European Commission

Study to assess requests for renewal of seven (-7-) exemptions 18(b), 18(b)-I, 24, 29, 32 and 34 of Annex III and exemption 34 of Annex IV of Directive 2011/65/EU (Pack 24) – Final Report

Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation

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Disclaimer

Oeko-Institut has 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 Oeko-Institut is not responsible for decisions or actions taken on the basis of the content of this report.

EUROPEAN COMMISSION

Directorate-General for Environment

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Table of Contents

List of Figures

List of Tables

1. Executive summary – English

With contract No. 07.0201/2020/840286/ENV.B.3 implementing Framework contract No ENV.B.3/FRA/2019/0017, a consortium led by Ramboll Deutschland GmbH, has been requested by DG Environment of the European Commission to provide technical and scientific support for the evaluation of exemption requests under the RoHS 2 regime. In the currents study, the work has been undertaken and peer reviewed by Oeko-Institut.

1.1. Background and objectives

The RoHS 2 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 electrical and electronic equipment (EEE; as referred to in Articles 2(1) and 3(1));
- The former list of exemptions has been transformed into 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 considering 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 consultant carried out evaluation of requests for renewal of eight exemptions in this study.

1.2. Key findings – Overview of the evaluation results

The exemption requests covered in this project and the name of the applicants concerned, as well as the final recommendations and proposed expiry dates are summarised in the table below (Table 1-1). Requests for renewal of eight exemptions listed in Annex III and Annex IV were included in the scope of this project. The reader is referred to the corresponding sections of this report for more details on the evaluation results.

Table 1-1: Overview of the exemptions requested for renewal, associated recommendations and expiry dates

Ex. Req. No.	Current exemption wording	Applicant/s	Recommendation	Expiry date and scope
Annex III, 5(b)	*"Lead in glass of fluorescent tubes not exceeding 0,2 % by weight."*	Lighting Europe	*"Lead (not intentionally added) in soda lime glass used in the glass tube of fluorescent lamps, not exceeding 0,2 % by weight*"*	21 July 2026 for category 5
Annex III, 18(b)	*"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."*	Lighting Europe	*"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)"*	21 July 2026 for categories 5, 8 and 9 21 July 2023 for category 8 in vitro diagnostic medical devices; 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11

Ex. Req. No.	Current exemption wording	Applicant/s	Recommendation	Expiry date and scope
Annex III, 18(b)-I	*"Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP when used in medical phototherapy equipment."*		It is recommended to group exemption 18(b)-I Annex III and exemption 34 Annex IV under a new item (18(b)-II) in Annex III. The proposed wording for the new item has no implications on the scope of existing exemptions 18(b)-I and Ex. 34. **New item: 18 (b)-II:** *"Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP ($BaSi_2O_5$:Pb) when used in medical phototherapy equipment, incl. extracorporeal photopheresis lamps"*	**For the new item 18 (b)-II** 21 July 2026 for categories 5, 8 and 9
Annex IV, 34	*"Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP ($BaSi_2O_5$:Pb) phosphors."*			
Annex III, 24	*"Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors."*	Knowles Precision Devices	*"Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors"*	18-month transition period
			New item:24(a): *"Lead in alloys used for soldering to through hole discoidal and/or planar array ceramic multilayer capacitors* *I) Not exceeding 50% by weight for applications where the components are mechanically mounted (e.g. by bolts, clips or screws) or bonded by a selective soldering / welding process and where the component will not exceed a temperature of 150ºC.* *II) In high melting point solders containing ⩾85 % lead by weight for cases where the components are mounted using an elevated temperature process (e.g. solder reflow, welding) at a temperature of ⩾150 ° C or where the component is rated to operate at a temperature of ⩾ 150°C"*	21 July 2026 for categories 1-11

Ex. Req. No.	Current exemption wording	Applicant/s	Recommendation	Expiry date and scope
Annex III, 29	*"Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC."*	European Domestic Glass & Lighting Europe	*"Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/ 493/EEC"*	21 July 2026 for categories 3, 4, 5 and 11; 21 July 2023 for category 8 in-vitro diagnostic medical devices; 21 July 2024 for category 9 industrial monitoring and control instruments.
Annex III, 32	*"Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes."*	Lumentum	*"Lead oxide in glass frit used as a sealing material for making window assemblies for argon and/or krypton laser tubes"*	21 July 2024 for category 11; 21 July 2026 for categories 6, 8 and 9.
Annex III, 34	*"Lead in cermet-based trimmer potentiometer elements."*	General Electric in the name of the Umbrella Project	*"Lead in cermet-based trimmer potentiometer elements"*	21 July 2024 for all categories

Note: ***As in the RoHS legal text, commas are used as a decimal separator for exemption formulations appearing in this table, in contrast to the decimal point used throughout the rest of the report as a separator***

2. Executive summary: French - Note de synthèse: Français

Conformément aux termes du contract-cadre ENV.B.3/FRA/2019/0017, un consortium mené par Ramboll Deutschland GmbH a été chargé par la direction générale (DG) de l'environnement de la Commission européenne afin d'apporter son concours technique et scientifique à l'évaluation des demandes d'exemption suivant le nouveau régime de la directive RoHS 2. Les travaux ont été réalisés par l'Oeko-Institut.

2.1. Contexte et objectifs

La directive RoHS 2011/65/UE est entrée en vigueur le 21 juillet 2011, ce qui a entraîné l'abrogation de la directive 2002/95/CE le 3 janvier 2013. Il est possible de considérer que la directive a prévu deux régimes qui ont permis de prendre en compte les exemptions, à savoir le régime RoHS 1 (l'ancienne directive 2002/95/CE) et le régime RoHS 2 (la directive actuelle 2011/65/UE).

- Le champ d'application couvert par la directive est désormais plus large sachant qu'il englobe l'intégralité des équipements électriques et électroniques (EEE ; tel que mentionné dans les articles 2(1) et 3(1)) ;
- L'ancienne liste d'exemptions a été transformée en annexe III et est susceptible de s'appliquer à toutes les catégories de produits conformément aux limitations énumérées dans l'article 5(2) de la Directive. L'annexe IV a été ajoutée et énumère les exemptions spécifiques aux catégories 8 et 9 ;
- La directive RoHS 2 inclut la disposition selon laquelle les demandes d'exemption doivent être déposées conformément aux termes de l'annexe V. Cependant, même si un certain nombre de points sont déjà énumérés dans cette annexe, l'article 5(8) prévoit qu'un format harmonisé et des lignes directrices détaillées prenant en compte la situation des PME, seront adoptés par la Commission Européenne ; et
- La procédure et les critères relatifs à l'adaptation au progrès scientifique et technique ont fait l'objet de modifications et comportent désormais certains points et conditions supplémentaires qu'il est nécessaire de prendre en considération. Ces derniers sont détaillés ci-dessous.

La nouvelle directive détaille les différents critères relatifs à l'adaptation de ses annexes au progrès scientifique et technique. L'article 5(1) énumère les différents critères et questions qui doivent être considérés pour justifier l'ajout d'une exemption aux annexes III et IV :

- Le premier critère est susceptible d'être perçu comme un critère de seuil et renvoie au règlement REACH (1907/2006/CE). Une exemption peut uniquement être accordée si elle ne fragilise pas la protection environnementale et sanitaire offerte par le règlement REACH ;

- De plus, une demande d'exemption doit être déclarée légitime selon l'une des trois conditions suivantes :
  - Une substitution est irréalisable d'un point de vue scientifique ou technique. Autrement dit, un matériau de substitution ou un substitut pour l'application dans laquelle la substance faisant l’objet d’une restriction est utilisée, doit encore être découvert, développé et, dans certains cas, jugé apte à une utilisation dans l'application spécifique ;
  - La fiabilité d'un substitut n'est pas garantie. En d'autres termes, la probabilité que les EEE recourant à un substitut assurent la fonction requise sans connaître de défaillance pendant une durée comparable à celle de l'application dans laquelle la substance d'origine est incluse, est inférieure à celle de l'application ;
  - Les impacts négatifs de la substitution sur l'environnement, la santé, et la sécurité des consommateurs l’emportent sur ses avantages.
- Dès lors que l'une de ces conditions est remplie, l'évaluation des exemptions, estimation de la durée nécessaire comprise, devra tenir compte de la disponibilité des substituts et de l'impact socio-économique de la substitution, ainsi que les effets néfastes sur l'innovation et une analyse du cycle de vie concernant les impacts globaux de l'exemption ; et
- Le fait que toutes les exemptions doivent désormais présenter une date d'expiration et qu'elles peuvent uniquement être renouvelées après soumission d'une nouvelle demande, constitue un aspect inédit.

Face à un tel contexte, et compte tenu du fait que les exemptions soumises au champ d'application élargi de la Directive RoHS 2 peuvent être demandées depuis l'entrée en vigueur de la directive (le 21 juillet 2011), les experts ont réalisé l'évaluation des demandes de renouvellement des huit exemptions dans le cadre de la présente mission.

2.2. Les principales conclusions – Synthèse des résultats de l'évaluation

Les demandes d'exemption couvertes dans le présent projet et les demandeurs concernés, de même que les recommandations finales et les dates d'expiration proposées, sont résumées dans le Tableau 2-1 ci-après.

Des demandes de renouvellement des huit exemptions ont été incluse dans la portée de ce projet. Le lecteur est invité à consulter les sections correspondantes du présent rapport pour plus de détails sur les résultats de l'évaluation.

Tableau 2-1 : Récapitulatif des demandes d'exemption, des recommandations associées et des dates d'expiration

Traduction en français fournie par souci de commodité. En cas de contradictions entre la traduction française et la version originale anglaise, cette dernière fait foi.

Table 2-1: Récapitulatif des demandes d'exemption, des recommandations associées et des dates d'expiration

Ex. Req. No.	Termes des exemptions	Demandeurs	Recommandation	Dates d'applicabilité et champs d'application
Annex III, 5(b)	*« Le plomb dans le verre des tubes fluorescents ne dépassant pas 0,2 % en poids »*	Lighting Europe	*« Plomb (non ajouté intentionnellement) dans le verre sodocalcique utilisé dans le tube de verre des lampes fluorescentes, n'excédant pas 0,2 % en poids*. »*	21 juillet 2026 pour la catégorie 5

Ex. Req. No.	Termes des exemptions	Demandeurs	Recommandation	Dates d'applicabilité et champs d'application
Annex III, 18(b)	*« Le plomb utilisé comme activateur dans la poudre fluorescente (maximum 1 % de plomb en poids) des lampes à décharge utilisées comme lampes de bronzage contenant des luminophores tels que $BaSi_2O_5$: Pb (BSP) »*	Lighting Europe	*« Plomb comme activateur dans la poudre fluorescente (1 % de plomb en poids ou moins) des lampes à décharge lorsqu'elles sont utilisées comme lampes de bronzage contenant des luminophores tels que le BSP ($BaSi_2O_5$:Pb). »*	21 juillet 2026 pour les catégories 5, 8 et 9 21 juillet 2023 pour les dispositifs médicaux de diagnostic in vitro de la catégorie 8 ; 21 juillet 2024 pour les instruments de surveillance et de contrôle industriels de la catégorie 9 et pour la catégorie 11.
Annex III, 18(b)-I	*« Le plomb utilisé comme activateur dans la poudre fluorescente (maximum 1 % de plomb en poids) des lampes à décharge contenant des luminophores tels que $BaSi_2O_5$: Pb (BSP), lorsqu'elles sont utilisées dans des équipements médicaux de photothérapie »*		Il est recommandé de regrouper l'exemption 18(b)-I Annexe III et l'exemption 34 Annexe IV sous une nouvelle rubrique (18(b)-II) à l'Annexe III. Le libellé proposé pour le nouveau point n'a aucune incidence sur le champ d'application des exemptions existantes 18(b)-I et Ex. 34. **Nouveau point : 18 (b)-II :** *« Plomb utilisé comme activateur dans la poudre fluorescente (1 % de plomb en poids ou moins) des lampes à décharge contenant des phosphores tels que le BSP ($BaSi_2O_5$:Pb) lorsqu'elles sont utilisées dans des équipements médicaux de photothérapie, y compris les lampes de photophérèse extracorporelle. »*	21 juillet 2026 pour les catégories 5, 8 et 9
Annex IV, 34	*« Le plomb en tant qu'activateur dans la poudre fluorescente des lampes à décharge contenant des luminophores BSP ($BaSi_2O_5$:Pb) qui sont utilisées pour la photophérèse extracorporelle. Expire le 22 juillet 2021. »*			

Ex. Req. No.	Termes des exemptions	Demandeurs	Recommandation	Dates d'applicabilité et champs d'application
Annex III, 24	*« Le plomb dans la pâte à braser pour condensateurs céramiques multicouche à trous métallisés, de forme discoïdale ou plane »*	Knowles Precision Devices	*« Plomb dans les alliages utilisés pour le soudage aux condensateurs multicouches en céramique à trous traversants usinés, discoïdaux et à réseau planaire. »*	Période de transition de 18 mois
			Nouveau point: 24 (a): *« Plomb dans les alliages utilisés pour le soudage des condensateurs multicouches en céramique à trous traversants discoïdaux et/ou planaires* *I) Ne dépassant pas 50 % en poids pour les applications où les composants sont montés mécaniquement (par exemple par des boulons, des clips ou des vis) ou collés par un processus de soudage sélectif et où le composant ne dépassera pas une température de 150ºC.* *II) Dans les soudures à point de fusion élevé contenant ⩾85 % de plomb en poids pour les cas où les composants sont montés à l'aide d'un processus à température élevée (par exemple, refusion de la soudure, soudage) à une température de ⩾150 °C ou lorsque le composant est prévu pour fonctionner à une température de ⩾150°C. »*	21 juillet 2026 pour les catégories 1-11

Ex. Req. No.	Termes des exemptions	Demandeurs	Recommandation	Dates d'applicabilité et champs d'application
Annex III, 29	*« Le plomb contenu dans le verre cristal tel que défini à l'annexe I (catégories 1, 2, 3 et 4) de la directive 69/493/CEE du Conseil (3) »*	European Domestic Glass & Lighting Europe	*« Plomb lié au verre de cristal tel que défini à l'annexe I (catégories 1, 2, 3 et 4) de la directive 69/493/CEE du Conseil. »*	21 juillet 2026 pour les catégories 3, 4, 5 et 11 ; 21 juillet 2023 pour les dispositifs médicaux de diagnostic in vitro de la catégorie 8 ; 21 juillet 2024 pour les instruments de surveillance et de contrôle industriels de la catégorie 9.
Annex III, 32	*« L'oxyde de plomb dans le joint de scellement des fenêtres entrant dans la fabrication des tubes laser à l'argon et au krypton »*	Lumentum	*« Oxyde de plomb dans une fritte de verre utilisée comme matériau de scellement pour la fabrication de fenêtres pour les tubes laser à argon et/ou krypton. »*	21 juillet 2024 pour la catégorie 11 21 juillet 2026 pour les catégories 6, 8 et 9
Annex III, 34	*« Le plomb dans les éléments en cermets des potentiomètres ajustables »*	General Electric in the name of the Umbrella Project	*« Le plomb dans les éléments de potentiomètre trimmer à base de cermet. »*	21 juillet 2024 pour toutes les catégories

Note : ***Comme dans le texte juridique de la directive RoHS, les virgules sont utilisées comme séparateur décimal pour les formules d'exemption figurant dans ce tableau, contrairement au point décimal utilisé comme séparateur dans le reste du rapport.***

3. Introduction

3.1. Project scope and methodology

The scope of the study covers the evaluation of requests for the renewal of eight exemptions. An overview on the exemption requests is given in **Table 1-1** in the Executive Summary.

