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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We would like to express our gratitude towards stakeholders who have taken an active role in the contribution of information concerning the requests for exemption handled in the course of this project.

Disclaimer:

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

Executive Summary

Under Framework Contract no. ENV.C.2/FRA/2011/0020, a consortium led by Eunomia Research & Consulting was requested by DG Environment of the European Commission to provide technical and scientific support for the evaluation of exemption requests under the new RoHS 2 regime. The work has been undertaken by the Oeko-Institut and Fraunhofer Institute IZM, and has been peer reviewed by Eunomia Research & Consulting.

E.1.0 Background and Objectives

The RoHS Directive 2011/65/EU entered into force on 21 July 2011 and led to the repeal of Directive 2002/95/EC on 3 January 2013. The Directive can be considered to have provided for two regimes under which exemptions could be considered, RoHS 1 (the former Directive 2002/95/EC) and RoHS 2 (the current Directive 2011/65/EU).

- The scope covered by the Directive is now broader as it covers all EEE (as referred to in Articles 2(1) and 3(1));
- The former list of exemptions has been transformed in to Annex III and may be valid for all product categories according to the limitations listed in Article 5(2) of the Directive. Annex IV has been added and lists exemptions specific to categories 8 and 9;
- The RoHS 2 Directive includes the provision that applications for exemptions have to be made in accordance with Annex V. However, even if a number of points are already listed therein, Article 5(8) provides that a harmonised format, as well as comprehensive guidance – taking the situation of SMEs into account – shall be adopted by the Commission; and
- The procedure and criteria for the adaptation to scientific and technical progress have changed and now include some additional conditions and points to be considered. These are detailed below.

The new Directive details the various criteria for the adaptation of its Annexes to scientific and technical progress. Article 5(1)(a) details the various criteria and issues that must be considered for justifying the addition of an exemption to Annexes III and IV:

- The first criterion may be seen as a threshold criterion and cross-refers to the REACH Regulation (1907/2006/EC). An exemption may only be granted if it does not weaken the environmental and health protection afforded by REACH;
- Furthermore, a request for exemption must be found justifiable according to one of the following three conditions:
    - Substitution is scientifically or technically impracticable, meaning that a substitute material, or a substitute for the application in which the

restricted substance is used, is yet to be discovered, developed and, in some cases, approved for use in the specific application;
    - The reliability of a substitute is not ensured, meaning that the probability that EEE using the substitute will perform the required function without failure for a period of time comparable to that of the application in which the original substance is included, is lower than for the application itself;
    - The negative environmental, health and consumer safety impacts of substitution outweigh the benefits thereof.
- Once one of these conditions is fulfilled, the evaluation of exemptions, including an assessment of the duration needed, shall consider the availability of substitutes and the socio-economic impact of substitution, as well as adverse impacts on innovation, and life cycle analysis concerning the overall impacts of the exemption; and
- A new aspect is that all exemptions now need to have an expiry date and that they can only be renewed upon submission of a new application.

Against this background, and taking into account that exemptions falling under the enlarged scope of RoHS 2 can be applied for since the entry into force of the Directive (21.7.2011), the consultants have undertaken evaluation of a range of exemptions in this work (new exemption requests, renewing existing exemptions, amending exemptions or revoking exemptions).

E.2.0 Key Findings – Overview of the Evaluation Results

The exemption requests covered in this project and the applicants concerned, as well as the final recommendations and proposed expiry dates are summarised in Figure E. 1. The reader is referred to the corresponding section of this report for more details on the evaluation results.

The – not legally binding – recommendations for the exemption requests for new exemptions (2015-1 through 2015-2) were submitted to the EU Commission by Oeko-Institut and have already been published at the EU CIRCA website on 19 July 2016. So far, the Commission has not adopted any revision of the Annex to Directive 2011/65/EU based on these recommendations.

Figure E. 1: Overview of the Exemption Requests, Associated Recommendations and Expiry Dates

Ex. Re. No.	Requested Exemption Wording	Applicant	Recommendation	Expiry date
2015-1	Lead in thin film electronic sensor elements such as pyroelectric sensors or piezoelectric sensors	Pyreos Ltd	Exemption suspended	
2015-2	Lead in high voltage cables and cable assemblies for a rated voltage higher than 250kV DC, containing up to 4% lead by weight" (for industrial monitoring and control instruments, Annex IV)	FEI	Exemption denied	
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).	LightingEurope	**Alternative A:** *(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 (BaSi2O5: 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
			Alternative B: 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

Contents

List of Figures

1.0 Introductions

1.1 Project Scope and Methodology

The scope of the project covers the evaluation of three requests for new exemptions. An overview of the exemption requests is given in Figure E. 1 in the Executive Summary.

In the course of the project, a stakeholder consultation was conducted. In agreement with the European Commission, the consultation was performed along with that of three additional requests for new exemptions (known as Pack 7 – originally four requests; however one was withdrawn by the applicant). The stakeholder consultation was launched on 24 April 2015 and held for a period of 8 weeks, thus concluding on 19 June 2015.

The specific project website was used in order to keep stakeholders informed on the progress of work: http://rohs.exemptions.oeko.info. The consultation held during the project was carried out according to the principles and requirements of the European Commission. Stakeholders who had registered at the website were informed through e-mail notifications about new steps within the project.

Information concerning the consultation was provided on the project website, including a general guidance document, the applicants' documents for each of the exemption requests, results of earlier evaluations where relevant, a specific questionnaire and a link to the EU CIRCA website. All non-confidential stakeholder comments, submitted during the consultation, were made available on the RoHS Evaluation website and on the EU CIRCABC website (Communication and Information Resource Centre for Administrations, Businesses and Citizens) [1].

The evaluation of the stakeholder contributions led to further consultation including, inter alia, engaging with stakeholders in further discussion, further exchanges in order to clarify remaining questions, cross-checking with regard to the accuracy of technical arguments, and checks in respect of confidentiality issues.

The requests were evaluated according to the relevant criteria laid down in the RoHS 2 Directive, as shown in the Executive Summary in Section E.1.0. The evaluations of each exemption request appear in the following chapters. The information provided by the applicants and by stakeholders is summarised in the first sections. This includes a general description of the application and requested exemption, a summary of the arguments made for justifying the exemption, information provided concerning possible alternatives and additional aspects raised by the applicants and other stakeholders. In

[1] EU CIRCABC website: https://circabc.europa.eu (Browse categories > European Commission > Environment > RoHS 2014 Evaluations Review, at top left, click on "Library")

some cases, reference is also made to information submitted by applicants and stakeholders in previous evaluations, in cases where a similar request has been reviewed or where a renewal has been requested of a request reviewed in the past. The Critical Review follows these sections, in which the submitted information is discussed, to clarify how the consultants evaluate the various information and what conclusions and recommendations have been made. For more detail, the general requirements for the evaluation of exemption requests may be found in the technical specifications of the project. [2]

1.2 Project Set-up

Assignment of project tasks to Oeko-Institut, started 29 December 2014. The overall project has been led by Carl-Otto Gensch. At Fraunhofer IZM the contact person is Otmar Deubzer. The project team at Oeko-Institut consists of the technical experts Yifaat Baron and Katja Moch. Eunomia, represented by Adrian Gibbs, have the role of ensuring quality management.

[2] Cf. under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_8/RoHS_Pack8_Technical_specifications.pdf

2.0 Links from the Directive to the REACH Regulation

Article 5 of the RoHS 2 Directive 2011/65/EU on "Adaptation of the Annexes to scientific and technical progress" provides for the:

> "*inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV, provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006*".

RoHS 2 does not further elaborate the meaning of this clause.

Regulation (EC) No 1907/2006 regulates the safe use of chemical substances, and is commonly referred to as the REACH Regulation since it deals with **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emical substances. REACH, for its part, addresses substances of concern through processes of authorisation and restriction:

- Substances that may have serious and often irreversible effects on human health and the environment can be added to the candidate list to be identified as Substances of Very High Concern (SVHCs). Following the identification as SVHC, a substance may be included in the Authorisation list, available under Annex XIV of the REACH Regulation: "List of Substances Subject to Authorisation". If a SVHC is placed on the Authorisation list, companies (manufacturers and importers) that wish to continue using it, or continue placing it on the market, must apply for an authorisation for a specified use. Article 22 of the REACH Regulation states that: *"Authorisations for the placing on the market and use should be granted by the Commission only if the risks arising from their use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable."*
- If the use of a substance (or compound) in specific articles, or its placement on the market in a certain form, poses an unacceptable risk to human health and/or to the environment that is not adequately controlled, the European Chemical Agency (ECHA) may restrict its use, or placement on the market. These restrictions are laid down in Annex XVII of the REACH Regulation: "Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Mixtures and Articles". The provisions of the restriction may be made subject to total or partial bans, or other restrictions, based on an assessment of those risks.

The approach adopted in this report is that once a substance has been included into the regulation related to authorization or restriction of substances and articles under REACH,

the environmental and health protection afforded by REACH may be weakened in cases where, an exemption would be granted for these uses under the provisions of RoHS. This is essentially the same approach as has already been adopted for the re-evaluation of some existing RoHS exemptions 7(c)-IV, 30, 31 and 40,[3] as well as for the evaluation of a range of requests assessed through previous projects in respect of RoHS 2.[4] Furthermore, substances for which an authorisation or restriction process is already underway are also reviewed, so that future developments may be considered where relevant.

