Clarification Questionnaire for BSP Lamp Exemptions:

Exemption 18(b), Annex III for "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)"

Exemption 18(b)-I, Annex III for "Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP ($BaSi_2O_5$:Pb) when used in medical phototherapy equipment"

Exemption 34, Annex IV for "Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis (ECP) lamps containing BSP ($BaSi_2O_5$:Pb) phosphors"

Abbreviations and Definitions

ECP	Extracorporeal Photopheresis
EEE	Electrical and Electronic Equipment
ESA	European Sunlight Association
LE	LightingEurope
NMSC	Non-melanoma skin cancer
Pb	Lead
PUVA	Psoralen and ultraviolet A (ultraviolet light therapy)
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment

Background

The Oeko-Institut has been appointed by the European Commission, within a framework contract[1], for the evaluation of applications for exemption from Directive 2011/65/EU (RoHS), to be listed in Annexes III and IV of the Directive.

LightingEurope (LE) with the support of the European Sunlight Association (ESA) and additional information provided by Mallinckrodt Pharmaceuticals c/o Therakos, Inc. submitted a request for the renewal of the three exemptions mentioned above, which has been subject to an initial evaluation. A summary of the main argumentation for justifying the request is provided below as a first basis to be used in the stakeholder consultation planned as part of this assessment.

Please read the summary of the argumentation provided to ensure that your line of argumentation has been understood correctly and provide answers to the questions that follow that address aspects requiring additional information and/or clarification.

[1] The contract is implemented through Framework Contract No. ENV.B.3/FRA/2019/0017, led by Ramboll Deutschland GmbH.

1. Summary of argumentation of applicant on the justification of the exemption

1.1. Background

Lead is used in the phosphor of tanning, phototherapy and extracorporeal photopheresis (ECP) lamps to produce UV radiation. The lead activator is required to allow the barium silicate phosphor to fluorescein the designated wavelength. 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, phototherapy and ECP lamps are in the UVA and UVB regions or 290-400nm. Lead is the primary activator for the barium silicate phosphors to fluoresce and is used in over 95% of the indoor low-pressure mercury vapour fluorescent lamps. Despite intensive research, no alternative substance has yet been found that leads to a compatible light spectrum. LED lamps are also currently ruled out as an alternative technology for several reasons.

Lighting Europe (LE) thus requests the renewal of the three exemptions referring to the existing wording in the section "Reason for application” of their request. In deviation from this, in the section “Summary of the exemption request” of the application LE requests `*the incorporation of Annex III Exemption 18(b)1 and Annex IV Exemption 34 for these three applications of “Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb)”*.[2]

The renewal is requested for the maximum validity period.

1.2. Volume of lead as activator in the fluorescent powder in the exemptions at hand

According to the applicant, there is no published data on lamps imported into the EU, neither for tanning lamps nor for those used for medical and phototherapeutic purposes. Based on market estimates, the maximum amounts of lead placed on the EU market through these applications are estimated as follows:

- Sun tanning lamps (Annex III, Ex. 18b): 190 kg lead p.a.
- Medical lamps (Annex III, Ex. 18(b)-I and Annex IV Ex. 34): 2.5 kg lead p.a.

Compared to the quantity in the request for extension of the exemption from 2015, the quantity is explained to be slightly decreasing.

1.3. Technical description

In all three exemptions requested for renewal, lead has the same functionality: As a component of the phosphors with a weight share of less than 1%, it serves as an activator 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 and phototherapy and ECP lamps are in the UVA and UVB regions or 290-400nm. Lead is the primary activator for the barium silicate phosphors to fluoresce and is used in over 95% of the indoor low-pressure mercury

[2] To resolve this ambiguity, see clarification questions.

vapour fluorescent lamps used for tanning and certain medical applications. The three exemptions differ with regard to the application areas of the lamps:

- **Annex III, 18b** covers indoor sun tanning discharge lamps, which produce UVA and UVB in predetermined dosages and ratios for the purpose of producing artificial sunlight. Indoor tanning lamps are light sources that produce ultraviolet light in the regions of the UVA and UVB spectrums. Their intent is to produce artificial sunlight to replicate sunlight exposure for the human body (similar to that as produced by the sun) yet applied in calculated doses per European regulations. It is estimated that over 90% of indoor tanning lamps produced and used throughout Europe are manufactured with BSP ($BaSi_2O_5$:Pb) phosphors containing 1% or less lead as an activator. The lamps are installed in various commercial and residential indoor tanning equipment which can be in the form of a tanning bed or booth or a tabletop appliance for facial tanning. The typical lifetime of these lamps ranges from 600 to 1000 hours with a session or usage time that ranges approximately from 5-30 minutes. The applicant assumes that market demand for tanning lamps will be stable for the coming years.
- **Annex III, 18(b)1** covers UV discharge lamps which are used for (medical) skin treatment such as PUVA phototherapy purposes. PUVA phototherapy is a very specific application enabling effective skin treatments used in medical applications. BSP phosphors have been used in lamps and devices for PUVA phototherapy for more than 25 years. According to the applicant, there is extensive literature on the effectiveness of PUVA phototherapy with lamps containing BSP. No studies have been conducted with effective results using fluorescent lamps with other phosphors or other technologies (LED) that emit UVA/UVB spectra. The release and approval of PUVA devices was always based on extensive patient testing with lamps containing BSP. The lamps are installed in dedicated phototherapy equipment. 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. The typical lifetime of these lamps ranges from 600 to 1000 hours with a session time that ranges approximately from 5-30 minutes. The applicant assumes that market demand for PUVA phototherapy lamps will be stable for the coming years.
- **Annex IV, 34** was previously requested by Therakos, Inc. for the use of lead activated phosphors in the lamps used in their Extracorporeal Photopheresis (ECP) equipment. The treatment involves exposure of leukocytes, that are temporarily removed from the patient's blood, to light from lamps with lead doped barium silicate phosphor. The light activates a drug which has been introduced into the leukocyte fraction of the blood. This type of phosphor emits a unique spectrum that is optimum for this medical treatment.

1.4. Applicant's justification for the requested exemption

The applicant justifies the requests for exemption essentially on the basis of technical aspects that are decisive for the fact that no adequate alternative substances are available that fulfil all the required properties, especially with regard to spectrum incompatibility when substituting lead in the fluorescent powder and with regard to UVA LED-Technology. In addition, socio-economic impacts are detailed that relate to the case that an exemption renewal is not granted.

1.4.1. Availability of alternatives (Substitution or Elimination, roadmap to substitution, reliability of substitutes)

With regard to the availability of substitutes at substance level, the applicant concludes that only Ce doped YPO phosphor comes close to lead in the fluorescent powder. Based on measurement results

of the emission spectrum of UV lamps doped with Ce doped phosphor, the applicant draws the following conclusions:

- 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.
- Therefore, the Cerium based material has a lower expected treatment effectiveness, with regard to Erythema and NMSC (non-melanoma skin cancer).

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

From the applicant's point of view, spectral incompatibility has also led to a lack of interest on the part of the medical community. Therefore, no adequate tests and clinical studies have been set up on patients to prove the effectiveness from Ce doped YPO phosphor for PUVA phototherapy and no approvals for such equipment exist. Therefore, this Ce-based material is not allowed for use in medical applications.

The applicant sees an additional problem with Ce-doped phosphors due to the variations in UV output over the lamp length due to the coating thickness. When fluorescent lamps are coated with a phosphor, the thickness of the coating varies over the length of the lamp. For current UV-fluorescent coatings used, like BSP, the thickness variations do not lead to a severe inhomogeneous output. However, for cerium doped phosphor this thickness difference leads to unacceptable UV output variations which will affect the skin treatment effectiveness.

On the technological level of alternatives, the applicant only considers LED technology, as other technologies (OLED, incandescent, halogen) do not radiate in the UVA spectrum. LED technology is currently not applicable as an alternative technology on the basis of an assessment against three criteria:

- The **Wall Plug Efficiency** is too low regarding wavelengths below 380 nm. In the UVC (100-280nm) and UVB (280-315nm), the WPE (wall plug efficiency) of LEDs are now close to 1%, where the wall plug efficiency of fluorescent lamps are close to 20% or even higher.
- **Effectiveness:**
  - For tanning applications, no test results are available yet regarding effectiveness in reaching the desired effect in a comparison study between equipment using fluorescent lamps and equipment using LEDs. For most of these applications that is not done yet as no LEDs were available. Hence effectiveness data are not available.
  - For PUVA phototherapy applications no test results are available yet regarding patient effectiveness to reach the desired effect in a comparison study between equipment using fluorescent lamps and equipment using LEDs. For most of these applications that is not done yet as no promising LEDs were available. Therefore, effectiveness data are not available.
- **Regulation / Approval:** CE conformity and other European directives for special purpose applications (like for instance approval of medical devices for phototherapy and CE regulations on

tanning lamps (CE 60335-2-27)) is based on fluorescent discharge lamps (with respect to safety and system responsibility). No CE conformity is available for other lamp technologies.

