Consultation 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. The applicants have been requested to answer additional questions and to provide additional information, available on the request webpage of the stakeholder consultation (http://rohs.exemptions.oeko.info/index.php?id=370).

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

For further details, please check the applicant's exemption request under the above link.

The objective of this consultation and the review process is to collect and to evaluate information and evidence according to the criteria listed in Art. 5 (1) (a) of Directive 2011/65/EU (RoHS 2), which can be found under:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT

If you intend to contribute to the stakeholder consultation, please read the summary of the argumentation provided and answer the questions that follow.

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)"*´.

In view of this inconsistency, the applicant was asked to clarify whether the existing three exemptions should indeed be bundled into a single, reformulated exemption - including the wording and indication of the relevant annex to the RoHS Directive. The applicant provided the following clarification:

"*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*[2]*. 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] Adding of the consultant "Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb)"

The renewal is requested for the maximum validity period.

1.2. Volume of lead bound in crystal glass to be placed on the EU market through the exemption

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. When asked, the applicant explained this statement as follows: "…*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*".

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 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.

With regard to the applicant`s statement 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*." the applicant details on request the situation as follows: "*LightingEurope members do not have concrete cost data on the cost of substantially equivalent UVA 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"*.

2. Questions for stakeholders

1. The applicants requested an exemption, proposing the following wording formulation:
   "Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb)"

   a. Do you agree with the applicant's proposal combine the three applications into a single exemption?

   b. Do you agree with the scope of the exemption as proposed by the applicant?

   c. Please suggest an alternative wording and explain your proposal, if you do not agree with the proposed exemption wording.

   d. Please explain why you either support the applicant's request or object to it. To support your views, please provide detailed technical argumentation / evidence in line with the criteria in Art. 5(1)(a) to support your statement.

2. Please provide information concerning possible substitutes or developments that may enable reduction, substitution or elimination, at present or in the future, of *"Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb)"*;

a. In this regard, please provide information as to alternatives that may cover part or all of the applicability range of *"*Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb)*"*;

b. Please provide quantitative data as to application specifications to support your view.

3. Please provide information as to research initiatives which are currently looking into the development of possible alternatives for some or all of the application range of *"Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb)"*.

   a. Please explain what part of the application range is of relevance for such initiatives (in what applications substitution may be possible in the future).

   b. Please provide a roadmap of such on-going research (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages.

4. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, please provide details in respect of the following:

   a. Please estimate possible amounts of waste to be generated through a forced substitution should the exemption not be granted. In this respect, please clarify whether devices placed on the market before the 22 July 2021 could still be serviced through the spare parts provision stipulated in the Directive under Article 4.

   b. Please estimate possible impacts on employment in total, in the EU and outside the EU, should the exemption not be granted. Please detail the main sectors in which possible impacts are expected – manufacture, supply chain, retail, etc.

   c. Please estimate additional costs associated with a forced substitution should the exemption not be granted, and how this is divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers, end-users).

5. Please provide any further information and/or data that you think is of importance to substantiate your views.

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.