When evaluating the exemption requests, with regard to REACH compliance, we have checked whether the substance / or its substitutes are:

- on the list of substances proposed for the adoption to the Candidate List (the Registry of Intentions);
- on the list of substances of very high concern (SVHCs- the Candidate List);
- in the recommendations of substances for Annex XIV (recommended to be added to the Authorisation List);
- listed in REACH Annex XIV itself (The Authorization List); or
- listed in REACH Annex XVII (the List of Restrictions).

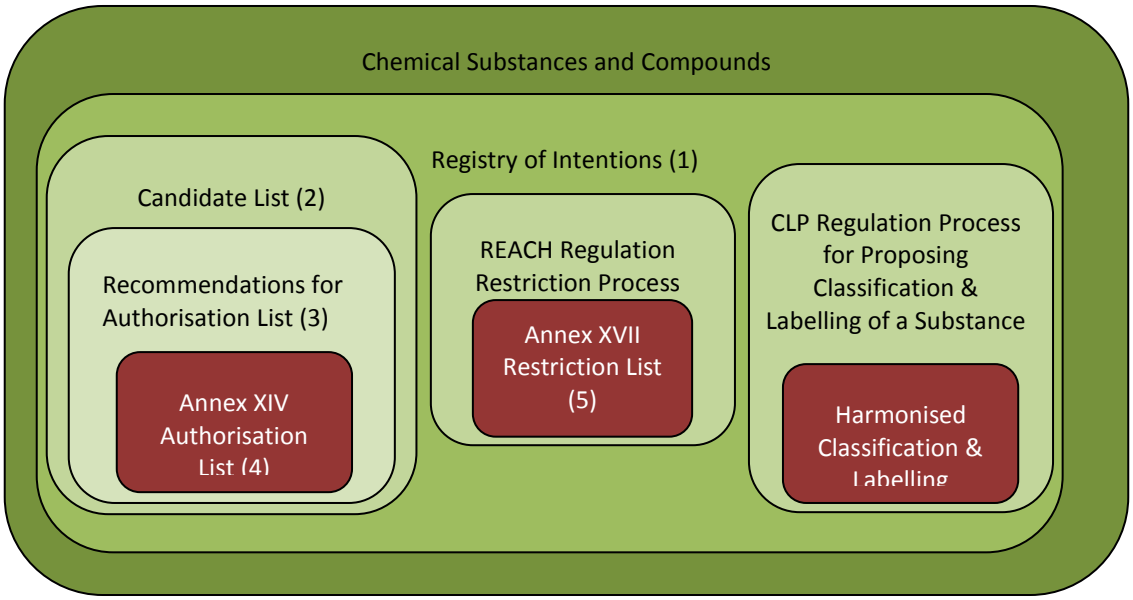
As the European Chemicals Agency (ECHA) is the driving force among regulatory authorities in implementing the EU's chemicals legislation, the ECHA website has been used as the reference point for the aforementioned lists, as well as for the exhaustive register of the Amendments to the REACH Legal Text.

Figure 2-1 shows the relationship between the two processes and categories. Substances included in the red areas may only be used when certain specifications and or conditions are fulfilled.

[3] See Zangl, S.; Blepp, M.; Deubzer, O. (2012) Adaptation to Scientific and Technical Progress under Directive 2011/65/EU - Transferability of previously reviewed exemptions to Annex III of Directive 2011/65/EU, Final Report, Oeko-Institut e. V. and Fraunhofer IZM, February 17, 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Re-evaluations_transfer_RoHS_I_RoHS_II_final.pdf

[4] Gensch, C., Baron, Y., Blepp, M., Deubzer, O., Manhart, A. & Moch, K. (2012) Assistance to the Commission on technological, socio-economic and cost-benefit assessment related to exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive), Final Report, Oeko-Institut e. V. and Fraunhofer IZM, 21.12.2012 http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/RoHS_V_Final_report_12_Dec_2012_final.pdf

Figure 2-1: Relation of REACH Categories and Lists to Other Chemical Substances



The following bullet points explain in detail the above mentioned lists and where they can be accessed:

- Member States Competent Authorities (MSCAs) / the European Chemicals Agency (ECHA), on request by the Commission, may prepare Annex XV dossiers for identification of Substances of Very High Concern (SVHC), Annex XV dossiers for proposing a harmonised Classification and Labelling, or Annex XV dossiers proposing restrictions. The aim of the public Registry of Intentions is to allow interested parties to be aware of the substances for which the authorities intend to submit Annex XV dossiers and, therefore, facilitates timely preparation of the interested parties for commenting later in the process. It is also important to avoid duplication of work and encourage co-operation between Member States when preparing dossiers. Note that the Registry of Intentions is divided into three separate sections: listing new intentions; intentions still subject to the decision making process; and withdrawn intentions. The registry of intentions is available at the ECHA website at: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions;
- The identification of a substance as a Substance of Very High Concern and its inclusion in the Candidate List is the first step in the authorisation procedure. The Candidate List is available at the ECHA website at http://echa.europa.eu/web/guest/candidate-list-table;
- The last step of the procedure, prior to inclusion of a substance into Annex XIV (the Authorisation list), involves ECHA issuing a Recommendation of substances for Annex XIV. The ECHA recommendations for inclusion in the Authorisation List are available at the ECHA website at

http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list;

- Once a decision is made, substances may be added to the Authorisation List available under Annex XIV of the REACH Regulation. The use of substances appearing on this list is prohibited unless an Authorisation for use in a specific application has been approved. The Annex can be found in the consolidated version of the REACH Legal Text (see below);
- In parallel, if a decision is made concerning the Restriction on the use of a substance in a specific article, or concerning the restriction of its provision on the European market, then a restriction is formulated to address the specific terms, and this shall be added to Annex XVII of the REACH Regulation. The Annex can be found in the consolidated version of the REACH Legal Text (see below); and
- As of the 28 of September, 2015, the last amendment of the REACH Legal Text was dated from 28 May 2015 (Commission Regulation (EU) No 2015/830) and so the updated consolidated version of the REACH Legal Text, dated 01.06.2015, was used to check Annex XIV and XVII: The consolidated version is presented at the ECHA website: http://echa.europa.eu/web/guest/regulations/reach/legislation.

Relevant annexes and processes related to the REACH Regulation have been cross-checked to clarify:

- In what cases granting an exemption could "weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006" (Article 5(1)(a), pg.1)
- Where processes related to the REACH regulation should be followed to understand where such cases may become relevant in the future;

In this respect, restrictions and authorisations as well as processes that may lead to their initiation, have been reviewed, in respect of where RoHS Annex II substances are mentioned (i.e. lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE).[5]

Compiled information in this respect has been included, with short clarifications where relevant, in Tables 1-5, which appear in Appendix A.1.0

The information has further been cross-checked in relation to the various exemptions evaluated in the course of this project. This has been done to clarify that the Article 5(1)(a) pg.1 threshold-criteria quoted above is complied with in cases where an

[5] This review currently does not address the 4 phthalates, DEHP, BBP, DBP and DIBP, which according to Commission Delegated Directive (EU) 2015/863 of 31 March 2015, have been added to the Annex. Information regarding these substances shall be added in future reviews.

exemption is to be granted / its duration renewed/ its formulation amended/ or where it is to be revoked and subsequently to expire as an exemption. The considerations in this regard are addressed in each of the separate chapters in which the exemption evaluations are documented (Chapters 3.0 through 5.0) under the relevant section titled "REACH Compliance – Relation to the REACH Regulation" (Sections 4.5.1 and 5.5.1 respectively).

3.0 Exemption 2015-1: "Lead in Thin Film Electronic Sensor Elements such as Pyroelectric Sensors or Piezoelectric Sensors"

Pyreos Ltd[6] has applied for a new exemption to be added to annexes III and IV of the RoHS Directive:

> "*Lead in thin film electronic sensor elements such as pyroelectric sensors or piezoelectric sensors*"

3.1 Background and Description of the Exemption

According to Pyreos Ltd[7], the request is related to lead in thin film PbZrTiO3 sensors for pyroelectric or piezoelectric applications. The sensors are currently used in monitoring and control instruments and future uses may possibly expand to other product categories under RoHS.

The applicant's thin film pyroelectric materials consist of PZT like piezoelectric ceramics. Exemption 7c-I in RoHS Annex III allows the use of lead in such ceramics including piezoelectric ceramics, as well as in glass and glass-ceramic matrix compounds in electrical and electronic components. Pyreos was therefore asked why it requested a new exemption instead of asking for the renewal or specification of exemption 7c-I.

Pyreos Ltd.[8] stated in its answers to a clarification questionnaire in April 2015 that it would be willing to consider revising the scope of its application in support of an amendment of the existing exemption 7c-I, to include an explicit reference to pyroelectric applications. Pyreos' primary request is, however, for a new exemption,

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[6] Pyreos Ltd. (2014): Document "RoHS_V_Application_Form-Pyreos_final 14112014 - publication.pdf". Exemption Request Form. PyreosLtd. Available online at http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015_1/RoHS_V_Application_Form-Pyreos_final_14112014_-_publication.pdf

[7] Op. cit. Pyreos Ltd. (2014)

[8] Pyreos Ltd. (2015a): Document "Questionnaire-1_Clarification_Exe-Req-Pyreos_cg130415 final - publication.pdf". 1st questionnaire (clarification questionnaire). Available online at http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015_1/Questionnaire-1_Clarification_Exe-Req-Pyreos_cg130415_final_-_publication.pdf

claiming that the quantity of lead and the technology used in its thin film sensors are fundamentally different from the conventional technology covered by exemption 7c-I.