In the course of the project, a stakeholder consultation was conducted. The stakeholder consultation was launched on 30 March 2021 and was held for duration of ten weeks thus concluding 08 June 2021.

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 email notifications about new steps within the project.

Information concerning the consultation was provided on the project website, including a general guidance document, the applicant's documents, a specific questionnaire and a link to the EU CIRCA website. Public contributions submitted were published on the EU CIRCA website.

Following the stakeholder consultation, an in-depth evaluation of the exemptions began. The requests were evaluated according to the relevant criteria laid down in Article 5 (1) of the RoHS 2 Directive, as shown in the section on background and objectives on page 11.

The assessment of the exemptions evaluated in the course of the study appear in chapters 5 to 10. Each of the sections thereafter addresses a specific exemption or one case a number of exemptions evaluated jointly. The information provided by the applicants and by stakeholders is summarised in the first sections of the respective chapter. 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 applicant and other stakeholders. In the Critical Review part, the submitted information is discussed, to clarify how the consultants evaluate the various information and what conclusions and recommendations have been made. The general requirements for the evaluation of exemption requests as set by the European Commission may be found in the technical specification of the project.[1]

[1] Cf. https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_22/Technical_Specifications_Pack_22.pdf

3.2. Project set-up

As of 17 December 2020, the evaluation of exemption 18(b), 18(b)-I, 24, 29, 32, 34 of Annex III and Ex. 34 of Annex IV of Directive 2011/65/EU was assigned by the Commission. The contract has been amended, adding a further task to cover a request for renewal of one additional exemption, namely exemption 5b of Annex III and a further request for renewal of Ex. 34 of Annex III for category 11. Thus, the study covers the evaluation of eight exemptions.

The overall study has been led by Yifaat Baron and is managed by Katja Moch.

4. Links between the RoHS Directive and 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 that:

> "*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*".

Regulation (EC) No 1907/2006 on the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH) regulates the manufacturing, use or placing on the market of chemical substances on the Union market. REACH, for its part, addresses hazardous substances through processes of authorisation (substances of very high concern) and restriction (substances of any concern):

- 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 Annex XIV of the REACH Regulation (Authorisation list): "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 a Member States or the European Chemicals Agency (ECHA) upon request of the Commission considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that it is not adequately controlled, it shall prepare a restriction dossier. ECHA has also the initiative to prepare a restriction dossier for any substance in the authorisation list if the use of that substance in articles poses a risk to human health and the environment that is not adequately controlled. The provisions of the restriction may be made subject to total or partial bans, or conditions for restrictions, based on an assessment of the risks and the assessment of the socio-economic elements.

The approach adopted in this report is that once a substance has been included into the Annexes related to authorisation or restriction of substances and articles under the REACH Regulation, 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 it has first been adopted for the re-evaluation of some existing RoHS exemptions 7(c)-IV, 30, 31 and 40, (Oeko-Institut e.V. and Fraunhofer IZM 2012b) and in the following for the evaluation of a range of requests assessed through previous projects in respect of RoHS 2 (Oeko-

Institut e.V. and Fraunhofer IZM 2012a). Substances for which an authorisation or restriction process is underway may be discussed in some cases in relation to a specific exemption, in order to check possible overlaps in the scope of such processes and of requested RoHS exemptions and to identify the need for possible alignments of these two legislations.[2]

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

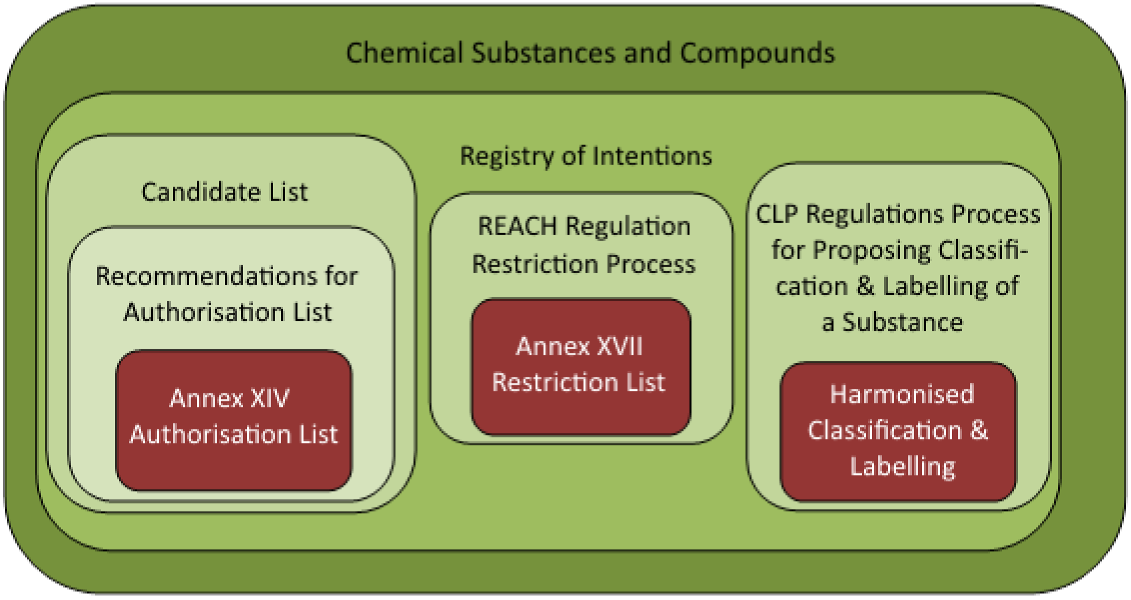
- on the list of substances of very high concern (SVHCs- the Candidate List);
- in the recommendations of substances for Annex XIV (recommended to be added to the Authorisation List);
- listed in REACH Annex XIV itself (the Authorisation List); or
- listed in REACH Annex XVII (the List of Restrictions).

As 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 register of the amendments to the REACH legal text.

The figure below shows the relationship between the two processes under REACH as well as the process on harmonized classification and labelling under the CLP regulation (Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging). Substances included in the red areas may only be used when certain specifications and or conditions are fulfilled.

[2] In 2014, the European Commission has prepared a Common Understanding Paper regarding the REACH and RoHS relationship in 2014 with a view to achieving coherence in relation to risk management measures, adopted under REACH and under RoHS:
REACH AND DIRECTIVE 2011/65/EU (RoHS) A Common Understanding; Ref. Ares(2014)2334574 - 14/07/2014 at http://ec.europa.eu/DocsRoom/documents/5804/attachments/1/translations

Figure 4-1: Relation of REACH Categories and Lists to Other Chemical Substances



Source: Own illustration

Before reaching the "Registry of Intentions" as shown in the figure above, there are additional activities and processes in order to identify substances of potential concern conducted by the ECHA together with the Member States and different ECHA Expert Groups.[3] If a Member State evaluates certain substance to clarify whether its use poses a risk to human health or the environment, the substance is subject to a Substance Evaluation. The objective is to request further information from the registrants of the substance to verify the suspected concern. Those selected substances are listed by ECHA in the community rolling action plan (CoRAP).[4] If the Substance Evaluation concludes that the risks are not sufficiently under control with the measures already in place and if a Risk Management Option (RMO) analyses does not conclude that there are appropriate instruments by other legislation / actions, the substance will be notified in the Registry of Intentions.

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

- Member States Competent Authorities (MSCAs) / ECHA, on request by the Commission, may prepare Annex XV dossiers for identification of SVHCs, 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

3 For an overview in these activities and processes see the ECHA webpage at: https://echa.europa.eu/substances-of-potential-concern

4 Updates and general information can be found under: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances. The list can be found on the following page: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

inform interested parties of the substances for which the authorities intend to submit Annex XV dossiers and, therefore, to facilitate 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: https://echa.europa.eu/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 https://echa.europa.eu/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 previous ECHA recommendations for inclusion in the Authorisation List are available at the ECHA website at https://echa.europa.eu/previous-recommendations;
- 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;
- 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; and

As of October 2021, the consolidated version of the REACH legal text, dated 25.08.2021, was used to reference Annexes XIV and XVII: The consolidated version is available at the EUR-Lex website: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20210825&qid=1633425938552. 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) of the RoHS Directive).
- 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) as well as bis(2-

ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DiBP).[5]

Compiled information in this respect has been included, with short clarifications where relevant, in Tables 1 and 2, which appear in Appendix 1.

The information has further been cross-checked in relation to the exemption evaluated in the course of this project. This has been done to clarify that the Article 5(1)(a) threshold-criteria quoted above is complied with in cases where an 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 the following section 4.1. Where conclusions of this analysis are to be taken into consideration in the individual evaluation of each assessment, this is specified in the final recommendations chapter of each exemption specific chapter.

4.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the consultant as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The evaluation thus includes a review of possible incoherence of the requested exemptions with the REACH Regulation.

As all exemption requests under evaluation in Pack 24 concerns the use of lead or lead oxide, the REACH compliance check focused on lead and its compounds is included here.

Annex XIV of the REACH Regulation lists substances, the use of which would require an authorisation in the EU. REACH Annex XIV includes three lead compounds:

- Lead chromate: According to applications for authorisation under REACH, lead chromate is used in pyrotechnical compositions contained in ammunition for naval self-protection;[6]
- Lead sulfochromate yellow: Applications for authorisation under REACH[7] point out a use as pigment in paints on metal surfaces, or to colour plastic/plasticised articles for non-consumer use;
- Lead chromate molybdate sulphate red: The applications for authorisation refer to the same uses as pigment lead sulfochromate yellow (pigment powder in an

5 The four phthalates, DEHP, BBP, DBP and DIBP have been added to the Annex according to Commission Delegated Directive (EU) 2015/863 of 31 March 2015.

6 https://echa.europa.eu/de/applications-for-authorisation-previous-consultations?diss=true&search_criteria_ecnumber=231-846-0&search_criteria_casnumber=7758-97-6&search_criteria_name=Lead+chromate

7 https://echa.europa.eu/de/applications-for-authorisation-previous-consultations?diss=true&search_criteria_ecnumber=215-693-7&search_criteria_casnumber=1344-37-2&search_criteria_name=Lead+sulfochromate+yellow

industrial environment into solvent-based paints for non-consumer use; paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.); to colour plastic/plasticised articles for non-consumer use)[8]

Annex XVII of the REACH Regulation contains entries restricting the use of lead compounds. The full wording of the entries is depicted in the Appendix (Aspects relevant to the REACH Regulation).

- Entry 16 restricts the use of lead carbonates in paints;[9]
- Entry 17 restricts the use of lead sulphates in paints;[10]
- Entry 19 refers to arsenic compounds but includes a few lead compounds and restricts their use as a fouling agent, for treatment of industrial water or for treatment of wood;[11]
- Entry 28 and 30 stipulate 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;[12]
- Entry 63 restricts the use of lead and its compounds:[13] in jewellery or in gunshot in or around wetlands. Furthermore, it 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/cm² 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. There are some derogations for specific articles e.g. keys and locks, including padlocks. Furthermore, articles within the scope of the RoHS Directive are derogated.
- Entry 72 stipulates that various lead compounds shall not be used in clothing textiles or footwear.[14]

The exemptions under evaluation here concern the use of

- Lead in glass of fluorescent tubes (Ex. 5(b));
- Lead as activator in the fluorescent powder of discharge lamps (Ex. 18(b), 18(b)-I and Annex IV Ex. 34);

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8 https://echa.europa.eu/de/applications-for-authorisation-previous-consultations?diss=true&search_criteria_ecnumber=235-759-9&search_criteria_casnumber=12656-85-8&search_criteria_name=Lead+chromate+molybdate+sulfate+red

9 https://echa.europa.eu/documents/10162/22dd9386-7fac-4e8d-953a-ef3c71025ad4

10 https://echa.europa.eu/documents/10162/ffd7653b-98cc-4bcc-9085-616559280314

11 https://echa.europa.eu/documents/10162/a798c758-371f-41e5-a38d-5f8dc9ba739d

12 See the conditions of restriction and the various Appendices (substance lists) at: https://echa.europa.eu/de/substances-restricted-under-reach

13 https://echa.europa.eu/documents/10162/851fb88e-9867-c5a0-bf15-2678ad831be6

14 https://echa.europa.eu/documents/10162/8db10905-d535-0a04-0af5-7628a210dc28

- Lead in solders through hole discoidal and planar array ceramic multilayer capacitors (Ex. 24);
- Lead bound in in crystal glass (Ex. 29);
- Lead oxide in seal frit in window assemblies for Argon and Krypton laser tubes (Ex. 32) and
- Lead in cermet-based trimmer potentiometer elements (Ex. 34).

