Mallinckrodt Pharmaceuticals, Answer to 2nd Questionnaire Regarding Exclusivity of Therakos Extracorpereal Photopheresis Lamps, submitted 25.01.2016 per e-mail

Figure 5-5: UVAR® lamp assembly for Therakos device

Source: Ob. Cit. Mallinckrodt (2016)

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. The Therakos lamp assembly is an exception to this rule as it is understood to be sold as part of a fixed assembly. Though one could take the assembly apart in theory, it can be followed that it would be unlikely to come across such an assembly on the open market. In contrast, 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 confirm that private consumers could have access to some lamps as is also apparent from searching the internet in this respect[97]. This can also be followed as it is understood that equipment both for tanning and for medical phototherapy can be purchased by private consumers.

As the technology is the same, it is assumed that once substitutes are found, that their applicability would be relevant for all types of equipment. In this respect the consultants conclude that merging the current request with Ex. 18b would be beneficial in terms of preventing multiple exemptions for very similar applications. Though extracorporeal medical applications could be merged with this exemption for the sake of simplicity and

[97] See for example: http://www.uvee.be/puva-uvb-lamps

to ensure mutual evaluations in the future, this aspect could also be taken into consideration during the next evaluation.

Even should the exemption not be merged with Ex. 18b, it would be recommended to align the expiration dates of all BSP exemptions with the duration of Ex. 34 of Annex IV, to ensure that the next review coincides; this despite the possibility of granting exemptions for medical devices for a period of up to 7 years.

5.5.7 Exemption Wording Formulation

LEU requests either a new exemption or an amendment of Ex. 34 to incorporate phototherapy lamps into the scope of Ex. 34. It should also be considered whether to merge the requested exemption with Ex. 18b, should it be decided to renew this exemption (evaluation is still ongoing). Both the medical applications are understood to require the use of BSP lamps for treatment of various skin conditions. The main difference is understood to be that in phototherapy the patient is treated with light, whereas in the equipment of Therakos, the medical procedure is external to the body – blood is extracted, treated with light and reinjected (see original application and evaluation report referenced in footnote 62).

Despite the possibility of a mutual exemption for medical applications, the consultants are concerned that some lamps could be interchangeable between phototherapy equipment and tanning equipment. In contrast, it is understood that extracorporeal photopheresis equipment uses a lamp assembly unique to this equipment. On this basis the consultants would suggest not to amend Ex. 34, but to add an entry to Ex. 18b or to reformulate the exemption to address both application types, this being under the assumption that Ex. 18b is to be renewed. As in the future, when substitutes are found, the implementation time between categories could differ, medical and tanning applications could still be separated through different items; however exemption durations should be adapted to ensure mutual evaluations. Furthermore, the aspect of articles that can be used exclusively in one area of application (e.g., medical and tanning) should be reviewed in more detail in future evaluations.

5.5.8 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 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 as a positive evaluation of Ex. 18b could result in the same expiration date, the consultants would recommend that should an exemption be approved for phototherapy applications, that its validity be aligned with this date, regardless of if the exemption is a new one or if it is merged with one of the existing ones.

5.6 Recommendation

It is recommended to grant the requested exemption. In the consultants view an amendment of Ex. 34 should be avoided and it would be recommended to add the following exemption to ex. 18b in Annex III, assuming that this exemption shall be renewed, with the following formulation:

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* II. *in category 8 medical phototherapy equipment – excluding applications falling under point 34 of Annex IV*	For Cat. 5: 21 July 2021

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, as in the evaluation of the current request and 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 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

Should Ex. 18b not be renewed the following exemption could be granted and added to annex III of the Directive.

Exemption formulation	**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 in Annex I category 8 medical phototherapy equipment – excluding applications falling under point 34 of Annex IV	For Cat. 5: 21 July 2021

The consultants recommend the next review to be performed along with the review of all other exemptions for BSP applications (Annex III Ex. 18b (I-II) and Annex IV Ex. 34), assuming applicants request the renewal of these exemptions.

5.7 References Exemption Request 2015-3

LEU (2015a) LightingEurope, Request for an Exemption for phototherapy lamps 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 phototherapy lamps containing phosphors such as BSP (BaSi2O5 :Pb), submitted 16.1.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-3/UV_Medical_LE_RoHS_Exemption_Req_Final.pdf

LEU (2015b) LightingEurope, Answers to 1st Clarification Questions, submitted 27.3.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-3/Oko_Ex_Re_2015_3_Answers_2_Clarification_Questions_20150327_final.pdf

LEU (2015c) LightingEurope, Answers to 1st Questionnaire Exemption No. 18b (renewal request), submitted 28.8.2015 and 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 e-mail.

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