In July 2015, Pyreos Ltd.[9] informed the consultants that it is willing to suspend its request for exemption with the prospect that Ex. 7c-I of Annex III of the RoHS Directive is amended in order to include a specific reference to "pyroelectric applications". As Ex. 7c-I is currently under evaluation, and it cannot be foreseen what the results of the evaluation shall be, Pyreos Ltd. [10] will, however, require that the process for its original application for a separate exemption for thin film sensors be resumed if exemption in 7c-I cannot be amended as requested above or if the competent EU Authorities consider exemption 7c-I not to be applicable to the thin film sensors defined in Pyreos' exemption request.

In the consultants' opinion, it makes sense to evaluate Pyreos' exemption request in parallel with the requests for renewal of exemption 7c-I under evaluation in the exemption evaluation project known as "Pack 9", rather than discussing the specification of exemption 7c-I in the current study, solely based on Pyreos' individual request. It is thus proposed not to continue the evaluation process of Pyreos' exemption request at this point in time, beyond the clarification questionnaire and the stakeholder consultation that have already taken place in this round of exemption request evaluations. The evaluation is to be suspended and the application to be taken into consideration in the coming evaluation of Ex. 7c-I.

3.2 References Exemption Request 2015-1

Pyreos Ltd. (2014): Document "RoHS_V_Application_Form-Pyreos_final 14112014 – publication.pdf". Exemption Request Form. PyreosLtd. Available online at http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015_1/RoHS_V_Application_Form-Pyreos_final_14112014_-_publication.pdf

Pyreos Ltd. (2015a): Document "Questionnaire-1_Clarification_Exe-Req-Pyreos_cg130415 final – publication.pdf". 1st questionnaire (clarification questionnaire). Available online at http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015_1/Questionnaire-1_Clarification_Exe-Req-Pyreos_cg130415_final_-_publication.pdf

Pyreos Ltd. (2015b): Document "Pyreos_Suspension-of-Request-with-Conditions.pdf", sent via e-mail to Dr. Otmar Deubzer, Fraunhofer IZM, by Torben Nørlem, Intertek, on 20 July 2015.

[9] Pyreos Ltd. (2015b): Document "Pyreos_Suspension-of-Request-with-Conditions.pdf", sent via e-mail to Dr. Otmar Deubzer, Fraunhofer IZM, by Torben Nørlem, Intertek, on 20 July 2015.
[10] Op. cit. Pyreos Ltd. (2015b)

4.0 Exemption 2015-2: "Lead in High Voltage Cables and Cable Assemblies for a Rated Voltage Higher than 250kV DC, Containing up to 4% Lead by Weight" (for Industrial Monitoring and Control Instruments, Annex IV)

Abbreviations

ECHA	European Chemicals Agency
EoL	End-of-life
EPR	Ethylene propylene rubber
FEI	FEI Company
Pb	Lead
SVHC	Substances of very high concern
TEM	Transmission electron microscope

4.1 Background

FEI[11] explain that a transmission electron microscope (TEM) transmits a beam of electrons through a specimen (sample) and forms an image from the interaction of the electrons transmitted through the specimen, which is focused and magnified by an imaging device. A higher acceleration voltage of the electron beam results in a higher image resolution of the TEM. TEMs operating at 300 kV acceleration voltage achieve images at atomic resolution. They are used for research of e.g. polymer materials and nanomaterials. According to FEI[12], in 300kV TEMs, a high voltage cable is needed for the transfer of the high voltage from the generator tank to the gun machine emitting the electron beam. FEI[13] specifies that the lead compound $Pb_3O_4$is used to improve the

[11] FEI (2014), FEI (2014), Original Application for Exemption, submitted 17.11.2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-2/Oko_Exemption_Request_Form_300kV_cable_FEI_without_confidential_data.pdf
[12] Op. cit. FEI (2014)
[13] Op. cit. FEI (2014)

thermal stability of the cable insulation. FEI cannot provide detailed information on the cable insulation. As the amount of lead is above 0.1% weight in the homogenous material, an exemption would be needed to allow placing 300kV TEMs and the respective cable on the market. FEI explains that TEMs fall under category 9 "industrial monitoring and control instruments", which only come into scope on 22 July 2017. In consequence, an exemption would be needed after this date to allow further marketing of such products in the EU.

FEI Company[14] thus submitted a request for exemption to allow using lead to a maximum of 4% by weight in high voltage cables and cable assemblies for use in transmission electron microscopes (TEM).

The applicant was requested to provide an exemption wording formulation that limits the scope of the exemption to the use of the specified applications in such devices. FEI[15] provided the following wording:

> "*Allow the use of lead to a maximum of 4% by weight in High Voltage Cables and Cable Assemblies for a rated voltage higher than 250kV DC and to be used in Electron Microscopy applications.*"

4.1.1 Amount of Lead Used under the Exemption

FEI estimates that with TEMs manufactured by FEI 30kg lead is put on the global market through the high voltage cables which are subject to this study. The amount of lead is indicated at maximum 2% Pb by weight of the cable.

4.2 Description of Requested Exemption

According to FEI[16], the lead compound Pb_3O_4 (orange lead)[17] is added to the polymer insulation of the cable in order to improve the thermal stability of the high voltage cable. FEI[18] does not have detailed information about the composition of the cable insulation but describes the composition as follows: "*Main parts: polymer (EPR), inorganic filler (china clay)*".

According to publically available descriptions of cable manufacturers[19], ethylene propylene rubber (EPR) insulation consists of rubber resin mixed with other additives

[14] Op. cit. FEI (2014)
[15] FEI (2015a), FEI (2015a), Answers to Clarification Questions, submitted 19.03.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-2/20150219_Ex_Re_2015_2_Clarification-Questions_feedback_FEI.pdf
[16] Op. cit. FEI (2014)
[17] Orange lead (lead tetroxide); EC Number: 215-235-6; CAS Number: 1314-41-6
[18] Op. cit. FEI (2014)
[19] See e.g. Southwire Company, LLC at http://www.southwire.com/commercial/NoLeadEthylenePropyleneRubberInsulationandSIMpullJacket.htm (retrieved 02.11.2015)

(inorganic mineral fillers, antioxidants/stabilizers, curing catalysts/co-agents, and metal oxides, including lead oxide) in order to improve the mechanical and electrical properties. Lead prevents physical degradation of the cable at elevated temperatures and in wet environments, and unstable electrical properties.[20] According to FEI, the thermal stability by heat dissipation, which is provided by the lead compound, is not important for the application of the cable in TEMs.[21] However, FEI[22] is of the opinion that lead oxide may have a positive influence on the reliability of the cable and the stability of the voltage, which is very important for the TEM application that needs to remain stable at 300kV: "*…for our purpose we need the 300kV (very stable) at pico-amperes of current.*". The consultants understand FEI's main concern with regard to substitutes is whether they shall provide the same reliability and stability as the lead based cables currently in use in the 300kV TEMs that FEI manufactures.

4.3 Applicant's Justification for Exemption

FEI argues that they need a cable that provides stable high voltage ("*ppm high voltage stability")*. Fluctuation in voltage will result in image fluctuations and poor image quality. FEI[23] explains that the leaded cable reliably provides this characteristic over a long time, which is comparable with the lifetime of the TEM that is ~15 years.

FEI[24] indicates that they are already cooperating with a cable supplier to develop a RoHS compliant cable. The applicant requests a minimum duration of seven years as long-term tests on stability and reliability need at least five years. The time stages are detailed in Section 4.3.4, which provides a road map to substitution.

4.3.1 Possible Alternatives for Substituting RoHS Substances

FEI[25] states that they completely rely on the expertise of the cable suppliers where the development of an alternative is concerned. It is further explained that there are very few suppliers of high voltage cables > 250 kV, which are mainly used in power plants (not in the scope of the RoHS Directive). The primary reason for using lead oxide in these cables is heat conduction since the original purpose of such cables, in power plants, is electric power transport and cables need to handle 3x15 Amp at 300 kV. In contrast FEI need the 300kV (very stable) at pico-amperes of current, which is why the heat dissipation is assumed not to be relevant. However it is still to be confirmed that the lead oxide does not affect the reliability and that stable voltage is enabled. Usage of the

[20] General Cable at http://www.jicable.org/TOUT_JICABLE_FIRST_PAGE/2011/2011-E7-1-2_page1.pdf (retrieved 02.11.2015).
[21] Op. cit. FEI (2014)
[22] Op. cit. FEI (2014)
[23] Op. cit. FEI (2014)
[24] Op. cit. FEI (2014, 2015a, 2015c)
[25] Op. cit. FEI (2014)

cables in TEM electron microscopes is explained to comprise a small percentage of market share, and thus FEI explain that their power to influence suppliers to develop alternatives is limited. According to FEI[26], some manufacturers were not willing to develop and produce alternatives, which is why FEI is not confident of completing substitution before the 2017 deadline. As for investment costs FEI[27] notes that "*in the eyes of the supplier, FEI is seen as a small customer that uses this cable and therefore we have little 'bargain power' to convince the supplier of developing a RoHS compliant derivative of the current used cable. Therefor it's foreseeable that the investment costs of a new cable will be taken by FEI.*"

FEI[28] have, however, found a cable manufacturer that is willing to provide a RoHS compliant cable which, once manufactured, shall need to undergo stability and reliability tests conducted by FEI. As this is yet to occur, FEI claims that alternatives, for which reliability and stability are proven to be comparable, are currently not available.