The requested exemptions do not regard paints or jewellery or textiles, nor components that could be expected to be placed in the mouth by children under normal or foreseeable use. Furthermore, the use of lead in the materials in the scope of the above-mentioned exemptions is not a supply of lead or lead compounds as a substance, mixture or constituent of other mixtures to the general public. Thus, entry 28 and 30 of Annex XVII of the REACH Regulation would not apply.

It is concluded that a renewal of the exemptions would not result in an overlap and would therefore not weaken the protection afforded by REACH through entries 16, 17, 19, 28, 30 and 72.

Entry 63 restricts the use of lead and its compounds in articles supplied to the general public. Articles within the scope of the RoHS Directive benefit from a derogation from these provisions. The consultant understands that this is to provide legal coherence as the RoHS Directive restricts lead with a maximum concentration value tolerated by weight in homogeneous materials of 0.1% and specifies some specific exemption for the use of lead. This view is supported in the Common Understanding Communication, which specifies: "*The simplest way to avoid duplications and/or inconsistencies for a given substance already included in RoHS is, to exclude EEE within the scope of RoHS from the scope of a proposed REACH restriction also covering EEE*".

For the exemption 29 hereunder evaluation, a derogation was granted in entry 63 for crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC. For all other exemption hereunder evaluation, lead is not applied in accessible parts.

To conclude, no other entries, relevant for the use of lead in the requested exemptions could be identified in Annex XIV and Annex XVII (status September 2021). 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. A renewal of the exemptions could be granted considering all consideration discussed above if other criteria of Art. 5(1)(a) apply.

5. Exemption 5(b): "Lead in glass of fluorescent tubes not exceeding 0,2 % by weight"

Declaration

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

Acronyms and definitions

CFL	Compact fluorescent lamp
EEE	Electrical and Electronic Equipment
LED	Light emitting diode
LE	LightingEurope
LFL	Linear Fluorescent Lamps
Pb	Lead
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
TLED	Linear tubular LED
WEEE	Waste Electrical and Electronic Equipment
wt %	Weight percent

5.1. Background of the exemption request

LightingEurope (2020) explains that lead (Pb) was used in the past for functional reasons in the production of glass for fluorescent tubes, and was contained in the glass at a concentration of up to 20%. Leaded glass is explained to have been easier to process in all steps of glass smelting and glass soldering, leading to lower failure amounts in the manufacture of fluorescent tubes. Pb, however, was successfully phased out and is no longer needed for functional purposes. Nonetheless, despite not being intentionally added, Pb is still present in the glass of fluorescent tubes due to the use of secondary glass recovered from the waste management of fluorescent tubes in the manufacture of new tubes. As this glass can contain differing amounts of Pb, an exemption is listed in Annex III of RoHS, allowing this practice. The current Formulation of exemption 5(b) in Annex III of the RoHS Directive is:

> "*Lead in glass of fluorescent tubes not exceeding 0,2 % by weight*"

The exemption was assessed in 2015-2016 but the renewal is still pending.

In January 2020, LightingEurope (2020) submitted a new application for the renewal of this exemption. LightingEurope requests the renewal of Ex. 5(b) for an additional 5 years, but proposes the following wording, with a view to extending the scope of the exemption:

> "*Lead in glass of fluorescent tubes and LED retrofit tubes (glass in lighting equipment) not exceeding 0.2 % by weight*"

5.1.1. The history of the exemption

An exemption for lead in the glass of fluorescent lamp glass was already listed in the first RoHS Directive (2002/95/EC)[15] when it was published in 2003. At the time it was annotated as Ex. 5 and formulated as follows:

> "*Lead in glass of cathode ray tubes, electronic components and fluorescent tubes*."

The exemption was reviewed under the RoHS 1 regime, with the last assessment taking place in 2008. The report (Gensch et al. 2009) refers to three application areas looked into separately: cathode ray tubes, fluorescent tubes and electronic components. The assessment concluded that an exemption was still justified for each application group and recommended that separate items be introduced into the annex instead of the existing exemption. The first two application were added as items of Ex. 5 and appear in the last consolidated version of the Directive[16] where the exemption has been split into two items:

- "*5(a) Lead in glass of cathode ray tubes*
- *5(b) Lead in glass of fluorescent tubes not exceeding 0,2 % by weight*"

Item 5(b), the subject of this assessment was justified on the base that lead had been phased out and was no longer necessary to achieve a certain function. However, impurities existed in the glass tube material due to the use of recycled content for which the exemption was requested. A further justification at the time (2008) stated by the association ELC was that "*As the use of lead in new glass is decreasing dramatically ELC do not expect to need this "exemption extension" for more than 1 period*". Both items were carried over to the current Directive, whereas the renewal of Ex. 5(a) was not applied for, leading to its expiration.

[15] Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, initial legal text, available under: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32002L0095&from=DE

[16] Consolidated text: Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, from 10.09.2011, available under: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002L0095-20110910

As for the scope of the original exemption for "*electronic components*", the assessment report (Gensch et al. 2009) specifies the following as example applications understood to be covered by this term "*lead-based electrodes, resistors, capacitors, chip coils, chip inductors, resistance networks, capacitor networks, hybrid ICs, power semiconductors etc*". The use of lead in such components was found to be justified at the time, but the wording recommended was added to the annex as Ex. 7c-I and not as part of Ex. 5(b):

> "*Electrical and electronic components which contain lead in a glass or ceramic other than a dielectric ceramic, or in a glass or ceramic matrix compound (e.g. piezoelectronic devices).*"

Despite ELCs expectation that the exemption would not be needed for more than 1 term, LightingEurope requested the exemption be renewed in 2015. In 2015-2016, Oeko-Institut performed an assessment of exemption 5(b), initiated through the submission of the renewal request. Again, it was understood that lead was unintentionally present as the glass collected and recovered from fluorescent lamps was then applied to produce the same type of lamps. Due to the expected savings in resources (e.g. material, energy) and seeing as the practice was performed in a semi-closed loop manner that did not introduce the lead into new material cycles, the exemption was considered justified. The study (Gensch et al. 2016) recommended the renewal of this exemption for five years until 21 July 2021, with the same wording:

> "*Lead in glass of fluorescent tubes not exceeding 0,2 % by weight*"

The revision of Annex III in relation to this exemption is still pending.

5.1.2. The scope of the requested exemption

LightingEurope (2021b) was asked to clarify for what equipment the extension of scope of the exemption is required. In this regard, LightingEurope states that the term "*lighting equipment*" of Annex I of the RoHS Directive covers products falling in Category 5. LightingEurope requests the exemption for lamps used in Category 5 EEE e.g. luminaires. "*The exemption is intended for products and components (e.g. lamps) using soda lime glass as a material, using during the production process a fraction of recycled glass stream on top of virgin minerals*". LightingEurope considers that the following lighting equipment, where lead is not intentionally added, should be included in the scope of a future exemption:

- Glass in LED lamps where recycled glass can be used to increase resource efficiency,
- Glass in luminaires, containing fixed installed LED modules, replacing luminaires for fluorescent lamps, where recycled glass can be used to increase resource efficiency.

According to LightingEurope (2021), glass is used as a functional or decorative material in many luminaires, irrespective whether it is used stand-alone (Cat. 5) or as part of a Cat 1-11 products, e.g. in a kitchen hood. Though, in the original application (LightingEurope 2020) only category 5 for lamps and lighting equipment is specified as relevant for the exemption, it is also raised that there is uncertainty whether a lamp in another EEE would fall under Cat. 5 or under the category of the EEE in which it is installed and placed on the market.

5.2. Technical description of the requested exemption

5.2.1. Technical background

LightingEurope (2020) explains that lead (Pb) was used in the past for functional reasons in the production of glass for fluorescent tubes, accounting for up to 20% of the glass composition. Pb, however, was successfully phased out and is no longer needed for functional purposes. Nonetheless, Pb is still present in the glass of fluorescent tubes due to the use of secondary glass recovered from the waste management of fluorescent tubes in the manufacture of new tubes. As this glass can contain differing amounts of Pb, LE explains that a maximum content of 0.2 wt % Pb can be contained in the glass of fluorescent or LED retrofit tubes, though from internal measurements, most lamps do not exceed the threshold of 0.1 wt % in glass.

5.2.2. Amount of lead used under this exemption

To estimate the amount of Pb to be placed on the EU market through this exemption, LightingEurope (2020) assumes an average Pb content of 500 ppm resulting from the recycled glass of old lamps. In 2022, 150 million fluorescent lamps will be placed on the EU-28 market per annum and about 50 million LED replacement lamps, with an average weight of 0.1 kg per lamp, of which the glass accounts for ca. 75 wt % (weight percent) per lamp "*= 50.000 tons; hereof 0.05/0.2% lead*". It is roughly estimated that 8 tons of lead would enter the EU-28 market bound in lamp glass with 30 tons being the worst case, assuming all lamp glass would contain 0.2% lead (which is stated to be an unrealistic assumption).

5.3. Applicant's justification for the requested exemption

LightingEurope (2020) states that fluorescent lamps and LED retrofit tubes have a long lifetime. Seeing as lead in glass of fluorescent tubes was allowed in the EU until 2010 and is still allowed in most countries outside the EU (e.g. in China), lead-containing recycled glass can be expected to be available for the foreseeable long term, probably decades. Lead in the glass is said to be safe, as it will not leave the glass matrix under any circumstances.

In this sense, using secondary glass recycled from fluorescent lamps in the manufacture of glass components for new ones is considered a practice that contributes to circularity, saving resources and energy in the production of new glass. This is the main reasoning of LE in the justification of the renewal of the exemption and the extension of its scope.

5.3.1. Substitution, elimination or reduction of lead

Regarding the availability of alternatives, it can be understood that newly manufactured glass could be used as a substitute and would not have reliability limitations. The main argumentation however is based on the environmental benefit of using recycled glass, resulting in the placing of Pb on the EU market through lamp glass.

5.3.2. Environmental arguments

According to LightingEurope (2020) the main justification for the exemption is that the use of recycled glass reduces the energy consumption required for glass production significantly, as the recycled glass amount needs up to 30% less energy for manufacture. Typically, in a glass production plant, 30 - 40 % recycled glass is used, whereas technically up to 80% is estimated to be possible. However, such high shares require the recycled glass to be nearly identical to the produced glass. Thus, the main source for the recycled glass is mainly glass from lamp recycling. The lead content (as well as mercury content) is measured regularly in the glass production plant.

The consultant understands the statements on the glass composition to refer to e.g. soda lime glass which is the type of glass used for producing the tube of fluorescent lamps, as opposed for example to glass from bottles and jars which has a different composition. The consultant further understands that the composition can vary at least in relation to the quantity of Pb, which will not be present in materials used to produce primary glass, but which could be present at different amounts in the secondary glass fraction. Secondary glass is mixed with raw materials needed for creating primary glass to create the glass material that can be used in the applications for which the exemption is requested.

LightingEurope (2020) expects a large amount of fluorescent lighting installations to be replaced in the coming years due to the transition to LED installations. This might result in a temporary increase in the Pb content in recycled glass. The exemption is to allow the use of glass recovered from these installations to be used in the manufacture of special purpose fluorescent lamps or for glass tubes for TLEDS (i.e. LED tubes).

LightingEurope (2020) believes the exemption is important to fulfil increasing EU requirements for the use of recycled materials in new products, in the production process of glass added as a fraction to the virgin minerals stream, as well as to reduce energy consumption in glass production.

Regarding the handling of lamps (and lamp glass) at end-of-life, LightingEurope (2021b) explains that "*depending on the system in place in the different EU countries, lamps are either collected and handled in the same waste stream or in other countries, there is a separation. During treatment fluorescent lamps are usually separated from LED lamps especially LED lamps containing plastic tubes and covers. Whether the glass fractions are separated depends on the recycling technology applied. Irrespective of the process: The same glass tubes, consisting of a fraction of recycling materials are used for new fluorescent lamps, as well as for LED lamp glass […]*".

5.3.3. Socioeconomic impacts

LightingEurope (2020) expresses concern that the denial of the exemption could lead to the limitation of the use of recycled glass for lamp glass production and thus to wasted glass, as well as to higher costs for ongoing product conformity assessments.

It is detailed that "*most LED lamps are produced outside the EU. In the production countries, the ban of lead in lamp glass was introduced later or is not yet in force. Recycled glass batches containing lead are used in the production of lamp glass in* *those countries and added as a fraction to the virgin minerals stream in a furnace, increasing the risk of lead content levels in final glass tubes. The exemption is necessary to avoid the unnecessary scrapping of products in accordance with circular economy principles*". (LightingEurope 2021b)

An example for this is provided in the same document (LightingEurope 2021b): "*The test report from SGS that has been submitted confidentially and should not be shared, contains another test report for an incident with soda lime glass tubes used for TLED lamps. It illustrates that the lead content was 1418 ppm, and this glass lamp batch needed to be scrapped as the lead content was in this case > 1000 ppm. The reason for this was that a certain fraction of recycled glass (containing lead) is used in the glass furnaces production process […] This reuse of recycled materials favours the environment as it prevents landfilling. It can however result in a lead content between 1000-2000 ppm for certain batches of glass productions of an LED lamp glass that was manufactured with glass produced in a country/region with no or more recent lead restrictions. In such a case, the complete molten content of the glass furnace is > 1000 ppm and cannot be used for TLED tubes and needs to be scrapped (tons of glass tubes for one furnace batch)*". Excerpts from measurement reports of the content of lead in recycled glass are detailed in the document.