With regard to future trends of substitution by LED technology, the applicant states that LEDs are available for other UVA applications. In contrast, he considers the development in tanning to be limited and it is impossible to predict at this stage if and when LED-based UVA devices will be feasible. Some UVA applications are already being converted to LEDs, but for medical applications, developments are limited. It is impossible to predict at the moment if and when UVA LED-based devices will be feasible, but the patient testing and approval process would take a very long time. Therefore, an extension with the maximum validity period is requested.

1.4.2. Environmental and health arguments (also LCA aspects)

With regard to health and safety impacts of substitutes the applicant concludes that the fluorescent tanning lamps in use today have undergone extensive testing and calibration in the equipment. 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, the effects on health and safety will have to be investigated.

1.4.3. Socioeconomic impacts

In the absence of reliable substitutes, from the applicant's point of view, a non-renewal of the exemption would shut down the **tanning industry** in Europe. It would have to be taken into account that almost 100% of these lamps used in Europe are manufactured in Europe by fluorescent lamp companies and that almost 100% of indoor tanning devices sold in Europe are manufactured in Europe. It is also estimated that almost 100% of tanning lamps sold as aftermarket lamps are sold by manufacturers or distributors in Europe, that over 90% of tanning lamps used in the US are manufactured in Europe and that over 75% of tanning devices sold in the US are manufactured in Europe.

In view of the **medical applications** and the fact that there are no reliable substitute products, the applicant sees the following impact on patients: Patients in Europe who require PUVA phototherapy will be left without appropriate treatment if the extension of the phototherapy exemption is not approved. It is estimated that almost 100% of these lamps used in Europe and even around the world are manufactured in Europe by fluorescent lamp companies. It is estimated that almost 80% of phototherapy devices sold in Europe are manufactured in Europe.

2. Clarification Questions

Please find below the answers provided by LightingEurope.

1. In section 2 of your application, you propose a continuation of the exemption with the existing wording. In section 3, on the other hand, you propose the following: `*In order to avoid ambiguity or repetition in the application for exemptions renewals and in further consideration of the extremely small volume of lamps entering the EU and their total lead content in Annex IV products, Lighting Europe requests and recommends the incorporation of Annex III Exemption 18(b)1 and Annex IV Exemption 34 for these three applications of "Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb)"´*.
   Please clarify what is meant. Should exemption Annex III 18(b)-I and Annex IV 34 in future be combined in a single exemption in Annex IV for all "*three applications*"? Please provide

exemption formulations for all exemptions you request to be available for BSP lamps in the future, specifying for which applications they are to be available and in which RoHS annex they should be listed.

LightingEurope would like to clarify that the renewal application indeed requests to combine the three applications into a single exemption. The proposed exemption wording/formulations are found on page 5 of the application we submitted in January 2020. The exemption formulations for the BSP phosphor for lamps in 18(b); 18(b)1 and Annex 34 have not changed. The recommendation to combine the exemptions is for ease of reference for authorities when reviewing and managing the requests as well as the manufacturers and users of those products in following the proper exemption number and responsibilities. As the lamps included in RoHS Annex III 18(b)I and in Annex IV exemption 34 are both used in medical equipment, LightingEurope recommended this combined request for efficiency. The Annex IV exemption 34 product is a proprietary phosphor mix using BSP phosphor which has not changed since the current exemption was granted. Exemption 18(b) should remain in Annex III as proposed and requested.

2. Your application contains some graphical representations of measurement results on lamps. However, there is no information on who and when these results were measured, under which conditions and from which types of lamps. Please provide the corresponding source information for the graphs and tables.

We would like to explain that:

- The spectrum displayed in the figure on page 8 is from a Philips Lamp produced by Signify: the lamp type is UVA TL, the exact type is F71T12 UVA 100W.
- The graph on page 9 is from a cooperation between the Philips/Signify and medical experts in a hospital in the Netherlands.
- Page 9 and 20 graph data source is the Lighttech Accredited Measurement Laboratory in accordance with the lamp measurements method of IEC61228.

3. Graph on page 8: How is the ordinate (i.e. the y-axis) defined here?

The vertical axis is the relative intensity, as a function of wavelength, it is intended to show the shape of the spectrum. The intensity can be made quantitative in the following way: the total integrated amount of radiation in this UV-A band is 27.5W after a stabilisation time of 100 hours with this number the vertical axes can be scaled. This is from a lamp that used 100W. Details can be found in the product leaflet here – link. For the y-axis, please use “relative UV irradiance”.

4. In section 4.1.3 you mention, that “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.” Which phosphor with which doping is used for the remaining 10%?