4.3.2 Environmental Arguments

A closed loop return system exists for FEI's electron microscopes and their component parts. Within this practice, FEI takes back equipment for repair and refurbishment. As part of this practice, parts are removed from used equipment to be refurbished and then used in the repair of similar devices. [29]

According to FEI[30], the repair is done by engineers approved by FEI who return the repaired part and use refurbished parts for repair. At the end of life, TEMs are collected and either completely refurbished or (in the case of parts that cannot be reused) disposed to professional recyclers. FEI[31] explains thus that the high voltage cables are also refurbished if possible. Otherwise, they are disposed to professional recyclers.

4.3.3 Socio-economic Impact of Substitution

FEI[32] claims that without the leaded cable, 300 kV TEMs cannot be put on the market in the EU, which would highly affect advanced research in the EU. FEI[33] lists economic

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[26] Op. cit. FEI (2014) and FEI (2015c), Information provided during a telephone conference on 28.09.2015.
[27] Op. cit. FEI (2014)
[28] Op. cit. FEI (2015c)
[29] FEI requested a new exemption or an amendment of a similar exemption for medical devices (category 8) related to this practice in the past. The request is understood to still be in discussion. Ex. 31 of Annex IV reads: "Lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before 22 July 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer" and expires on 21 July 2021."; see consolidated version of 24 June 2015 at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011L0065-20150624&from=EN (as of November 2015).
[30] Op. cit. FEI (2014)
[31] Op. cit. FEI (2015c)
[32] Op. cit. FEI (2014)

effects such as loss of PhD jobs, and loss of jobs for Electron Microscope developers and manufacturers. FEI does not, however, provide further information and data to substantiate these statements.

4.3.4 Road Map to Substitution

FEI[34] explains that the development and testing of a lead free cable takes, in the best-case three years. FEI[35] states that a RoHS compliant cable is under development in cooperation with a cable supplier. After the development of a lead-free cable by the cable manufacturer, the cable supplier has to perform the re-design of the end connectors to this cable. The re-design of the cable is expected to take until mid-2016. The cable than has to undergo reliability testing in TEMs. Such testing is performed by FEI and includes:[36]

- Test performance on high voltage stability until end of 2016 and;
- Long term stability test and reliability of the cable assembly until the end of 2017 (best case).

FEI notes[37] that the development of a lead free cable is not a straightforward process, but needs iterations if the cable assembly fails at some stage. FEI thus requests a duration of seven years for the exemption (until 2022) because some testing might be performed iteratively if the cable does not perform well and e.g. the design of the end connectors has to be changed.

The consultants understand this to mean that at best the remaining testing and redesign stages could take a total of three years and at worst up to seven years.

4.4 Stakeholder Contributions

Two contributions were submitted during the stakeholder consultation concerning the exemption request. One by JEOL, a TEM manufacturer and one by the association Europacable. Their statements are summarized in the following:

- The TEM manufacturer **JEOL**[38] who also manufactures 300 kV TEMs for the EU market states that they have developed a lead-free high-voltage cable (including the cable assembly) capable of high voltage up to 300 kV in

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[33] Op. cit. FEI (2014)
[34] Op. cit. FEI (2015c)
[35] Op. cit. FEI (2014)
[36] Op. cit. FEI (2014)
[37] Op. cit. FEI (2015c)
[38] JEOL (2015a), JEOL Ltd. (2015a), Contribution to Stakeholders Consultation Regarding Exemption Request 2015-2, submitted per e-mail 29.05.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-2/20150529_JEOL_Answers_to_Consultation_Questionnaire_Exemption_Request_2015-2.pdf

cooperation with a major cable manufacturer in Japan. JEOL[39] further states that the lead free high voltage cables are already applied in its TEMs and that the 300 kV TEMs using this cable are already placed on the EU market.
After being requested additional information, JEOL[40] stated that "*According to the answer from the cable manufacturer, they use calcium-zinc thermal stabilizer for the TEM high voltage cable (>250kV) as substitute for lead thermal stabilizer and neither of these compounds (calcium and zinc compounds) is listed in REACH Annex XIV or Annex XVII.*"

- The association **Europacable**[41] states that the high voltage cables > 250 kV are out of scope of RoHS 2 and that technically there would be no need to request an exemption. Europacable further questions whether the 300kV TEM are to be considered as EEE and whether they are designed for use with a voltage rating not exceeding 1kV AC or 1,5kV DC. Europacable[42] proposes the following wording for the exemption, should it be granted:

  "Allow the use of lead to a maximum of 4% by weight in High Voltage Cables and Cable Assemblies for a rated voltage higher than 250kV DC and to be used in Electron Microscopy applications designed for use with a voltage rating not exceeding 1kV AC or 1,5kV DC."

4.5 Critical Review

4.5.1 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. The lead compound used in high voltage cable insulation, in the consultants' point of view is not a supply of lead and its compounds as a substance, mixture or constituent of other

[39] Op. cit. JEOL (2015a)
[40] JEOL (2015b), JEOL Ltd. (2015b), e-mail communication of Hiroyuki Nishiyama, 19.10.2015.
[41] Europacable (2015), Europacable (2015), Contribution to Stakeholders Consultation Regarding Exemption Request 2015-2, submitted per e-mail 05.06.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-2/201500605_Europacable_Stakeholder_Contribution_questions_RoHS_exemption_request_-_final_050615.pdf
[42] Op. cit. Europacable (2015)

mixtures to the general public. Pb is part of an article and as such, entry 30 of Annex XVII of the REACH Regulation would not apply.

The lead compound used in the cables is orange lead (lead tetroxide, CAS 1314-41-6). Orange lead was added to the REACH Candidate List of substances of very high concern (SVHC) for Authorisation on 19 December 2012 for reasons of being toxic for reproduction (REACH Article 57 c)[43]. For substances on the REACH candidate list, there are communication duties along the supply chain according to REACH Article 33: The content of such substances in a concentration above 0, 1% weight has to be communicated through the product documentation supplied with the product.

Orange lead was assessed by the European Chemicals Agency (ECHA) to determine whether it should be included in the Authorisation List as a priority. According to the 6th Annex XIV recommendation of 1 July 2015, orange lead is not yet recommended for inclusion in Annex XIV[44].

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

Possible substitutes relevant for the exemption request were reviewed to see if specific provisions under REACH exist, e.g. conditions of restriction in REACH Annex XVII and Annex XIV. JEOL indicated a calcium-zinc stabilizer as alternative. JEOL does not further specify the calcium and zinc compounds.

Therefore, REACH Annex XIV and XVII were assessed for entries on calcium and zinc compounds, which are compiled in the following table.

[43] http://echa.europa.eu/candidate-list-table?search_criteria_name=Orange%20lead%20%28lead%20tetroxide%29&search_criteria_ecnumber=215-235-6&search_criteria=Orange%20lead%20%28lead%20tetroxide%29

[44] http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/-/substance-rev/1803/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_NAME=Orange+lead+%28lead+tetroxide%29&_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=215-235-6

Table 4-1: Check of Conditions of Restriction and Authorisation in REACH Annex XVII and Annex XIV, for Possible Substitutes in Alphabetical Order

Substance or compounds	CAS Number	Specific provisions etc. under REACH
Pentazinc chromate octahydroxide	49663-84-5	Annex XIV; sunset date 22/01/2019; latest application date: 22/07/2017
Potassium hydroxyoctaoxodizincate-dichromate	11103-86-9	Annex XIV; sunset date 22/01/2019; latest application date: 22/07/2017
Phosphoric acid, calcium nickel salt	17169-61-8	Carcinogen category 1A falling under Annex XVII entry 28.
Calcium chromate	13765-19-0	Carcinogen category 1B falling under Annex XVII entry 28.

Source: ECHA, November 2015

JEOL states that "*neither of these compounds (calcium and zinc compounds) is listed in REACH Annex XIV or Annex XVII.*" The consultants are thus led to conclude that the calcium-zinc thermal stabilizer does not contain the compounds mentioned in Table 4-1.

4.5.2 Scientific and Technical Practicability of Substitution

In their contribution, JEOL[45] briefly stated that they have successfully substituted lead in their high voltage cables and that 300 kV TEMs with a lead free cable are already placed on the EU market. Thus, it is understood that there is at least one alternative manufacturer of 300kV TEMs that has successfully implemented substitutes.

The applicant of the exemption request, FEI, agrees with the basic availability of substitutes; however FEI stresses that the time consuming part of substitution is the long term testing of the lead free cable in equipment. Every manufacturer has to explore and test alternative solutions to ensure their reliability for its equipment. FEI[46] states that "*The High Voltage Tank, Cable and Electron Emitters are all part of a fine tuned 300KV system. It is not possible to simply remove any of these elements and replace this with another element. For the cable the impedance, resistance and capacitance are important aspects. What JEOL has used in their system cannot simply be used as a replacement into FEI systems. We are currently working with a Supplier for developing and testing a RoHS compliant replacement High Voltage Cable. The effect of aging on listed aspects is a high risk in this development hence a reliable replacement cannot be guaranteed before 22nd July 2017.*"

TEMs are highly complex and fine-tuned equipment. The high value 300 kV TEMs are sold in very limited number. There are three manufacturers worldwide providing 300kV

[45] Op. cit. JEOL (2015a)
[46] Op. cit. FEI (2015b)

TEMs. Besides FEI[47] and JEOL[48], 300kV TEMs are produced by Hitachi[49]. JEOL declared that their 300kV TEMs cover the functionality and performance of FEI's 300kV TEMs (Titan and Tecnai series) and thus provide the same services.