In a later communication, it is further stated that "*the content of lead is usually not exceeding 0.1%. In very exceptional cases however, if the lead content is exceeding 0.1% but below 0.2 % the products would not conform with RoHS and would consequently be destroyed and recycled without using them […] Without the exemption the risk of having non-RoHS conforming products increases leading to a reduced use of recycled glass*" (Lighting Europe 2021a). The consultant understands this statement to refer to cases where the glass recovered from fluorescent lamps is used in the manufacture of soda lime glass for other applications, which at present do not benefit from the exemption, e.g. TLEDs or glass components of luminaires.

5.4. Stakeholder contributions

A single contribution was made to the stakeholder consultation on this exemption, submitted by the Swedish Chemicals Agency (KEMI).

KEMI (2021) states that "*To make the shift towards toxic-free material cycles and clean recycling, it is necessary to phase out substances of very high concern and minimise substances of concern in products and recycled material, as outlined in the EU Chemicals Strategy for Sustainability – Towards a Toxic-Free Environment. Lead is a substance that has such properties of concern that it should be phased out as far as possible in consumer products*".

KEMI (2021) refers to the Chemicals Strategy that "sets out as a principle that the same limit value for hazardous substances should apply for new and recycled materials with derogations in only exceptional and justified cases". In the opinion of KEMI, "*accepting a higher limit value of lead (0.2% instead of 0.1%) due to the use of recycled material is not in line with the principle of having the same limit values to new and recycled material as outlined in the Chemicals Strategy. We doubt that this exemption is truly an exceptional and justified case as envisioned in the Chemicals Strategy*".

As regards the main argumentation of LE which focuses on the possible energy savings that the use of secondary glass with lead impurities enables, KEMI (2021) states: "*A lower energy consumption does not per se justify the use of the restricted substance through an exemption. We believe that this type of reasoning shifts the focus from the intended scope of the RoHS Directive: to protect the environment and human health by restricting the use of hazardous substances in EEE. If the goal is energy saving, there are other instruments in the EU to deal with this type of problem, e.g. the Ecodesign Directive [...] Risks to human health and the environment from lead-containing glass can arise e.g. in improper/incomplete collection of lamps at their end-of-life as well as exposure to workers and emissions to the environment during the glass recycling and manufacturing processes of new lamps".*

KEMI (2021) also refers to the need to consider possibilities to decontaminate the waste stream as a first step, and to consider recycling lead-containing glass in a separate loop from clean glass in a second step, where the resulting secondary material should only be used "*in well-defined and controlled applications*". In this context, a new technique to decontaminate lead from glass being developed by the Swedish Research Institute RISE is mentioned.

5.5. Critical Review

The scope of exemption 5(b) as it is currently (January 2022) listed under Annex III of the RoHS Directive is only applicable to the "glass of fluorescent tubes". The requested exemption, however, is aimed to support the use of secondary glass in the manufacture of various types of lamps and lighting equipment because such glass may contain lead as an impurity. Secondary glass can be applied when manufacturing glass to produce components such as lamp glass tubes or glass bodies. Based on the LE request, it can also be understood that this could also feed into the production of lighting equipment parts made of glass. The scope of such articles is not completely clear and is addressed later in this chapter under section 5.5.4.

5.5.1. REACH compliance – Relation to the REACH Regulation

See details in chapter 4.

5.5.2. Scientific and technical practicability of substitution

It can be understood that secondary glass can be mixed with materials used to manufacture primary glass in the production of the soda lime glass from which glass components are later formed. The inclusion of secondary glass in this mix has developed as a practice in glass manufacturing as it reduces the amount of energy needed for producing the glass and the need for new resources. The share of secondary glass can vary, where higher amounts of secondary glass would require the latter to be relatively similar to primary glass in composition, referring to the purity of the glass material. Though this aspect limits the amounts of secondary material that can be used in a certain batch, there is principally no restriction to using only primary glass in this production process, aside from the fact that this would increase the energy consumption of the production process.

In other words, it can be understood that substitutes are available in the form of primary glass, i.e. the resources needed for its manufacture. Such materials are furthermore applied in practice also in cases where the amounts or quality of secondary materials are insufficient and would not lead to different performance or reliability of the glass components it is used to produce.

Though not addressed in detail, it is also understood that secondary glass fractions are available in some cases with very small amounts of lead impurities (less than 0.1%). LightingEurope (2020) states "*from internal measurements, most lamps do not exceed the threshold of 0.1 wt % in glass*". It is conceivable thus that in some cases recycled glass could be lead free (already at present or in the future), where care was taken to only include lead-free glass in the waste glass fraction that is recycled. Though such fractions may be rare at present, this could change in the future, depending on the sector and the allowances that are provided for using lead in glass. In the EEE sector, it is more likely that recycled glass streams from mixed WEEE will have lead content, due to the various exemptions[17] that currently exist in the RoHS Directive and how EEE is segregated at waste management into various fractions prior to treatment (see further details under section 6.5.5).

To summarise, substitutes can be considered available, in the form of primary glass production and possibly also in specific secondary glass batches. The reliability of such fractions as a substitute is also not questioned. However, whether such materials should be preferred or so to speak actively applied as substitutes in this case depends on related environmental impacts and on the general availability of such fractions. This is further discussed in the following section 5.5.3)

5.5.3. Environmental arguments and socioeconomic impacts

The main argumentation that LE raises to justify the renewal of exemption 5(b) and also of the possible extension of its scope refers to the range of benefits that the use of secondary glass can generate in terms of decreasing the amount of energy needed to produce soda lime glass. "*The reason for using recycled glass is to ensure good quality, preserve minerals (resource efficiency and material recovery), to achieve a circular economy by reclaiming the glass that can be reintroduced in the manufacturing process and to reduce energy consumption.*" (Lighting Europe 2021a). The range of benefit will vary in a specific batch respective of the amount of secondary glass added to the mix. LE did not provide quantification for the benefits related to the production of soda lime. Instead Lighting Europe (2021a) refers to the savings related to the production with secondary glass "*Using recycled glass is also positive from the*

[17] This includes for example the following exemptions currently listed in the annexes:

Ex. 7(c)-I, Annex III: Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound;

Ex. 13(a), Annex III: Lead in white glasses used for optical applications;

Ex. 13(b), Annex III: Cadmium and lead in filter glasses and glasses used for reflectance standards;

Ex. 29, Annex III: Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC *perspective of resource efficiency (preserving minerals and allowing material recovery). Ecosystem*[18] *indicates that recycling the glass contained in 1 tonne of tubes and lamps avoids the emission of 595 kg of CO_2 equivalent and preserves 3 kg of raw materials […] Ecosystem indicates that closed loop recycling of the glass in tubes and lamps (i.e. reintegrating it into tubes and lamps) is approximately 80 times more beneficial than material recovery (e.g. using the materials in another application) in terms of climate change (CO_2 equivalent). It is about 50 times more beneficial than material recovery in terms of and preserving fossil resources*."

Though this statement provides an indication of possible savings, it is not provided in context of the CO_2 *equivalent* emissions of the production of primary glass and as such does not allow a comparison and a conclusion as to the rate of expected benefits expected from replacing one tonne of primary glass with recycled glass. This makes the quantification of the use of recycled content with small amounts of lead difficult to compare to the case of using only primary material.

It is not straightforward to find data in the potential savings that the use of recycled glass can derive in the manufacture of glass lamps. LE were asked to "*provide detail and quantification of environmental and health impacts (both negative and positive) that can be associated to the use of virgin soda lime glass in comparison to the use of soda lime glass with recycled content*". Detail was not provided beyond the statements cited above. The European Glass Container Federation states that in glass containers, when using recycled glass (cullet), a "*10% increase in cullet usage results in up to 3% energy savings*[19]". Based on the LightingEurope (2020) statements that cullet can be used at amounts of 30-40% (typical) and up to 80% (when it is relatively pure), this would mean that energy savings could range between 9 % to 24 %, assuming that the savings for lamp production soda lime glass are in a similar range. Also in relation to container glass, an older publication (Gaines & Mintz 1994) specifies that "*Less energy is required to melt cullet than to melt and react the batch materials [of primary glass]. The primary energy consumption totals are 17.0 x 106 Btu/ton of bottles with no postconsumer recycling, 14.8 x 106 Btu/ton with maximum recycling, and 15.9 x 106 Btu/ton for the current mix of recycling. The total primary energy use decreases as the percent of glass recycled rises, but the maximum energy saved is only about 13%. If distance to the landfill is kept fixed and that to the recovery facility multiplied by about eight, to 100 mi, a break-even point is reached, and recycling saves no energy […] Recycling of glass does not save much energy or valuable raw material and does not reduce air or water pollution significantly. The most important impacts are the small reduction of waste sent to the landfill and increased production rates at glass plants*". The relation to lamp glass is unknown, however, this questions the argumen tation raised by LE and sets the focus on the savings of glass disposal.

18 According to LightingEurope (2022), Ecosystem "*is a Producer Responsibility Organisation (PRO) accredited by the French Public Authorities to collect, decontaminate and recycle household waste electrical and electronic equipment (WEEE), professional equipment (professional WEEE), lamps and small fire extinguishers*."

19 See following page on "GLASS IS A PERMANENT MATERIAL, ENDLESSLY RECYCLABLE": https://feve.org/case_study/glass-is-a-permanent-material-endlessly-recyclable/, last viewed 26.11.2021

As for possible emissions of lead, LE states that Pb is bound in glass and therefore does not leave the glass matrix, thus LE expects there to be no health impact. "*For both use phase and end of life stage (recycling process), there will be no exposure, as the lead is bound in the glass matrix*". (Lighting Europe 2021a)

In this regard, KEMI (2021) states that risks to human health and the environment from lead-containing glass can arise e.g. in improper/incomplete collection of lamps at their end-of-life as well as exposure to workers and emissions to the environment during the glass recycling and manufacturing processes of new lamps. However, this statement is not substantiated further.

In lack of a comprehensive quantification of costs and benefits to the environment and health it is difficult to conclude as to the significance of the range of benefits of the use of secondary glass containing lead in comparison to the use of primary glass. The consultant's sees however a difference between the case of recycled glass used in the manufacture of lamp glass and that used for other glass components of luminaries or EEE containing a lighting component.

Fluorescent lamp glass

In the EU, the WEEE Directive[20] lays down as a matter of priority that fluorescent lamps, which were the only applications that originally benefited from the exemption, are collected separately from other WEEE.[21] Annex VII of the WEEE Directive requires that the following substances, mixtures and components have to be removed from any separately collected WEEE and subsequently refers to "*mercury containing components, such as switches or backlighting lamps"* and *"gas discharge lamps*" among others. This means that the mercury is removed from gas discharge lamps. This requirement basically leads to fluorescent lamps (possible with other lamps)[22] being collected and treated separately from other WEEE. As result, the glass recovered from this stream is separate from other recycled glass and has been used over the years for the manufacture of new lamp glass in a semi-closed loop practice. With the understanding that under normal operation conditions, the lead is encapsulated in the glass, it can be concluded that the risk for emissions during use is small. As for emissions at end-of-life, for lamps collected and treated in the EU with WEEE, it is assumed that the treatment facilities will have sufficient abatement technologies in place to protect workers and the environment not only because of the risk for lead emissions but also of mercury emissions. The reuse of the recovered glass in this case is assumed to create a closed loop and to ensure that the treatment does not result in emissions. When lamps are not disposed of correctly, the situation will differ,

20 Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

21 According to Article 5 (1) Member States shall adopt appropriate measures to minimise the disposal of WEEE in the form of unsorted municipal waste, to ensure the correct treatment of all collected WEEE and to achieve a high level of separate collection of WEEE, notably, and as a matter of priority, for […] fluorescent lamps containing mercury, […].

22 LE explains that "*LED lamps are collected together with all other lamps (including mercury-containing lamps), because consumers cannot distinguish between the various technologies. Mercury lamps are treated as hazardous waste. Because LED retrofit lamps are mixed with mercury lamps, the entire batch is treated as hazardous waste.*"

depending on where they end up. For reference, according to EUROSTAT, in 2018, the collection rate of WEEE was 47 % in the European Union. It cannot be concluded if the collection of lamps was higher or lower than this level in 2018, but it is likely that some lamps are not disposed of properly, possibly leading to emissions.

LED fluorescent retrofit lamps

As for LED lamps designed as fluorescent lamp retrofits, Lighting Europe (2021a) states that "*In principle, LED lamps are currently collected in the same way as fluorescent lamps because consumers cannot distinguish between the different technologies*". Assuming that this is indeed the case, the glass recovered from such LED lamps together with glass from fluorescent lamps could be considered to be in the same semi-controlled loop (depending on the rate of lamps correctly disposed of to WEEE collection systems). In this case, the consultant considers that the material loop for this lamp glass is well controlled and held separate from normal glass. Once it is technically and economically feasible to extract lead from such glass, this technology could be applied to this stream.

Alternatively, should it be decided to discontinue the using recycling glass from LED/fluorescent lamps in order to clean the material cycle, this would also be easier to implement, as LED lamps disposed of together with fluorescent lamps will result in a separate recycled glass stream which can then be stabilised and disposed of as hazardous waste. The difficulty is that probably not all LED retrofits are disposed of together with fluorescent lamps in a joint separate stream. Some are probably disposed of together with mixed WEEE (or even worse with municipal waste). Glass from LEDs that are disposed of with mixed WEEE would end up in the mixed glass fraction, which will be treated differently. If glass with lead impurities is allowed for use in LED retrofits, then this could lead to unwanted contamination of other glass fractions when such lamps are disposed of with mixed WEEE.