Only one alternative material comes close: Ce doped YPO phosphor. Please see pages 19, 20, 21 Section 6.1.1 for the spectrum of Ce doped YPO phosphor in comparison to BSP. These pages illustrate the phosphor types comparison of lead-activated vs. non-lead activated demonstrating outputs over the relevant nm wavelengths. The main non-lead activated phosphor uses Cerium as an activator, but it might be that there are others too. The “other” non-lead activated phosphor is used for the small percentage of lamps in equipment that is validated and listed for new and replacement use.

5. Your application contains different assumptions about future market developments. While you state "*The market demand for tanning lamps remains stable for the coming years*" in view of exemption 18b on page 10 above, section 4.2.4 forecasts a decrease in the market. We ask you to clarify the facts.

We would like to clarify that page 10 refers to exemption 18(b)1 which is lamps for medical photo-therapy equipment. The statement that this market remains stable is correct.

The reference to the last sentence on page 9 should not have been included in 18(b)1 as it relates to tanning lamps.

However, for clarification purposes, although there are no accurate published numbers for this niche market, according to confidential numbers reported to LightingEurope by its members, it was estimated that the tanning market for the period 2015-2019 had declined. Additionally, LightingEurope members estimate that the market will remain flat or will continue to slightly decline in the coming years.

6. Table 1 on page 21, section 6.1.2: Can you please explain the designations “1 P” to “10 P” in the left column? Are these measuring points? Here again please provide the corresponding source information for the table.

The designations refer to the 10 individual prototype lamps prepared for these measurements. These prototype lamps were made during the development of these lamps at the company Philips (now Signify).

7. Figure 1 on page 25, section 6.2.1.2: How is the ordinate (i.e. the y-axis) defined here?

To make a fair comparison of the shapes of the spectra, the graphs of the UV LED and of the fluorescent lamps are scaled in such a way that the surface under the graphs is the same. The vertical axis is now a relative intensity of the radiation. The graph indicates that the spectrum of the UV-B LED is much wider and produces light at wavelengths where it damages the human skin. Please use “UV irradiance in W/m2” for the y-axis.

8. In section 6.2.3.3 you expect, 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 this can have a significant impact on the application*.” Please support this statement with concrete cost data (or cost estimations).

LightingEurope members do not have concrete cost data on the cost of substantially equivalent UV-A LED tubular lamps that match the output spectrums of tanning and/or medical lamps. To the best of our knowledge there are no LED tubular replacement tanning lamps. There are some available UV-A LEDs on the market used for other applications. The market data for these seems to indicate a minimum of 5-10 x higher cost per watt plus other associated costs for equipment redesign.

9. Further in the same section you state “*It could 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.*” Does this statement refer to the replacement of lead in the phosphors or to the switch to LED technology?

We would like to clarify that this statement refers to the socio-economic impact of a change to non-lead activated phosphors in low-pressure tanning lamps.

10. Section 6.2.4: Here you mention that "*some other UVA applications are already switching to LEDs but on medical application the developments are limited*". Can you explain in more detail the reasons for this?

Medical photo-therapy equipment requires patient clinical testing and approval processes before a change can be made or a new device is approved for use. At the time of writing, LightingEurope members are unaware of developments in UV-A LEDs in the medical fields using the lamps in 18(b)1. The first UV-A LEDs are used successfully in situations where only a small amount of UV-A is needed e.g. for checking if banknotes are genuine. This has lead to acceptable priced solutions.

11. Furthermore, you state in the same section "… *however the patient tests and approval process would take a very long period*". Can you please describe the required timeframe in more detail, with milestones if necessary?

We would like to refer to the same answer as above in question 10, as well as page 12 of the original request for exemption 34 of Annex IV which includes a possible timetable that still applies (link). LightingEurope lamp manufacturing members are not directly involved in the clinical testing and development of such equipment and it is the equipment that becomes certified with a designated lamp. If in fact a medical equipment manufacturer wanted to design new equipment with an LED light source, they could work with an LED producer to match a particular wavelength or design to a particular wavelength or use multiple LEDs for a band of wavelengths. This could be part of a LED component development process followed by the patient studies, but all of this becomes very specific to the treatment protocol. The costs for LED development and production for specific wavelengths will also depend on quantities to be produced and unlike general lighting, these special applications are for niche market applications where the quantities are low and unit costs are high.

In case parts of your contribution are confidential, please provide your contribution in two versions (public /confidential). Please also note, however, that requested exemptions cannot be granted based on confidential information!

Finally, please do not forget to provide your contact details (Name, Organisation, e-mail and phone number) so that Oeko-Institut can contact you in case there are questions concerning your contribution.