To summarize, the consultants can follow that there are substitutes available but that their implementation by FEI in TEMs may require time in light of the need to test and sometimes redesign cable interface and assembly. However, it is understood that manufacturers are not at the same point of development in this respect. At least one manufacturer, JEOL, has managed to substitute, claiming that the 300 kV TEMs currently placed on the market already use the substitute cables. A third manufacturer of 300 kV TEMs, Hitachi, did not contribute in the consultation, but it has to be assumed that if their products required the exemption after 2017 that they would have at least supported the request. Information provided by stakeholders[50] suggests that the differences between the FEI and JEOL equipment are design details that do not affect the services provided by equipment to end-users. Thus, though the implementation of substitutes may be realised at different times by the various manufacturers in light of the need to independently test equipment, it can be understood that implementation is already realised in products on the market, at least of some manufacturers.

4.5.3 Environmental Arguments

As already explored in Section 4.3.2, from information provided by FEI, the consultants can follow that leaded cables used in the applicants current TEM systems are collected at end-of-life (EoL) of equipment, refurbished and reused where possible or otherwise properly disposed of to professional recyclers.

Though this information suggests that possible environmental emissions related to EoL would be controlled, it does not allow concluding as to possible differences between the use of the lead based cable and between the uses of RoHS compliant alternatives in other life cycle stages including primary material resource extraction, refining, product construction, product use stage etc. Such differences could be relevant to understand how the two cables perform in comparison with each other in relation to the Article 5(1)(a) criteria, which can be used to justify an exemption in cases where alternatives show higher negative impacts on the environment, on health and on consumer safety. As such, in the lack of detailed information, it could not be concluded, between cables manufactured with lead and cables which have already the substituted lead, which has a higher negative impact on the environment, on health and on consumer safety.

[47] http://www.fei.com/products/tem/
[48] http://www.jeol.co.jp/en/products/list_tem.html
[49] http://www.hitachi-hightech.com/us/product_list/?ld=sms2&md=sms2-1&sd=sms2-1-4
[50] Op. cit. FEI (2015c) and JEOL (2015b)

4.5.4 Stakeholder Contributions

Besides the input of JEOL, Europacable[51] proposed to modify the exemption wording formulation related to the exemption request (see Section 4.4). FEI[52] corrected that "*To avoid misunderstanding a clear distinction should be made by "use" and "internal use": Electron microscopes are designed to use input voltages 110/230V AC or 3-phase 380V AC to power the EEE. Also Electron Microscopes are designed to "use internal" voltage up to 300KV DC generated EEE internal".* It is understood that Europacable[53] view the cable as out of scope of the RoHS 2 Directive. FEI[54] state that "*As FEI is using the 300KV cable as integral part of Electron Microscope, FEI classified the (same) 300KV cable as regular part of Electron Microscopes, therefor placed in Cat9 of RoHS regulations.*" This view is supported by the RoHS 2 FAQ document[55] that states "*Cables specifically intended for medical equipment and monitoring and control equipment will come under the RoHS provisions on the appropriate dates.*"

To conclude, the consultants assume that if as stated by the applicant, its equipment is in scope of the RoHS Directive, that all components would need to comply with the Directive substance restrictions, including any cables, regardless of their rated voltage.

4.5.5 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.

From the available information it is observed that substitutes have become available on the market. Though different manufacturers may reach compliance at different times, this is understood to be related to the time needed for finding a suitable supplier and to possible design aspects that may need to be changed to allow use of the new cable.

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[51] "Allow the use of lead to a maximum of 4% by weight in High Voltage Cables and Cable Assemblies for a rated voltage higher than 250kV DC and to be used in Electron Microscopy applications designed for use with a voltage rating not exceeding 1kV AC or 1,5kV DC."
[52] Op. cit. FEI (2015b)
[53] Op. cit. Europacable (2015)
[54] Op. cit. FEI (2015b)
[55] EU COM (2012), RoHS 2 FAQ Document, available under: http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf

However, such aspects (i.e. allowing all manufacturers of competing products time to individually adapt their own products) do not fulfil one of the above mentioned criteria.

To conclude against the Article 5(1)(a) criteria:

- The **substitution of lead in high voltage cables is understood to be scientifically and technically possible** as one TEM manufacturer (JEOL) is already placing 300kV TEMs on the market that use RoHS compliant cables;
- It can also be understood that the RoHS **compliant cable used by the other identified manufacturer does not affect the reliability of the equipment**; and furthermore
- The **information provided does not suggest that the RoHS compliant cable would be inferior in terms of possible impacts on the environment, on health and on consumer safety**.

Thus the consultants conclude that an exemption cannot be justified based on the Article 5(1)(a) criteria.

4.6 Recommendation

As explained, there are manufacturers of 300kV TEM that use a RoHS compliant high voltage cable, which means that reliable and competitive substitutes are available on the market. Though there are design differences in the cable assemblies, requiring each manufacturer to perform its reliability testing of its equipment, the fact that one manufacturer has achieved substitution almost two years ahead of time shows that the time available for substitution has been sufficient. Therefore the consultants recommend not granting the exemption request.

4.7 References Exemption Request 2015-2

Europacable (2015)	Europacable (2015), Contribution to Stakeholders Consultation Regarding Exemption Request 2015-2, submitted per e-mail 05.06.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-2/201500605_Europacable_Stakeholder_Contribution_questions_RoHS_exemption_request_-_final_050615.pdf
FEI (2013)	FEI Company (2013), Original exemption request submitted by FEI Company on 25.6.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/Request_2013-6/20130625_Oko_Exemption_Request_Form_FEI.pdf
FEI (2014)	FEI Company (2014), Original Application for Exemption, submitted 17.11.2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-2/Oko_Exemption_Request_Form_300kV_cable_FEI_without_confidential_data.pdf

FEI (2015a)	FEI Company (2015a), Answers to Clarification Questions, submitted 19.03.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-2/20150219_Ex_Re_2015_2_Clarification-Questions_feedback_FEI.pdf
FEI (2015b)	FEI Company (2015b), Answers to 2nd Round of Clarification Questions, submitted per e-mail on 01.09.2015.
FEI (2015c)	FEI Company (2015c), Information provided during a telephone conference on 28.09.2015.
FEI (2015d)	FEI Company (2015d); e-mail communication of Casper Kruijer, 08.10.2015.
JEOL (2015a)	JEOL Ltd. (2015a), Contribution to Stakeholders Consultation Regarding Exemption Request 2015-2, submitted per e-mail 29.05.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_7/2015-2/20150529_JEOL_Answers_to_Consultation_Questionnaire_Exemption_Request_2015-2.pdf
JEOL (2015b)	JEOL Ltd. (2015b), e-mail communication of Hiroyuki Nishiyama, 19.10.2015.

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.

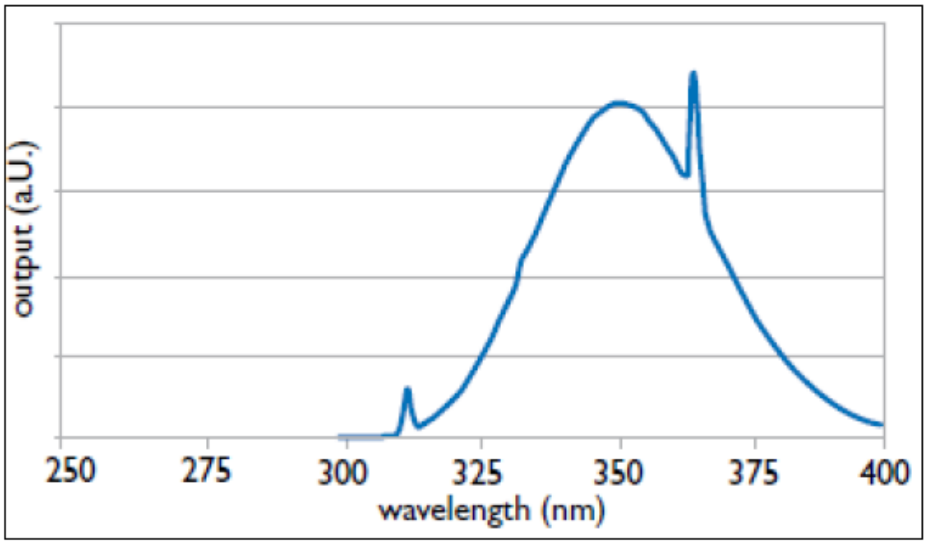
Figure 5-1: Examples of Phototherapy Equipment

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)*."