Glass components in luminaries

The case of glass components in luminaires and EEE with a lighting component is different. Regarding their waste treatment at EoL, Lighting Europe (2021a) states that "*Luminaires are in a different/separate waste stream*". From the general knowledge of the consultant, this would suggest that such products are first treated mechanically (shredder) to allow the separation of different materials from the mixed fraction. It is unclear if glass that would be separated from this fraction could still be used in the manufacture of soda lime glass as also other types of glass could be contained in mixed WEEE. LE also does not indicate such glass as a source of use of secondary material for producing soda-lime glass. This route could thus be said to contribute to the general contamination of glass recovered from WEEE, if the glass components in luminaires contain e.g. lead.

It is assumed that lead is not intentionally added in glass components in luminaires. The predecessor exemption did not allow lead in such components. However, there are other exemptions in the RoHS Directive that allow the use of lead in glass components (e.g. Ex. 7(c)-I mentioned above), which could become part of the same waste stream. It could be said that the contribution of applications placed on the market through this exemption to the total amount of Pb in glass recycled form mixed WEEE are more modest in relation to other exemptions where much higher levels of lead may be included in the glass. However, in the case of other exemptions, the lead is added purposefully to provide a specific function in cases where substitutes are claimed not to be available. In the case at hand, including lighting equipment in the scope of the exemption would allow the placing of lead on the market in an application where it is not needed and where it will contribute to the general dispersion of lead rather than to its controlled management or prevention. In the consultant's view this would not be in line with the intention of the Directive.

5.5.4. Scope of the Exemption

LE requests the exemption to be amended to a more extended scope, covering glass in "*fluorescent tubes and LED retrofit tubes (glass in lighting equipment)*". LE were thus asked whether this extension should only serve the purpose of using lead-based glass in fluorescent tubes (such as those applied in compact and linear fluorescent lamps - CFLs and LFLs) and in LED retrofits[23].

However, LE also request the exemption for glass in luminaires, which can contain fixed installed LED modules, replacing luminaires for fluorescent lamps. The consultant understands this to mean not just the retrofit LED lamp glass, which can be expected to have a similar form to the original lamp (e.g. CFL, LFL), but also new luminaires in which an LED module may be integrated. LE were thus asked to communicate more clearly for what equipment and material the exemption is requested.

Lighting Europe (2021a) states that they "*request the exemption for all soda lime glass used in lamps and luminaires*". As lamps can also be integrated into other equipment, such as a mirror or oven, in the consultant's opinion, it was not clear if the requested exemption would also benefit glass used in such equipment or not. Looking at Commission Regulation (EU) 2019/2020 (Ecodesign) the term 'containing product' is defined as "*a product containing one or more light sources, or separate control gears, or both. Examples of containing products are luminaires that can be taken apart to allow separate verification of the contained light source(s), household appliances containing light source(s), furniture (shelves, mirrors, display cabinets) containing light source(s)[...]*". LE were asked to comment on this and stated that they request "*the exemption for Cat. 1-11 lamps and luminaires, provided the soda lime glass is used in that application*". LE provides an alternative for the exemption formulation to restrict it to the material and applications for which it is requested:

> "*Lead (not intentionally added) in soda lime glass used in lamps and luminaires, not exceeding 0,2 % by weight*."

Asked again as to the scope of the term "lighting equipment", LightingEurope (2022) provides the examples reproduced in Figure 5-1 and explains that it refers to:

> "*Any soda-lime glass used in any lighting equipment. Main examples are Linear Fluorescent lamps, linear TLED replacement lamps and shaped or flat glass*

[23] CFLs and LFLs contain mercury and efforts have been made to develop alternatives that would allow their replacement and phase out, such as LED retrofits. Retrofit lamps can be used in luminaries or equipment in which CFLs and LFLs were originally installed.

covers used in luminaires. There is no intentional use of lead in such glass but the risk of contaminations coming from use of recycling glass. If a value exceeding 0.1% is detected in incoming or laboratory inspections this batch of products would not be compliant and would not be allowed to be put on the market. The only consequence would be to destroy and recycle the products prior to use. With a limit of 0,2% lead in glass there is no realistic risk anymore to exceed this limit."

Figure 5-1: Examples of uses of secondary glass that LightingEurope request to be covered in the renewal of Ex. 5(b)

Examples of Outdoor luminaires with flat glass cover and table- and ceiling lamps with shaped glass covers.

Examples of tube glass for CFL.ni, Linear fluorescent lamps and Linear LED lamps.

Note: Figures reproduced from LE document
Source: (LightingEurope 2022)

It is the consultant's opinion, extending the scope of the exemption to LED retrofits for fluorescent lamps may be in line with the current scope of the exemption, seeing as the products are similar in form and use and could be assumed to have the same route of collection and treatment at end-of-life. For luminaires and even more so "containing products" this is not the case and this practice would actually be considered to contribute to the "loss" or dilution of the lead in the lamp glass and could lead to more dispersive uses (for example when mineral fractions are recovered from WEEE and used in construction or backfilling).

LightingEurope (2020) mentions that a large amount of fluorescent lighting installations are to be replaced in the coming years due to the transition to LED installations. This is raised to further support the exemption, explaining that it could result in a temporary increase in the Pb content in recycled glass, hindering the use of secondary glass. It is not clear why this aspect would result in the increase in the Pb content of glass. This statement might refer to the end-of-life of installations, i.e. luminaires and not specifically to the fluorescent lamps they contain. However, information in the LE documents suggests that only secondary glass recovered for the separate recycling of lamp glass is directed to the production of new lamp glass. When asked about the sources of secondary materials for manufacturing glass for lamps and lighting equipment, LightingEurope (2022) stated that "*the secondary raw materials (recycled) which are used as a fraction in the production of new glass tubes come mainly from recycling of fluorescent lamps*". Thus, leaded glass contained in other parts of the luminaire would not be expected to be recycled and sent to lamp manufacture but would rather be treated with mixed WEEE. If only the lamps are referred to – the 0.2% threshold was added to the exemption following the 2009 review and lamps placed on the market can be expected to have lower amounts of lead in their glass since at least a decade. Though lamps used by private consumers can have a longer service life (shorter daily operation), most of these can be expected to remain in use until the lamp malfunctions, irrespective of the phasing out of certain lamp types. In contrast, where lamps are used in commercial or industrial uses, their average lifetime is expected to be under ten years meaning that such lamps now reaching end-of-life would already contain 0.2% lead and less. Thus, it cannot be followed why more lamps reaching end-of-life at the same time would result in higher amounts of lead in the recycled glass sent to lamp manufacture. In contrast, should the use of lead glass in articles other than lamp tube glass be allowed, this would probably contribute to the accelerated dilution of the amount of lead in this fraction as glass used in luminaires would be removed from the recycled glass stream used for lamp manufacture.

The reference to the import of lamps from outside the EU and the larger amounts of lead that such countries may have in their glass waste streams may also mean that outside the EU, this stream is fed from additional end-of-life applications and not just lamps. Allowing recycled glass a higher threshold in this case would, as KEMI states, "*undermine the purpose of adopting legislation to restrict the use of hazardous chemicals to protect human health and the environment*". Looking at the European practice that discharge lamps are separated from other WEEE at end-of-life and treated separately, in the consultant's opinion, extending the scope to glass in luminaires would be contra-productive to the concept of circularity: the waste stream of lamps (when disposed of properly) can be considered to have a semi-closed loop nature, whereas allowing the use of such glass in other products would open this loop and contribute to the dispersion of glass in other applications where its potential for further recycling and reuse is unknown (e.g. filling materials in construction).

5.5.5. 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 (the resources used to produce primary glass) are available for use in the manufacture of lamp glass and are also not considered to lead to reliability issues. However, lead is not intentionally added to the glass but an impurity that is a result of the use of secondary (recycled) glass in the manufacture of new lamps.

Therefore, the main argumentation of the applicant refers to the third criterion above as the use of secondary raw material has the positive affect that:

- it supports resource efficiency (reducing the need for primary materials),
- it may also conserve energy (lowering the temperature needed to melt the resources comprising the glass mix), and
- it saves land needed for disposal of contaminated glass to landfill.

The numbers provided on the latter affects only partly reflect the share of benefit that the use of secondary material generates, making it difficult to consider if the third article is fulfilled or not.

In general, practices that contribute to circularity are considered positively in terms of the third criterion, however in parallel, as raised by KEMI, it is also necessary to consider if such practices are to be looked at differently when the recycled material contains a hazardous material that has been banned. In the opinion of KEMI (2021) "*using recycled glass with a higher level of lead and mixing it with new uncontaminated glass results in contamination of a pure material stream. This will result in larger volumes of contaminated material that will need to be taken care of at a later waste stage. This further delays the shift to toxic-free material cycles and prevents the transition to a clean circular economy, which is not in line with neither the EU Circular Economy Action Plan, nor the EU Chemicals Strategy for Sustainability*". KEMI recommends that, "*lamps with a higher level of lead should preferably be sorted out at the waste phase (in particular very old lighting installations) to prevent reintroducing lead into new consumer products*".

The Chemicals Strategy states that "*To move towards toxic-free material cycles and clean recycling and ensure that "Recycled in the EU" becomes a benchmark worldwide, it is necessary to ensure that substances of concern in products and recycled materials are minimised. As a principle, the same limit value for hazardous substances should apply for virgin and recycled material. However, there may be exceptional circumstances where a derogation to this principle may be necessary. This would be under the condition that the use of the recycled material is limited to clearly defined applications where there is no negative impact on consumer health and the environment, and where the use of recycled material compared to virgin material is justified on the basis of a case by case analysis*."

This suggests that the general direction should be towards cleaner material cycles. It also states that derogations could be considered in certain cases. The Strategy however does not put forward specific criteria for evaluating a specific case. It does, however, refer to the condition that the use needs to be "*limited to clearly defined applications"* suggesting that the application of secondary material in the tube glass of lamps may be permissible, as it is a clearly defined component which is furthermore required to be collected and treated separately. This is opposed to luminaires that nowadays can encompass any article in which a lighting component has been integrated and which are collected and treated with mixed WEEE[24]. The understanding that these two application groups differ at end of life in the treatment of waste and the resulting secondary material, and its potential uses further strengthens the conclusion that extending the scope to glass components of luminaires would be counterproductive to the "*move towards toxic-free material cycles".*

In the case of fluorescent lamps, assuming that the Commission considers an exemption for lead in lamp glass to be in line with the Chemicals Strategy (i.e. a limited and clearly defined application), an exemption could be granted to allow this practice to continue. In part, the premise of this conclusion is that it allows the further use of a leaded glass in a semi-closed stream, which would facilitate changes in this stream in the future (e.g. discontinuing use to clean the glass material stream or extraction of lead to contribute to a non-toxic material stream). This is under the understanding that though new material is added to the glass cycle, the recycled content would only be used for the same purpose and would thus probably be collected and treated separately, remaining in the same material cycle. One aspect here that should be considered in relation to this decision is that the production of fluorescent lamps has decreased in the EU, meaning that finding a sink for such recyclate may require export of the glass in the future if the scope is not extended, possibly changing the ratio of environmental benefits and costs. Some fluorescent lamps have been phased-out through the Ecodesign Regulation and decisions in relation to the future of CFL and LFLs under RoHS are expected to significantly reduce the number and type of new fluorescent lamps coming on the market in the future.

The case of LEDs is more complex. Some LED modules are part of lamps that are sold as such and used by consumers in existing luminaires similarly as fluorescent lamps are used. These can be termed retrofit lamps. Such lamps are not required to be collected and treated separately but as they look similar to their fluorescent counterparts, they often have the same waste management. This could support their inclusion in an exemption; however, it is unclear if this joint waste management is the case in all Member States and whether this situation will continue once after the fluorescent lamps are phased out.

For other LEDs, particularly those integrated in a luminaire, it is assumed that they are collected and treated with mixed WEEE. In such cases, despite the application being limited, in the consultant's opinion an exemption would not be recommended as the collection and treatment contribute to the further dispersion of lead in a larger material stream which is contra productive to the transition to clean material streams. Extending the exemption to LEDs, luminaires or containing products would contribute

24 Both for lamps and for luminaires, the collection and treatment described are the route specified legally. The consultant is aware that not all lamps and luminaires are disposed of properly, not always landing in the specified treatment fraction.

to the dispersal of lead in a larger material stream and is not considered to be in line with the Chemical Strategy at this stage. In the consultant's opinion, to allow the extension of the scope of the exemption to LED lamps and other lighting equipment would require ensuring that fluorescent lamps, LED lamps and lighting equipment are all collected and treated separately to ensure that the material cycle remains as closed as possible.

Also supporting this approach would be that lead is understood to be inert in glass in which it is encapsulated, reducing the risk of emissions as long as the glass is properly disposed of so that the treatment can be controlled. As long as the waste management route does not ensure this, an exemption for lead in glass in such application would contribute to the contamination of a wider material cycle and would not be recommended.

A further aspect to consider in the final decision on this exemption relates to the source of the lamps to be placed on the market. LE argues the exemption among others in expectation of the glass used in non-EU countries that may result in lead levels above 0.1% in lamp glass. In this regard, KEMI (2021) states that the "*import of lighting equipment from outside the EU that are not compliant with EU law, and consequently contain lead above 0,1%, should not be a reason for accepting an exemption to recycle glass with a higher lead content. This would undermine the purpose of adopting legislation to restrict the use of hazardous chemicals to protect human health and the environment*". Considering that the manufacture of fluorescent lamps in the EU has significantly decreased in the last years, it is hard to determine if the case of lamps manufactured in the EU would be the same or different were manufacture distributed more evenly. LightingEurope (2022) states that "*Both manufacture of lamps and lighting equipment in the EU and outside the EU needs the exemption, e.g. for glass tubes and final articles/products imported to the EU*". However, this does not confirm that the exemption is needed for the manufacture of <u>fluorescent</u> lamps in the EU, but rather only for lamps in general for which the use of the glass recycled from fluorescent lamps is currently not permitted. Though the use of recycled glass may have a certain benefit for such manufacturers, a scenario of no exemption will not hinder the manufacture of lamps nor of lighting equipment.

LightingEurope (2022) further explains that "*it is correct that in case of production in the EU or outside of the EU the glass can be investigated in incoming inspections and can be sent back to a producer. But it is also possible that only in finalised products it is detected that they contain more > 0,1 and < 0,2 % lead. In this case the complete product might have to be destroyed. This is especially the case as in most cases reworking of the products is technically or economically not possible (e.g. Fluorescent lamps or TLED lamps for which the exemption is still valid)*". Though an exemption would prevent the scrapping of WEEE in such cases, which is a benefit to those that have to pay for the disposal, in the consultants view this is not the type of benefit targeted by the Article 5(1)(a) third criterion. An exemption in this case would rather award the cases of non-compliance instead of ensuring that they are not permitted market access.

5.6. Recommendation

Assuming that an exemption would still be in line with the Chemicals Strategy in terms of contributing to the circular economy while not undermining the promotion of a non-toxic material stream the renewal of the exemption could be recommended with its current scope. In the consultant's opinion, this should only be considered for the use of leaded-recycled glass in fluorescent lamps, where such lamps are collected at end-of-life and treated separately. The use of recycled glass from such lamps in the manufacture of new ones creates a semi-closed loop material cycle, preventing the contamination of other material cycles with the lead from the glass of such lamps. It allows conserving on primary resources (minerals but to a latter degree also energy) as well as land that would otherwise be needed to dispose of such lamps.

Considering the still expected amounts of fluorescent lamps expected to arrive at end-of-life and to promote the recycling of glass, an exemption could be granted for a duration of five years. In the consultant's opinion, the exemption could be limited to Cat. 5, with the understanding that it may benefit lamps when sold separately as well as when sold as part of an installation, provided that the leaded-glass is only used for lamp glass of fluorescent lamps.

In line with the above, the following formulation is recommended for the renewal of the exemption:

Exemption formulation	Duration
Lead (not intentionally added) in soda lime glass used in the glass tube of fluorescent lamps, not exceeding 0,2 % by weight	21 July 2026 for category 5

To support future assessments of the exemption, should it be requested for further renewal:

- The lighting sector (also including its end-of-life waste management) should be monitored:
  - To determine the actual amounts and concentrations of lead still in the material cycle and how this is expected to change in the future;
  - To determine changes in the amount of lamps collected and treated at end-of-life and the further potential for the closed loop practice in the future, particularly when fluorescent lamps are no longer common and when it is focused solely on LED retrofits;
  - To determine on the one side the emissions and on the other side resource savings related to the presence of lead in glass in the waste management of lamps.
- Information about separation technologies to remove lead from glass (e.g. the RISE study) should be researched further to consider their applicability.
- Should the lighting industry seek an exemption for lead in glass for LED lamps and/or lighting equipment in the future, it should:

- support this request with a systematic study of the actual amounts of lead in glass of such articles (to show that lead amounts in excess of 0.1% are the exception and not the rule,
- actively engage in a change of the waste management of such articles to ensure that lead is kept within a closed material cycle.

5.7. References

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LightingEurope (ed.) (2021b): LightingEurope. Answer to clarification questions regarding Ex. 5b of Annex III, 15 Mar 2021.

LightingEurope (ed.) (2022): LightingEurope. LightingEurope answers to the additional questions on ex 5b. LightingEurope, 21 Jan 2022.

6. Exemption 18b, 18(b)-I and Annex IV 34:

Annex III, 18(b): "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."

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

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

Declaration

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

Acronyms and definitions

BSP	Barium silicate phosphor doped with lead, also known as BaSi2O5:Pb
CFL	Compact fluorescent lamp
EEE	Electrical and Electronic Equipment
ESA	European Sunlight Association
Hg	Mercury
HID	High intensity discharge lamps
InGaN	Indium gallium nitride

LED	Light emitting diode
OLED	Organic LED
LE	LightingEurope
NARVA	NARVA Lichtquellen GmbH + Co. KG
NMSC	Non-melanoma skin cancer
Pb	Lead
PUVA	Psoralen (P) and ultraviolet A (UVA) therapy
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
UV	Ultraviolet
UVA	Ultraviolet radiation in the range of 315-360 nm
UVB	Ultraviolet radiation in the range of 280-315 nm
UVC	Ultraviolet radiation in the range of 100-280 nm
WEEE	Waste Electrical and Electronic Equipment
WPE	Wall plug efficiency
YPO	Yttrium phosphate phosphor

6.1. Background of the exemption request

LightingEurope (LE) with the support of the European Sunlight Association (ESA) and based on additional information provided by Mallinckrodt Pharmaceuticals c/o Therakos, Inc.[25] submitted a request for the renewal of the three exemptions mentioned above.

In the beginning, the applicant's intention was not clear when requesting '*the incorporation of Annex III Exemption 18(b)-I and Annex IV Ex. 34*' at the same time proposing '*to continue using the existing wording'* (LightingEurope 2020) and in a later stage clarifying that '*the renewal application indeed request to combine the three applications into a single exemption*' (LightingEurope 2021a). Finally, behind the interest in '*avoiding ambiguity or repetition in the application for exemptions renewals'* (LightingEurope 2020) a preference for the merge of the medical applications covered

[25] The application is structured in two parts: The first part addressing all three exemptions under evaluation and includes information provided by LE, the second part relates specifically to Annex IV Ex. 34. The second part has exclusively been compiled by Mallinckrodt Pharmaceuticals c/o Therakos. In this report, wherever, information from the second part of the application is cited, reference is made to Mallinckrodt Pharmaceuticals c/o Therakos on the same time citing the total application as LightingEurope (2020).

under Annex III 18(b)-I and Annex IV Ex. 34 on the one hand and keeping Annex III 18(b) separately on the other hand could be identified. Thereby it was intended by the applicant that the scope of the exemptions should not be changed.

The renewal is requested for EEE Categories 5, 8, and 9 with a maximum possible validity period.

6.2. Technical description of the requested exemption

6.2.1. Technical background

Discharge lamps for the purpose of (sun) tanning and for medical purposes (phototherapy and extracorporeal photopheresis (ECP)) contain BaSi2O5:Pb (BSP) as a phosphor (activator) to produce UV radiation of dedicated wave lengths. An (inorganic) phosphor is a doped (here Pb) pigment that emits electromagnetic radiation– in this case UV (290nm-400nm)– after being stimulated – also through UV radiation (254 nm; Jüstel 2016). The lead is required to activate the barium silicate phosphor to be able to fluoresce in the designated wavelength. Pb-doped barium silicate phosphor is used in over 95% of the indoor low-pressure mercury vapour fluorescent lamps[26] (LightingEurope 2020).

In all three exemptions requested for renewal, lead has the same functionality, the three exemptions differ with regard to the application areas of the lamps. The applicant describes the applications as follows (LightingEurope 2020):

- **Annex III, 18b** covers indoor sun tanning discharge lamps, which produce UVA and UVB in predetermined dosages and ratios for the purpose of producing artificial sunlight. Their intent is to produce artificial sunlight to replicate sunlight exposure for the human body (like that produced by the sun) yet applied in calculated doses per European regulations. It is estimated that over 90% of indoor tanning lamps produced and used throughout Europe are manufactured with BSP ($BaSi_2O_5$:Pb) phosphors containing 1% or less lead as an activator. The lamps are installed in various commercial and residential indoor tanning equipment which can be in the form of a tanning bed or booth or a tabletop appliance for facial tanning. The typical lifetime of these lamps ranges from 600 to 1000 hours with single session or usage time that ranges approximately from 5-30 minutes. The applicant assumes that market demand for tanning lamps will be stable for the coming years.
- **Annex III, 18(b)-I** covers UV discharge lamps used for (medical) skin treatment such as PUVA phototherapy which is explained as being a combination of a drug e.g. the substance psoralen and ultraviolet A radiation. The release and approval of PUVA devices was always based on extensive patient testing with lamps containing BSP. The lamps are installed in dedicated phototherapy equipment. Although PUVA phototherapy lamps are very similar to tanning lamps in construction and incorporate lead-activated phosphors, they may have small differences in spectral distribution and exposure schedules depending on the application and the patient

[26] Low-pressure mercury vapour fluorescent lamps and neon lights based on cold cathode fluorescent lamp (CCFL), e.g. for advertisement, are different types of fluorescent lamps and should not be confused.

needs. The typical lifetime of these lamps ranges from 600 to 1000 hours with a session time that ranges approximately from 5-30 minutes. The applicant assumes that market demand for PUVA phototherapy lamps will be stable for the coming years.

- **Annex IV, 34** was previously requested by Therakos, Inc. for the use of lead activated phosphors in the lamps used in their Extracorporeal Photopheresis (ECP) equipment. The treatment involves exposure of leukocytes, that are temporarily removed from the patient's blood, to light from lamps with lead doped barium silicate phosphor. The light activates a drug which has been introduced into the leukocyte fraction of the blood. This type of phosphor emits a unique spectrum that is optimum for this medical treatment.

6.2.2. Amount of lead used under this exemption

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

- Sun tanning lamps (Annex III, Ex. 18b): 190 kg lead p.a.
- Medical lamps (Annex III, Ex. 18(b)-I and Annex IV Ex. 34): 2.5 kg lead p.a.[27]

Compared to the quantity in the request for extension of the exemption from 2015, the quantity is explained to be slightly decreasing, i.e. in 2015 Lighting Europe estimated the lead content of tanning lamps to 250 kg of lead in total per annum (Gensch et al. 2016). When asked, the applicant explained this statement as follows: *"…although there are no accurate published numbers for this niche market, according to confidential numbers reported to LightingEurope by its members, it was estimated that the tanning market for the period 2015-2019 had declined. Additionally, LightingEurope members estimate that the market will remain flat or will continue to slightly decline in the coming years*".

6.3. Applicant's justification for the requested exemption

The applicant justifies the requests for exemption essentially on the basis of technical aspects that are decisive for the fact that no adequate alternative substances are available that fulfil all the required properties. In addition, socio-economic impacts are detailed that relate to the case that an exemption renewal is not granted. As an environmental argument, the applicant compares current discharge lamps with LEDs with regards to the efficiency to convert electricity into UV (in %) and describes the waste stream of the lamps.

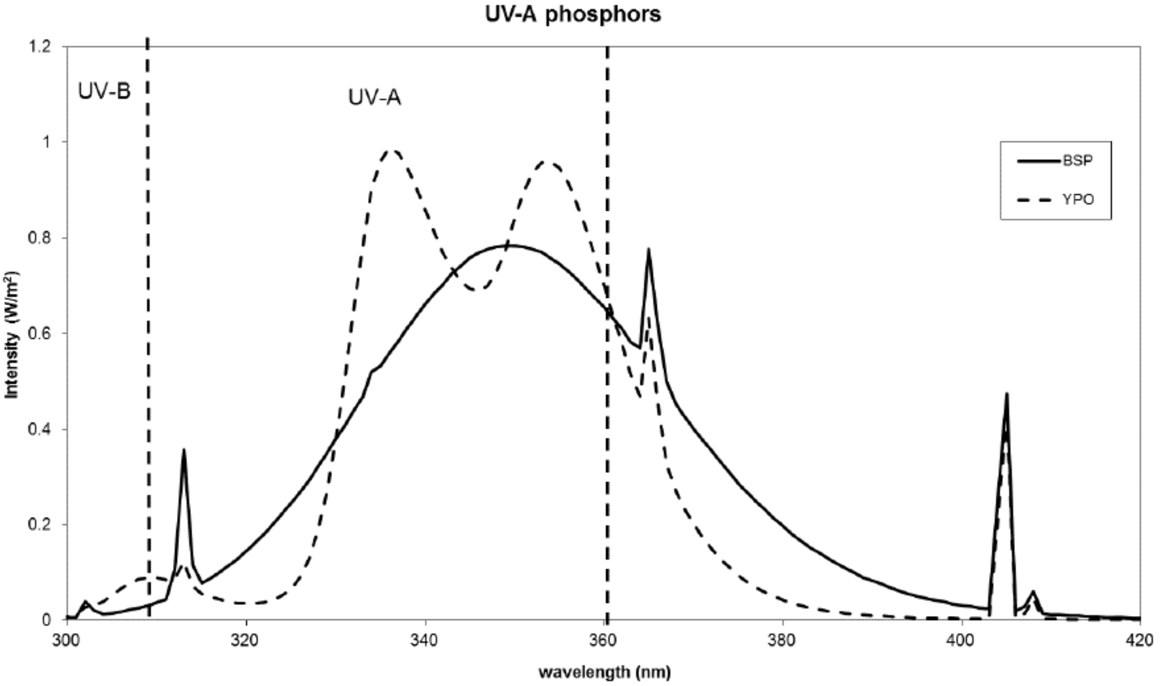
[27] More specifically, Mallinckrodt Pharmaceuticals c/o Therakos points out that '*each lamp [covered under Annex IV Ex. 34] contains ~1 gram of phosphor material and this material contains ~0.7% lead as the dopant. Therefore, each lamp will contain 7µg of lead. The estimated number of BSP lamps placed on the EU market in 2012 for photopheresis treatment is 4600.Therefore it is estimated that EU consumption of lead for this application is ~ 32g. Market usage is expected to grow to an equivalent of 74 grams of lead by 2020*'.