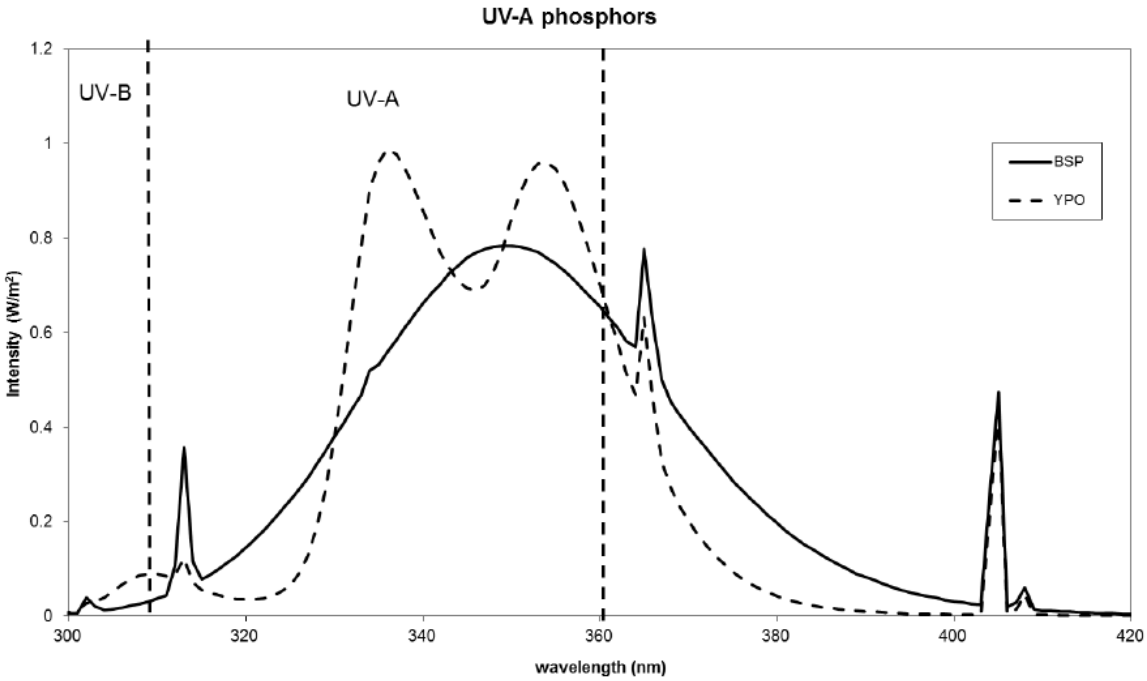
In this respect, it should be noted that erythema and possibly non-melanoma skin cancer (NMSC) are side effects of phototherapy. Treating skin diseases (like psoriasis) with phototherapy can lead to unwanted erythema (skin reddening) and a risk of creating NMSC. In this sense, alternatives need to be 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.

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

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

Mallinckrodt (2016) Mallinckrodt Pharmaceuticals, Answer to 2nd Questionnaire Regarding Exclusivity of Therakos Extracorpereal Photopheresis Lamps, submitted 25.1.2016 per e-mail

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

APPENDICES

A.1.0 Appendix 1: Aspects Relevant to the REACH Regulation

Relevant annexes and processes related to the REACH Regulation have been cross-checked to clarify:

- In what cases granting an exemption could "weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006" (Article 5(1)(a), pg.1)
- Where processes related to the REACH regulation should be followed to understand where such cases may become relevant in the future;

Compiled information in this respect has been included, with short clarifications where relevant, in the following tables:

Table 1 lists those substances appearing in Annex XIV, subject to Authorisation, which are relevant to the RoHS substances dealt with in the requests evaluated in this project. As can be seen, at present, exemptions have not been granted for the use of these substances.

Table 1: Relevant Entries from Annex XIV: The List of Substances Subject to Authorization

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
10. Lead chromate **EC No: 231-846-0** **CAS No: 7758-97-6**	21 Nov 2013	21 May 2015	-
11. Lead sulfochromate yellow (C.I. Pigment Yellow 34) **EC No: 215-693-7** **CAS No: 1344-37-2**	21 Nov 2013	21 May 2015	-
12. Lead chromate molybdate sulphate red (C.I. Pigment Red 104) **EC No: 235-759-9** **CAS No: 12656-85-8**	21 Nov 2013	21 May 2015	-
16. Chromium trioxide **EC No: 215-607-8** **CAS No: 1333-82-0**	21 Mar 2016	21 Sep 2017	-
17. Acids generated from chromium trioxide and their oligomers **Group containing:** **Chromic acid**	21 Mar 2016	21 Sep 2017	-

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
EC No: 231-801-5 **CAS No: 7738-94-5** **Dichromic acid** **EC No: 236-881-5** **CAS No: 13530-68-2** **Oligomers of chromic acid and dichromic acid** **EC No: not yet assigned** **CAS No: not yet assigned**			
18. Sodium dichromate **EC No: 234-190-3** **CAS No: 7789-12-0** **10588-01-9**	21 Mar 2016	21 Sep 2017	-
19. Potassium dichromate **EC No: 231-906-6** **CAS No: 7778-50-9**	21 Mar 2016	21 Sep 2017	-
20. Ammonium dichromate **EC No: 232-143-1** **CAS No: 7789-09-5**	21 Mar 2016	21 Sep 2017	-
21. Potassium chromate **EC No: 232-140-5** **CAS No: 7789-00-6**	21 Mar 2016	21 Sep 2017	
22. Sodium chromate **EC No: 231-889-5** **CAS No: 7775-11-3**	21 Mar 2016	21 Sep 2017	
28. Dichromium tris(-chromate) **EC No: 246-356-2** **CAS No: 24613-89-6**	22. July 2017	22 January 2019	
29. Strontium chromate **EC No: 232-142-6 CAS** **No: 7789-06-2**	22 July 2017	22 January 2019	
30. Potassium hydroxyoctaoxodizincatedichromate **EC No: 234-329-8** **CAS No: 11103-86-9**	22 July 2017	22 January 2019	
31. Pentazinc chromate octahydroxide **EC No: 256-418-0** **CAS No: 49663-84-5**	22 July 2017	22 January 2019	

For the substances currently restricted according to RoHS Annex II: cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls and polybrominated diphenyl ethers and their compounds, we have found that some relevant entries are listed in

Annex XVII of the REACH Regulation. The conditions of restriction are presented in Table 2 below. Additionally, some amendments have been decided upon, and are still to be included in the concise version. These may be seen in Table 3.

Table 2: Conditions of Restriction in REACH Annex XVII for RoHS Substances and Compounds

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
8. Polybromobiphenyls; Polybrominatedbiphenyls (PBB) **CAS No 59536-65-1**	1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin. 2. Articles not complying with paragraph 1 shall not be placed on the market.
16. Lead carbonates: **(a) Neutral anhydrous carbonate (PbCO 3)** **CAS No 598-63-0** **EC No 209-943-4** **(b) Trilead-bis(carbonate)-dihydroxide 2Pb CO 3 -Pb(OH) 2** **CAS No 1319-46-6** **EC No 215-290-6**	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
17. Lead sulphates: **(a) PbSO 4** **CAS No 7446-14-2** **EC No 231-198-9** **(b) Pb x SO 4** **CAS No 15739-80-7** **EC No 239-831-0**	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
18. Mercury compounds	Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use: (a) to prevent the fouling by micro-organisms, plants or animals of: — the hulls of boats, — cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, — any totally or partly submerged appliances or equipment; (b) in the preservation of wood; (c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture; (d) in the treatment of industrial waters, irrespective of their use.
18a. Mercury **CAS No 7439-97-6** **EC No 231-106-7**	1. Shall not be placed on the market: (a) in fever thermometers; (b) in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers).

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	2. The restriction in paragraph 1 shall not apply to measuring devices that were in use in the Community before 3 April 2009. However Member States may restrict or prohibit the placing on the market of such measuring devices. 3. The restriction in paragraph 1(b) shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007; (b) barometers (except barometers within point (a)) until 3 October 2009. 5. The following mercury-containing measuring devices intended for industrial and professional uses shall not be placed on the market after 10 April 2014: (a) barometers; (b) hygrometers; (c) manometers; (d) sphygmomanometers; (e) strain gauges to be used with plethysmographs; (f) tensiometers; (g) thermometers and other non-electrical thermometric applications. The restriction shall also apply to measuring devices under points (a) to (g) which are placed on the market empty if intended to be filled with mercury. 6. The restriction in paragraph 5 shall not apply to: (a) sphygmomanometers to be used: (i) in epidemiological studies which are ongoing on 10 October 2012; (ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers; (b) thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers until 10 October 2017; (c) mercury triple point cells which are used for the calibration of platinum resistance thermometers. 7. The following mercury-using measuring devices intended for professional and industrial uses shall not be placed on the market after 10 April 2014: (a) mercury pycnometers; (b) mercury metering devices for determination of the softening point. 8. The restrictions in paragraphs 5 and 7 shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007; (b) measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.
23. Cadmium and its compounds **CAS No 7440-43-9** **EC No 231-152-8**	For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87 (1). 1. Shall not be used in mixtures and articles produced from the