6.3.1. Substitution, elimination or reduction of lead

Substitution

With regard to the availability of substitutes at substance level, the applicant concludes that only Ce doped YPO_4 phosphor "*comes close*" (LightingEurope 2020) to lead in the fluorescent powder: Pb doped BaSi2O5 has its peak emission at 350 nm, the peak emission of Ce doped YPO_4 is at 335 nm and 355 nm, see the comparison of emissions of both phosphors in **Figure 6-1**.

Figure 6-1: Emission Spectrum of a Cerium-doped UV lamp (dotted line) as compared to a Lead-doped UV lamp (solid line)



Note: Vertical dotted lines mark out the UV B (<310 nm) and UV A (310 nm < UVA > 360 nm) wavelength area.
Source: (LightingEurope 2020)

However, the applicant draws the following conclusions (LightingEurope 2020):

- *"The emission spectrum shows differences in the UVA and UVB range.*
- *The ratio for UVA and UVB output is different which is an important factor for tanning applications and is governed by EU regulations.*[28]
- *Therefore, the Cerium based material has a lower expected treatment effectiveness, regarding Erythema and NMSC (non-melanoma skin cancer)."*

More specifically, Mallinckrodt pharmaceuticals c/o Therakos, Inc. adds that "*the currently used BSP phosphor which has a symmetrical spectrum with a peak*

[28] This ratio is of importance as a higher share of UVB in the spectrum increases the potential for health damages, e.g. cancer, due to the fact that lower wavelengths have a higher intensity.

wavelength of 350nm and a bandwidth of 41 nm. This has a symmetrical spectrum which is the basis for the entire safety and effectiveness profile of this lamp" (LightingEurope 2020). There is a limited number of phosphors (17 types) that emit in the UV spectrum, as the emission in UV is a substance characteristic, it is not expected, that additional phosphors will be developed which are not already known today: *"All other UVA phosphors contain less light of the effective wavelengths or have shorter wavelengths that cause further damage to cells. Therefore, there is currently no substitute lamp type for treatment of this disease by extracorporeal photopheresis as described in this application."* (LightingEurope 2020)

From the applicant's point of view, *"spectral incompatibility has also led to a lack of interest on the part of the medical community. Therefore, no adequate tests and clinical studies have been set up on patients to prove the effectiveness from Ce doped YPO phosphor for PUVA phototherapy and no approvals for such equipment exist*." As a consequence of a lack of tests and clinical studies, Ce-based material is not allowed for the use in medical applications. (LightingEurope 2020)

When fluorescent lamps are coated with a phosphor, the thickness of the coating varies over the length of the lamp. The applicant sees an additional problem with Ce-doped phosphors due to the UV output variations over the lamp length due to the differing coating thicknesses which will affect the skin treatment effectiveness.

Elimination

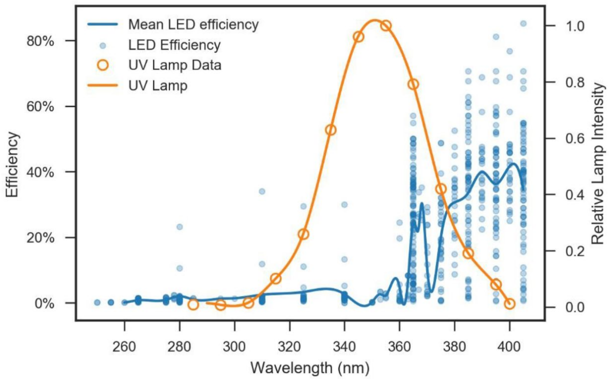
On the technological level of alternatives, the applicant only considers LED technology for further analysis, as other technologies (OLED, incandescent, halogen) do not radiate in the UVA spectrum. LED and discharge lamp technologies are compared based on energy conversion efficiencies (referred to as Wall Plug efficiency), thus, will be addressed under environmental arguments.

For **tanning** applications, no test results are available yet regarding the effectiveness in reaching the desired effect in a comparative study between equipment using fluorescent lamps and equipment using LEDs. For most of the applications tests are not done yet as no LEDs were available. Hence data on the effectiveness is not available.

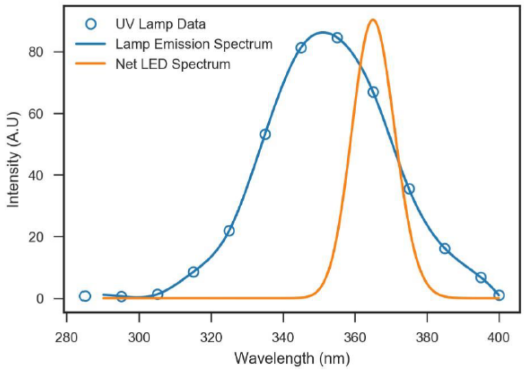
For **medical applications**, Mallinckrodt Pharmaceuticals c/o Therakos presents a feasibility study using LED light technology in lieu of fluorescent for the current lamps in the Photopheresis System: *'This study indicated that current LED technology is unlikely to precisely match the spectral (wavelength) output of the current lamp system and would have a reduced wavelength range, or at best a modified distribution of irradiance for the full wavelength range. No alternative LED lamps have shown to have the desired medical effect comparable to the current fluorescent lamps.'* See the results in **Figure 6-2** (LightingEurope 2020).

Figure 6-2: Scenarios of LED setup in feasibility study in the Photopheresis System

a) Selection of suitable LEDs

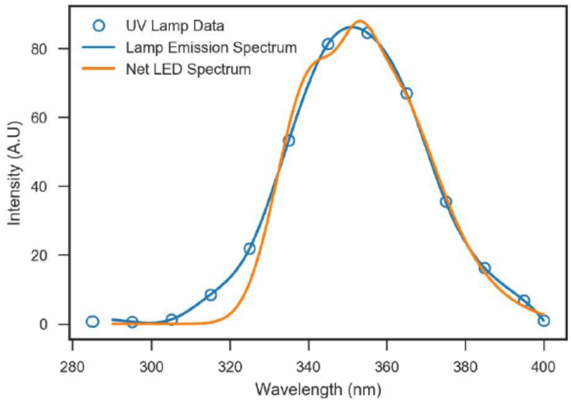


b) Single wavelength LEDs (max. eff.)

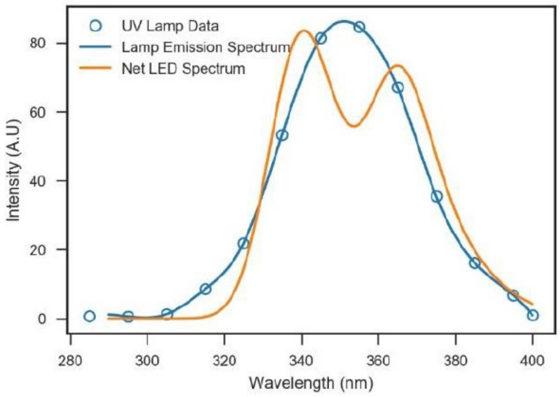


Multiple wavelength LEDs:

c) Best replication of the UV lamp spectrum



d) Partial replication, limiting total number



Source: (LightingEurope 2020)

Based on the overview provided in **Figure 6-2**, in a first scenario (b) single wavelength LEDs at 365nm were chosen for maximum efficiency. '*This scenario met the objective of maximised wall-plug efficiency, was found to be the simplest, most cost-effective solution, however, this concept would require a redesign and clinical evaluations to determine the feasibility of the light source in meeting the therapeutical expectations*'. The second scenario (c) '*best met the requirement to match the spectral output of the current lamp system but was not found to be practical due to the poorest efficiency*' (large number of LEDs, making manufacture challenging or unfeasible). The third scenario (d) '*was an iteration on Concept 2 that utilized only efficient LED types to reduce the total number of LEDs required, whilst still preserving the breadth of wavelengths emitted by the fluorescent lamp. This concept however exhibited a dip at around 350nm due to the availability of efficient LEDs in this region.*' (LightingEurope 2020)

In addition, as no alternative LED technology is yet close to market readiness, the CE conformity and other European Directives for special purpose applications (like for instance approval of medical devices for phototherapy and CE regulations on tanning lamps, see chapter 6.5.2) which are based on fluorescent discharge lamps, are not available for other lamp technologies.

Reduction

It is further stated that a reduction of lead in activators to below 1 % by weight in the homogenous material is not possible.

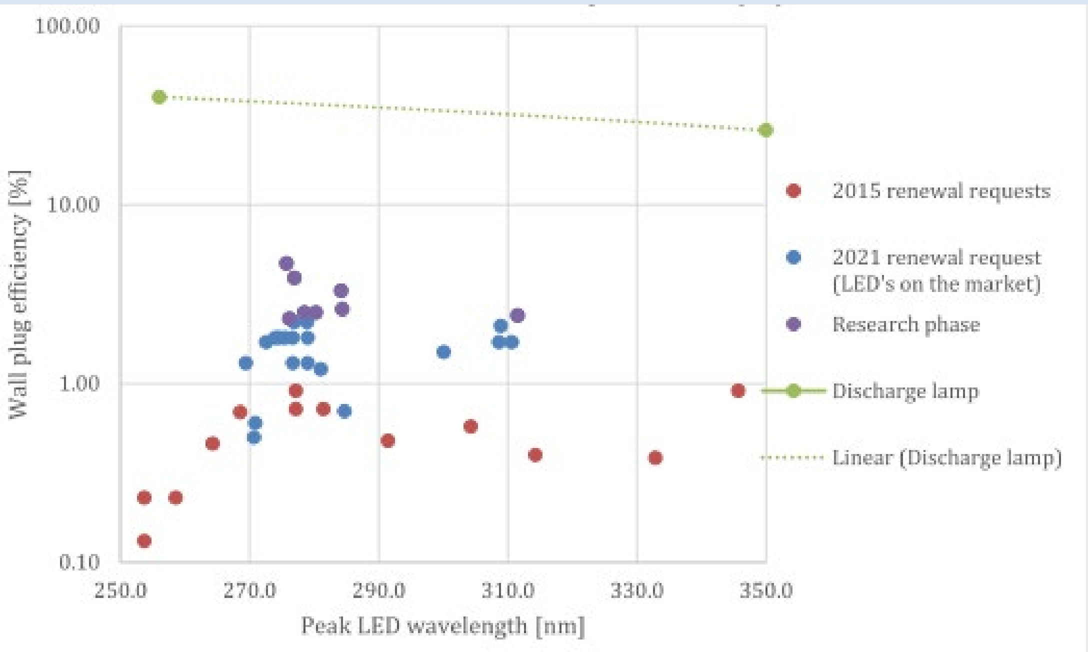
6.3.2. Environmental arguments

In light of the fact that both alternatives presented – Ce-doped YPO and a LED technology – do not meet the technical requirements for effectively and practically substituting Pb-doped BSP, the applicant sees the section on environmental impacts *"not applicable"* (LightingEurope 2020).

The consultant, however, points out that the comparison of discharge lamps and LEDs in terms of their so-called Wall Plug Efficiency (WPE) relates to environmental arguments: In both cases, the stimulation for UV radiation emissions is originating from electricity. The energy conversion efficiency with which the system converts electrical power into optical power is thus of importance.

Even though LEDs tested in 2021 (blue and purple dots) show higher WPEs than those LEDs tested in 2015 (red dots), LEDs do not reach efficiencies (WPE) over 10%. The applicant concludes that the WPE is too low regarding wavelengths below 380 nm, in the UVA area, as to see from **Figure 6-3**.

Figure 6-3: Comparison of discharge lamps and LEDs in terms of efficiency to convert electricity into UV (%)



Source: (LightingEurope 2020)

With regards to health impacts, the effect of Ce doped phosphor the applicant cannot exclude considerable impact on health and safety of customers as the manufacturing tolerance in output and spectrum cannot be controlled to the extent required by EU regulations. Mallinckrodt Pharmaceuticals c/o Therakos adds that *"Cerium is a rare earth element which is not rare although currently its supply is restricted."* (LightingEurope 2020)

For LED as an alternative technology, effects on health and safety will have to be investigated once candidates are developed.

Initially provided information on waste management of discharge lamps (LightingEurope 2020) – and more detailed information provided up on request (LightingEurope 2021b) – list the various take back and recycling systems established for the waste management according to the WEEE Directive's provisions. In addition, the standard end of life procedure (recycling, recovery, disposal) for the various materials retrieved from the collection of the lamps was provided as well as their share (wt.%) in the common lamps, the information was submitted confidentially.

6.3.3. Socioeconomic impacts

In the absence of reliable substitutes, from the applicant's point of view, a non-renewal of the exemption would shut down the **tanning industry** in Europe. It would have to be considered that almost 100% of these lamps used in Europe are manufactured in Europe by fluorescent lamp companies. It is also estimated that almost 100% of tanning lamps sold as aftermarket lamps are sold by manufacturers or distributors in Europe, that over 90% of tanning lamps used in the US are manufactured in Europe and that over 75% of tanning devices sold in the US are manufactured in Europe (LightingEurope 2020).

The applicant states that *"even if UVA LEDs become available with feasible specifications, tanning equipment may become much more expensive. It will become therefore an economically unattractive solution, and this can have a significant impact on the application*." (LightingEurope 2020) The applicant details on request the situation as follows: *"LightingEurope members do not have concrete cost data on the cost of substantially equivalent UVA LED tubular lamps that match the output spectrums of tanning and/or medical lamps. To the best of our knowledge there are no LED tubular replacement tanning lamps. There are some available UV-A LEDs on the market used for other applications. The market data for these seems to indicate a minimum of 5-10 x higher cost per watt plus other associated costs for equipment redesign"*. (LightingEurope 2021a)

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

6.3.4. Roadmap to substitution

According to LightingEurope, no plans are made to replace Pb with Ce as earlier tests were unsuccessful and no new insights have been created.