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	following synthetic organic polymers (hereafter referred to as plastic material): — polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21] — polyurethane (PUR) [3909 50] — low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] — cellulose acetate (CA) [3912 11] — cellulose acetate butyrate (CAB) [3912 11] — epoxy resins [3907 30] — melamine-formaldehyde (MF) resins [3909 20] — urea-formaldehyde (UF) resins [3909 10] — unsaturated polyesters (UP) [3907 91] — polyethylene terephthalate (PET) [3907 60] — polybutylene terephthalate (PBT) — transparent/general-purpose polystyrene [3903 11] — acrylonitrile methylmethacrylate (AMMA) — cross-linked polyethylene (VPE) — high-impact polystyrene — polypropylene (PP) [3902 10] Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01% by weight of the plastic material. By way of derogation, the second subparagraph shall not apply to articles placed on the market before 10 December 2011. The first and second subparagraphs apply without prejudice to Council Directive 94/62/EC (13) and acts adopted on its basis. By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be restricted. 2. Shall not be used in paints [3208] [3209]. For paints with a zinc content exceeding 10% by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0,1% by weight. Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,1% by weight of the paint on the painted article. 3. By way of derogation, paragraphs 1 and 2 shall not apply to articles coloured with mixtures containing cadmium for safety reasons. 4. By way of derogation, paragraph 1, second subparagraph shall not apply to: — mixtures produced from PVC waste, hereinafter referred to as 'recovered PVC',

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	— mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0,1% by weight of the plastic material in the following rigid PVC applications: (a) profiles and rigid sheets for building applications; (b) doors, windows, shutters, walls, blinds, fences, and roof gutters; (c) decks and terraces; (d) cable ducts; (e) pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC in compliance with paragraph 1 above. Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: '*Contains recovered PVC*' or with the following pictogram:  In accordance with Article 69 of this Regulation, the derogation granted in paragraph 4 will be reviewed, in particular with a view to reducing the limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e), by 31 December 2017. 5. For the purpose of this entry, 'cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface. Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications: (a) equipment and machinery for: — food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] — agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] — cooling and freezing [8418] — printing and book-binding [8440] [8442] [8443] (b) equipment and machinery for the production of: — household goods [7321] [8421 12] [8450] [8509] [8516] — furniture [8465] [8466] [9401] [9402] [9403] [9404] — sanitary ware [7324] — central heating and air conditioning plant [7322] [8403] [8404] [8415] In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b)

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	above is prohibited. 6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below: (a) equipment and machinery for the production of: — paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] (b) equipment and machinery for the production of: — industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431] — road and agricultural vehicles [chapter 87] — rolling stock [chapter 86] — vessels [chapter 89] 7. However, the restrictions in paragraphs 5 and 6 shall not apply to: — articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. 8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01% by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01% by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C. 9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons. 10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01% by weight of the metal in: (i) metal beads and other metal components for jewellery making; (ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including: — bracelets, necklaces and rings, — piercing jewellery, — wrist-watches and wrist-wear, — brooches and cufflinks. 11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011.

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
28. **Carcinogen category 1A or 1B or carcinogen category 1 or 2** **According to Appendices 1 and 2:** **Cadmium oxide** **Cadmium chloride** **Cadmium fluoride** **Cadmium Sulphate** **Cadmium sulphide** **Cadmium (pyrophoric)** **Chromium (VI) trioxide** **Zinc chromates including zinc potassium chromate** **Nickel Chromate** **Nickel dichromate** **Potassium dichromate** **Ammonium dichromate** **Sodium dichromate** **Chromyl dichloride; chromic oxychloride** **Potassium chromate** **Calcium chromate** **Strontium chromate** **Chromium III chromate; chromic chromate** **Sodium chromate** **Lead Chromate** **Lead hydrogen arsenate** **Lead Nickel Salt** **Lead sulfochromate yellow; C.I. Pigment Yellow 34;** **Lead chromate molybdate sulfate red; C.I. Pigment Red 104;**	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.
29. **Mutagens: category 1B or category 2 According to Appendices 3 and 4:** **Cadmium chloride** **Cadmium fluoride** **Cadmium Sulphate** **Chromium (VI) trioxide** **Potassium dichromate**	

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
Ammonium dichromate **Sodium dichromate** **Chromyl dichloride; chromic oxychloride** **Potassium chromate** **Sodium chromate**	
30. **Toxic to reproduction: category 1A or 1B or toxic to reproduction category 1 or 2** **According to Appendices 5 and 6:** **Cadmium chloride** **Cadmium fluoride** **Cadmium Sulphate** **Potassium dichromate** **Ammonium dichromate** **Sodium dichromate** **Sodium chromate** **Nickel dichromate** **Lead compounds with the exception of those specified elsewhere in this Annex** **Lead Arsenate** **Lead acetate** **Lead alkyls** **Lead azide** **Lead Chromate** **Lead di(acetate)** **Lead hydrogen arsenate** **Lead 2,4,6-trinitroresorcinoxide, lead styphnate** **Lead(II) methane- sulphonate** **Trilead bis- (orthophosphate)** **Lead hexa-fluorosilicate** **Mercury** **Silicic acid, lead nickel salt**	
47. Chromium VI compounds	1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002%) soluble chromium VI of the total dry weight of the cement. 2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1. 3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin. 4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1. 5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003% by weight) of the total dry weight of the leather. 6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003% by weight) of the total dry weight of that leather part. 7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.
63. Lead and its compounds CAS No 7439-92-1 EC No 231-100-4	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05% by weight. 2. For the purposes of paragraph 1: (i) 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; (ii) 'any individual part' shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*); (b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion,

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	vitrification or sintering of minerals melted at a temperature of at least 500 °C. 5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961. 6. By 9 October 2017, the Commission shall re-evaluate paragraphs 1 to 5 of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly. 7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05% by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm 2 per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size. 8. By way of derogation, paragraph 7 shall not apply to: (a) jewellery articles covered by paragraph 1; (b) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Directive 69/493/ EEC; (c) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/ 87) unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500 ° C; (e) keys and locks, including padlocks; (f) musical instruments; (g) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0,5% by weight; (h) the tips of writing instruments (i) religious articles; (j) portable zinc-carbon batteries and button cell batteries; (k) articles within the scope of: (i) Directive 94/62/EC; (ii) Regulation (EC) No 1935/2004; (iii) Directive 2009/48/EC of the European

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	Parliament and of the Council (**); (iv) Directive 2011/65/EU of the European Parliament and of the Council (***) 9. By 1 July 2019, the Commission shall re-evaluate paragraphs 7 and 8(e), (f), (i) and (j) of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 7, including the requirement on coating integrity, and, if appropriate, modify this entry accordingly. 10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 1 June 2016. (*) OJ L 326, 29.12.1969, p. 36. (**) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1). (***) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

Table 3: Summary of Relevant Amendments to Annexes Not Updated in the Last Concise Version of the REACH Regulation

Designation of the substance, of the group of sub-stances, or of the mixture	Conditions of restriction	Amended Annex	Amendment date
Addition of Entry 62 concerning: **(a) Phenylmercury acetate** **EC No: 200-532-5** **CAS No: 62-38-4** **(b) Phenylmercury propionate** **EC No: 203-094-3** **CAS No: 103-27-5** **(c) Phenylmercury 2-ethylhexanoate** **EC No: 236-326-7** **CAS No: 13302-00-6** **(d) Phenylmercury octanoate** **EC No: –** **CAS No: 13864-38-5** **(e) Phenylmercury neodecanoate** **EC No: 247-783-7** **CAS No: 26545-49-3**	1. Shall not be manufactured, placed on the market or used as substances or in mixtures after 10 October 2017 if the concentration of mercury in the mixtures is equal to or greater than 0,01% by weight. 2. Articles or any parts thereof containing one or more of these substances shall not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than 0,01% by weight.'	Annex XVII, entry 62	20 Sep 2012

As of 28 September 2015, the REACH Regulation Candidate list includes those substances relevant for RoHS listed in Table 4 (i.e., proceedings concerning the addition of these substances to the Authorisation list (Annex XIV) have begun and shall be followed by the evaluation team to determine possible discrepancies with future requests of exemption from RoHS (new exemptions, renewals and revocals))[98]:

[98] Updated according to http://echa.europa.eu/web/guest/candidate-list-table

Table 4: Summary of Relevant Substances Currently on the REACH Candidate List

Substance Name	EC No.	CAS No.	Date of Inclusion	Reason for inclusion
Cadmium fluoride	232-222-0	7790-79-6	17 December 2014	Carcinogenic (Article 57 a); Mutagenic (Article 57 b); Toxic for reproduction (Article 57 c); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Cadmium sulphate	233-331-6	10124-36-4 31119-53-6	17 December 2014	Carcinogenic (Article 57 a); Mutagenic (Article 57 b); Toxic for reproduction (Article 57 c); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Cadmium chloride	233-296-7	10108-64-2	16 June 2014	Carcinogenic (Article 57a);
Cadmium sulphide	215-147-8	1306-23-6	16 Dec 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Lead di(acetate)	206-104-4	301-04-2	16 Dec 2013	Toxic for reproduction (Article 57 c);
Cadmium	231-152-8	7440-43-9	20 Jun 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Cadmium oxide	215-146-2	1306-19-0	20 Jun 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Pyrochlore, antimony lead yellow	232-382-1	8012-00-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead bis(tetrafluoroborate)	237-486-0	13814-96-5	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead dinitrate	233-245-9	10099-74-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Silicic acid, lead salt	234-363-3	11120-22-2	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead titanium zirconium oxide	235-727-4	12626-81-2	19 Dec 2012	Toxic for reproduction (Article 57 c)

Substance Name	EC No.	CAS No.	Date of Inclusion	Reason for inclusion
Lead monoxide (lead oxide)	215-267-0	1317-36-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Silicic acid ($H_2Si_2O_5$), barium salt (1:1), lead-doped ***[with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]***	272-271-5	68784-75-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Trilead bis(carbonate)dihydroxide	215-290-6	1319-46-6	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead oxide sulfate	234-853-7	12036-76-9	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead titanium trioxide	235-038-9	12060-00-3	19 Dec 2012	Toxic for reproduction (Article 57 c)
Acetic acid, lead salt, basic	257-175-3	51404-69-4	19 Dec 2012	Toxic for reproduction (Article 57 c)
[Phthalato(2-)]dioxotrilead	273-688-5	69011-06-9	19 Dec 2012	Toxic for reproduction (Article 57 c)
Tetralead trioxide sulphate	235-380-9	12202-17-4	19 Dec 2012	Toxic for reproduction (Article 57 c)
Dioxobis(stearato)trilead	235-702-8	12578-12-0	19 Dec 2012	Toxic for reproduction (Article 57 c)
Tetraethyllead	201-075-4	78-00-2	19 Dec 2012	Toxic for reproduction (Article 57 c)
Pentalead tetraoxide sulphate	235-067-7	12065-90-6	19 Dec 2012	Toxic for reproduction (Article 57 c)
Trilead dioxide phosphonate	235-252-2	12141-20-7	19 Dec 2012	Toxic for reproduction (Article 57 c)
Orange lead (lead tetroxide)	215-235-6	1314-41-6	19 Dec 2012	Toxic for reproduction (Article 57 c)
Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead cyanamidate	244-073-9	20837-86-9	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead(II) bis(methanesulfonate)	401-750-5	17570-76-2	18 Jun 2012	Toxic for reproduction (Article 57 c)
Lead diazide, Lead azide	236-542-1	13424-46-9	19 Dec 2011	Toxic for reproduction (article 57 c),
Lead dipicrate	229-335-2	6477-64-1	19 Dec 2011	Toxic for reproduction (article 57 c)
Dichromium tris(chromate)	246-356-2	24613-89-6	19 Dec 2011	Carcinogenic (article 57 a)
Pentazinc chromate octahydroxide	256-418-0	49663-84-5	19 Dec 2011	Carcinogenic (article 57 a)

Substance Name	EC No.	CAS No.	Date of Inclusion	Reason for inclusion
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9	19 Dec 2011	Carcinogenic (article 57 a)
Lead styphnate	239-290-0	15245-44-0	19 Dec 2011	Toxic for reproduction (article 57 c)
Trilead diarsenate	222-979-5	3687-31-8	19 Dec 2011	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Strontium chromate	232-142-6	7789-06-2	20 Jun 2011	Carcinogenic (article 57a)
Acids generated from chromium trioxide and their oligomers. Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid.	231-801-5, 236-881-5	7738-94-5, 13530-68-2	15 Dec 2010	Carcinogenic (article 57a)
Chromium trioxide	215-607-8	1333-82-0	15 Dec 2010	Carcinogenic and mutagenic (articles 57 a and 57 b)
Potassium dichromate	231-906-6	7778-50-9	18 Jun 2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Ammonium dichromate	232-143-1	7789-09-5	18 Jun 2010	Carcinogenic, mutagenic and toxic for reproduce-tion (articles 57 a, 57 b and 57 c)
Sodium chromate	231-889-5	7775-11-3	18 Jun 2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Potassium chromate	232-140-5	7789-00-6	18 Jun 2010	Carcinogenic and mutagenic (articles 57 a and 57 b).
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2	13 Jan 2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c))
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8	13 Jan 2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Lead chromate	231-846-0	7758-97-6	13 Jan 2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Lead hydrogen arsenate	232-064-2	7784-40-9	28 Oct 2008	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Sodium dichromate	234-190-3	7789-12-0, 10588-01-9	28 Oct 2008	Carcinogenic, mutagenic and toxic for reproduction (articles 57a, 57b and 57c)

Additionally, Member States can register intentions to propose restrictions or to classify substances as SVHC. The first step is to announce such an intention. Once the respective dossier is submitted, it is reviewed and it is decided if the restriction or authorisation process should be further pursued or if the intention should be withdrawn.

As at the time of writing (Fall 2015), it cannot yet be foreseen how these procedures will conclude. It is thus not yet possible to determine if the protection afforded by REACH Regulation would in these cases consequently be weakened by approving the exemption requests dealt with in this report. For this reason, the implications of these decisions have not been considered in the review of the exemption requests dealt with in this report. However for the sake of future reviews, the latest authorisation or restriction process results shall be followed and carefully considered where relevant.[99]

As for registries of intentions to identify substances as SVHC, as of 28 September 2015, Sweden has submitted intentions regarding the classification of cadmium fluoride and cadmium sulphate as CMR, intending to submit dossiers in August 2014.None of the current registries of intentions to propose restrictions apply to RoHs regulated substances.[100]

As for prior registrations of intention, dossiers have been submitted for the substances listed in table Table 5.

Table 5: Summary of Substances for which a Dossier has been submitted, following the initial registration of intention

Restriction / SVHC Classification	Substance Name	Submission Date	Submitted by	Comments
Restriction	Cadmium and its compounds	17 Jan 2014	Sweden	Artist paints
	Cadmium and its compounds	17 Oct 2013	ECHA	Amendment of the current restriction (entry 23) on use of paints with TARIC codes [3208] & [3209] containing cadmium and cadmium compounds to include placing on the market of such paints and a concentration limit.

[99] European Chemicals Agency (ECHA), Registry of intentions to propose restrictions: http://echa.europa.eu/registry-of-current-restriction-proposal-intentions/-/substance/1402/search/+/term (28.09.2015)

[100] ECHA website, accessed 28.09.2015: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions

Restriction / SVHC Classification	Substance Name	Submission Date	Submitted by	Comments
	Lead and lead compounds	18 Jan 2013	Sweden	Placing on the market of consumer articles containing Lead and its compounds
	Chromium VI	20 Jan 2012	Denmark	Placing on the market of leather articles containing Chromium VI
	Phenylmercuric octanoate; Phenylmercury propionate; Phenylmercury 2-ethylhexanoate; Phenylmercury acetate; Phenylmercury	15 Jun 2010	Norway	Mercury compounds
	Mercury in measuring devices	15 Jun 2010	ECHA	Mercury compounds
	Lead and its compounds in jewellery	15 Apr 2010	France	Substances containing lead
SVHC Classification	Cadmium chloride	03 Feb 2014	Sweden	CMR; other;
	Cadmium sulphide	05 Aug 2013	Sweden	CMR; other;
	Lead di(acetate)	05 Aug 2013	Netherlands	CMR
	Cadmium	04 Feb 2013	Sweden	CMR; other;
	Cadmium oxide	04 Feb 2013	Sweden	Substances containing Cd CMR; other; Substances Containing Cd
	Trilead dioxide Phosphonate; Lead Monoxide (Lead Oxide); Trilead bis(carbonate)di-hydroxide; Lead Dinitrate; Lead Oxide Sulphate; Acetic acid, lead salt, basic; Dioxobis(stearato)trilead; Lead bis(tetrafluoroborate); Tetraethyllead; Pentalead tetraoxide sulphate; Lead cyanamidate; Lead titanium trioxide; Silicic acid ($H_2Si_2O_5$), barium salt (1:1), lead-doped; Silicic acid, lead salt; Sulfurous acid, lead salt, dibasic; Tetralead trioxide sulphate; [Phthalato(2-)]dioxotrilead; Orange lead (lead tetroxide);	30 Aug 2012	ECHA	CMR; substances Containing Lead

Restriction / SVHC Classification	Substance Name	Submission Date	Submitted by	Comments
	Fatty acids, C16-18, lead salts; Lead titanium zirconium oxide			
	Lead(II) bis(methanesulfonate)	30 Jan 2012	Netherlands	CMR; Amides
	Lead styphnate; Lead diazide; Lead azide; Lead dipicrate	01 Aug 2011	ECHA	CMR; Substances containing lead
	Trilead diarsenate			CMR; Arsenic compounds
	Strontium Chromate	24 Jan 2011	France	CMR; Substances containing chromate
	Acids generated from chromium trioxide and their oligomers: Chromic acid; Dichromic acid; Oligomers of chromic acid and dichromic acid	27 Aug 2010	Germany	CMR; Substances containing chromate
	Chromium Trioxide	02 Aug 2010	Germany	CMR; Substances containing chromate
	Sodium chromate; Potassium chromate; Potassium Dichromate	10 Feb 2010	France	CMR; Substances containing chromate
	Lead chromate molybdate sulfate red (C.I. Pigment Red 104); Lead sulfochromate yellow (C.I. Pigment Yellow 34)	03 Aug 2009	France	CMR; substances Containing Lead
	Lead Chromate	03 Aug 2009	France	CMR; Substances containing chromate
	Lead hydrogen arsenate	27 Jun 2008	Norway	CMR; Arsenic compounds
	Sodium dichromate	26 Jun 2008	France	CMR; Substances containing chromate

Concerning the above mentioned processes, as at present, it cannot be foreseen if, or when, new restrictions or identification as SVHC might be implemented as a result of this proposal; its implications have not been considered in the review of the exemption requests dealt with in this report. In future reviews, however, on-going research into restriction and identification as SVHC processes and the results of on-going proceedings shall be followed and carefully considered where relevant.

A.2.0 Appendix 2: Ce-doped Phosphor Coating Variations

Copied from 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

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

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

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