With regard to future trends of substitution by LED technology, for both application areas – sun tanning as well as medical applications – the applicant sees *"limited possibilities"* for the development of a suitable LED technology (LightingEurope 2020): the applicant states that LEDs are available for other UVA applications. In contrast, he considers the development in tanning to be limited and it is impossible to predict at this stage if and when LED-based UVA devices will be feasible. It is understood that the fact BSP phosphors emit UVA and UVB wavelengths from the same lamp compared to LEDs being optimised for one wavelength is another reason for LED technology to be less preferred.

With regards to future trends of substation in the medical applications of BSP lamps, the applicant concludes that *"the only way to establish this would be to conduct an experimental study to investigate which wavelengths contribute to the photopheresis process."* (LightingEurope 2020) Mallinckrodt Pharmaceuticals c/o Therakos points out that the company is investigating photoadducts *"which have shown to be sensitive to the proportion of UVA and UVB emitted by the irradiation source […] the downstream impact of a spectral change on Extracorporeal Photopheresis efficacy will remain unknow"*" (LightingEurope 2020).

6.4. Stakeholder contributions

One contribution has been submitted during the consultation period from 30 March 2021 to 08 June 2021 by NARVA (2021a). It should be noted that NARVA is not a stakeholder in the strict sense of the term, as it also manufactures lamps that are affected by the exemptions discussed here[29].

Through answers to the consultation questions raised, NARVA (2021a) supports the renewal, agrees with the scope of the exemption and supports the combination of the three applications into a single exemption. **Regarding Ce-doped YPO**, NARVA comments that this compound *"disqualified itself for the reason that the ratio for UVA and UVB radiation output is different to lead-doped BSP phosphor and therefore the needed compatibility is not given. There are also some other reasons which prevent YPO for being a practical substitution candidate (for example a lack of efficiency evidence for medical applications, availability as a pure rare earth phosphor and much higher costs."* In addition, NARVA mentions the possibility of using **high-pressure lamps** (in contrast to the currently used low-pressure lamp). However, they would need a completely different tanning device design and respect certain health security provisions:" tanning *systems with high-pressure lamps (for example face tanning units) must be equipped with appropriate filter disks for safety reasons (too high UVC and UVB output) and are inferior to low pressure lamps with BSP phosphors in terms*

[29] NARVA provided a filled exemption request form as an Annex to the contribution NARVA (2021b). In addition to the main contribution NARVA (2021a), aspects of the legislation which applies to phosphors (EU 2019/177), poor prospects for finding substitutes and the lengths of clinical trials were regarded as relevant.

of energy efficiency and thermal power loss. They are also significantly more expensive and not suitable for medical phototherapy appliances to our knowledge."

Socio-economic impacts of not granting an extension of the exemption are among others that alternatives do not comply with current CE regulations and *"the discontinuation of this product portfolio would mean massive economic and personnel cuts for our company, as this decision would probably result in a relocation of production and sales to countries outside the EU with less restrictive regulations* […] *As there will probably be no adequate alternatives for some applications of the current exemptions in the foreseeable future, an impending ban could also have very negative impacts on the distributers, users (e.g. tanning salons) and end users of these special lamps."*

In addition, "*interpretation [of] Article 4 of the directive [regarding] spare parts supply of tanning devices with corresponding lamps is not given from our point of view […] a defect or end-of-life tanning lamp with BSP phosphor in a tanning device per se cannot be repaired or reused and must be replaced by a new lamp. In a worst-case scenario, all existing tanning devices that are currently operated with lamps with BSP phosphor would have to be disposed of."*

6.5. Critical Review

6.5.1. REACH compliance – Relation to the REACH Regulation

See section 4.1 for details.

6.5.2. Legal aspects

The applicant points out that *"the tanning industry is closely monitored and regulated by European authorities and is subject to standards such as EN 60335-2-27*[30] *and EN 61228*[31]*."* (LightingEurope 2020) These standards address, as far as applicable, the usual hazards arising from equipment used by persons in tanning salons, beauty parlours and similar establishments or at home. The use of the equipment by children is excluded.

In addition, risks of sunbeds for cosmetic purposes can be regulated under Directive 2014/35/EU[32], the so-called Low Voltage Directive.

6.5.3. Scientific and technical practicability of substitution

The applicant proposes a one-to-one substitute [cerium (Ce) doped yttrium phosphate phosphor (YPO)] which is an alternative phosphor (lead in barium silicate cannot be substituted directly through another activator from a molecular structural point of view) based on comparable radiation intensity. However, the applicant also explains

30 *EN 60335-2-27:2013* Household and similar electrical appliances - Safety - Part 2-27: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation (amended, now: EN 60335-2-27:2013/A2:2020-04)

31 EN 61228:2021 Fluorescent ultraviolet lamps used for tanning - Measurement and specification method

32 Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits

that *"tests have been done using these phosphors for tanning lamps showing that the spread in UVA and UVB output is too high to be viable as a practically feasible alternative. It would not be able to comply with CE Regulations for tanning lamps (due to spectral incompatibility)"* (LightingEurope 2020).

In the opinion of the consultant, this would suggest that industry does not continue to research Ce-doped YPO as a potential substitute. It is understood that the limited number of phosphors (17 different types as presented by Mallinckrodt Pharmaceuticals c/o Therakos) that emit in the UV wavelengths limit the developments: Based on the theory of inorganic phosphors consisting of a host material and doping elements and against the background of a limited number of options for doping, it can be expected that based on the current knowledge no alternative phosphor is expected to be found to replace Pb-doped BSP. The switch to other phosphors subsequently entails a change in the emission spectrum, which can cause harm due to wavelengths emitting radiation in a range where health effects could not be excluded.

Moreover, the applicant presents an alternative technology based on LEDs. Other radiation technologies such as incandescent, halogen and OLED do not emit within the spectrum of necessary wavelengths, thus, UVA/B. Various LEDs exist and are available on the market, however, the emitted light is not optimal in the necessary wavelength ranges. Meeting the specific wavelengths that on the one hand side provide the expected effect and but on the other side ensure health security of users of sunbeds as well as for medical applications, is of importance for both application areas under discussion. As shown based on the feasibility study conducted by Mallinckrodt, it is possible to use various LEDs in an LED array to produce an emission spectrum according to the needs. Such concept has its limiting factors in the number of LEDs in the array as well as in economics and manufacturing. While the studied LED arrays does not meet the needs in terms of specific wave lengths for the medical therapy addressed under Ex. 34, it is not clear as to whether the concept of LED arrays could work to overcome the shortcomings pointed out regarding single LEDs, as displayed in Figure 6-2.

The consultant takes note of NARVA's comment and follows the argumentation that *"there will probably be no adequate alternatives for some applications of the current exemptions in a foreseeable future"* (NARVA 2021a). The fact that substitution and the implementation thereof, if a substitute was found is not foreseeable relates to the long timeline for medical tests and trials: NARVA expect the process of research and medical trials to be 13 years plus additional 5 years of post-treatment follow up (NARVA 2021a). As tanning equipment is a dermatological application in-depth clarification of any health implications of a substitution entail a prolonged test phase of substitutes for lamps in tanning equipment.

More precisely, the consultant concludes that

- Ce-doped YPO does not represent a technically feasible substitute today, nor will it become a substitute in the future due to inherent material characteristics,
- The current approaches based on LED technology are not suitable. For other approaches, e.g. multi-LEDs, suitability is not yet enough researched and actual substitution potential is unknown, and

- Lead reduction is physically/chemically not possible as a certain amount of lead is needed to activate the phosphor's emissions,
- As medical and dermatological applications are concerned, the assessment of exemptions covering lead-doped phosphor lamps should consider the long period of medical trials to ensure health safety.

As to the extent and efforts presented through the application, the consultant concludes that compared to the evaluation in 2015/16, the applicant (LE) provided only a slightly adapted version of the application text. The feasibility study provided by Mallinckrodt is an exception compared to the rest of the application, especially with regards to the sun tanning sector. No additional or new information is presented regarding the Ce-doped YPO phosphors, the suitability of different setup of LED technologies, nor any other substitute is presented. Against this background, the consultant expects from an application for renewal for this exemption that it clearly elaborates on the progress made in between one exemption evaluation and another.

6.5.4. Environmental arguments and socioeconomic impacts

As to environmental, health and safety impacts, information is very limited. Because substitutes are seen as technically not feasible, this section is seen as '*not applicable*' (LightingEurope 2020). The comparison of the Wall Plug Efficiencies (WPE) of discharge lamps with LEDs in the respective spectrum is, however, an aspect with impact on the environment. As shown in **Figure 6-3**, the WPEs of the UV-emitting diodes (LEDs) are many times smaller than the WPEs for two tested discharge lamps [WPE (discharge lamp) = ~50 %; WPE(LEDs)= 0.1-5 %]. From the fact that the WPE describes the conversion efficiency from electrical into optical power follows that the lower the WPE, the higher the energy demand for the same expected output, e.g. the degree of skin tanning. A factor 10 to 50 in the energy demand entails non-negligible additional environmental impacts.

The information does not allow any additional comparison of Pb-doped BSP with alternatives from an environmental point of view (which are in any case understood to not be technically practical substitutes).

The end of life of lamps under this exemption has also been mentioned in the context of this exemption. However, no information, i.e. collection quotas, were provided which would allow the consultant to conclude on the effectiveness of the collection scheme. Collection is expected to take place to a large degree of lamps used by professional users such as sun tanning equipment in salons and medical equipment in hospitals and medical practices. Assuming health insurances cover the costs of thera-py where applications under Ex. 18(b)-I and Ex. 34 are used by private consumers at home, such equipment is leased, and thus assumed to be professionally maintained. This suggests that collection in this case would be performed by the leasing company as part of maintenance services. With regards to private ownership of (smaller) types of sun tanning equipment, it cannot be guaranteed that consumers are aware and/or use the take back systems. The consultant concludes that the end of life of lamps under this exemption may differ, depending on the consumer.

With regards to socio-economic impacts, the consultant finds a clear dependency of the sectors applying lead-activated phosphor discharge lamps on these lamps and the respective type of phosphor.

It is understood that substitution has an overall negative socio-economic impact, e.g. it would lead to the closure of nearly all small business owners such as tanning salons and dermatologists[33]. The EU market for the applications in scope of the exemptions is nearly fully supplied by European Manufacturers. Also, the US market is majorly supplied by EU manufacturers of the respective lamps and equipment. In the case of revoking the exemptions, NARVA mentions substantial personnel cuts, impacts on relocation of business, and supports the aspect of negative impacts for SMEs and distributers outlined by the applicant. The consultant also takes note of the time-intensive clinical studies and trials and that alternatives are so far not covered by CE regulation (NARVA 2021a; LightingEurope 2020). Moreover, NARVA states that tanning lamps do not fall under spare part provision (Art. 4, RoHS II). As the consultant recommends a renewal of the exemption, this aspect shall not be further discussed.

6.5.5. Scope of the Exemption

The exemptions under review in this report were requested as new exemptions in different years, i.e. Ex. 34 in 2012, Ex. 18(b)-I in 2015. Ex. 18(b) existed prior to 2015 and was renewed in 2016. This current assessment is the first timewise assessment of the three exemptions and thus represents a first possibility for alignment. In the beginning (chapter 6.2) it is explained that the function that lead has in discharge lamps does not differ amongst the applications in scope of each of the three exemptions. However, it is not seen practical to merge all three applications into one exemption, but to divide between medical and non-medical applications based on different roadmaps for substitution as well as different end-of-life options for both groups of applications. In addition, this is recommended as the markets function differently regarding substitution: Based on the comparison of 2,5 kg lead p.a. from medical equipment to 190 kg lead p.a. for tanning equipment the higher market volume of tanning industry is clearly identified. Thus, in the case of sun tanning lamps, the costs for tests for the suitability of LEDs would pay off more quickly than in the case of medical applications. Also, costumers and their impact on the supply is differently: Medical applications are ultimately prescribed by doctors, while the users themselves decide whether to go to a tanning salon or buy their own solarium.

As earlier mentioned, (chapter 6.1), at the beginning of the evaluation process the applicant's intention was not clear with regards to how to combine exemptions 18(b), 18(b)-I and Ex. 34. NARVA (2021a) indicated a preference for '*consolidate the 3 existing exemptions into just one'.* Finally, LE's preference for the merge of the medical applications covered under Annex III 18(b)-I and Annex IV Ex. 34 on the one hand and keeping Annex III 18(b) separately on the other hand was identified. Thereby the scope of the exemptions should not be changed. LE was asked whether it is correct to understand that if the scope addressed through the wording of the exemption is not

33 Over 90% (rather 99%) of tanning and medical equipment covered by the three exemptions is based on lead-activated phosphors (LightingEurope (2020).

changed the exemption would cover the same applications independent of whether categories 1-11 are specified or the exemption applies to Cat 5, 8, & 9. LE replied that due to the specialty of the lamps and dedicated applications / equipment, the lamps are used in, only cat. 5, 8, and 9 are of relevance. Thus, the consultant sees no obstacles in following the applicant's proposal for the requested categories.

In consequence, the consultant agrees with the applicant in the grouping of medical applications under one exemption and separating the tanning equipment. However, the consultant recommends aligning the validity periods of both exemptions to be able to conclude on substitutes if available in the future for both exemptions.

However, more generally with regards to lamps, the applicant is aware *"of the difficulty to unambiguously classify certain lamps in the categories set out by RoHS legislation. For lamp producers it is essential to have legal certainty regarding the possibility to put the products on the market irrespective of the planned application as we are not able to control the use of the lamps in products. Specific special purpose lamps indeed can be considered also as spare part (or consumable) in certain applications such as sun-tanning cabins and medical equipment."* (LightingEurope 2020). The consultant is aware of this aspect which has already been raised in the assessments in 2015/16. Since then, the European Commission has not clarified whether exemptions should be targeting lamps or EEE applications in which lamps are used. The consultant follows the argumentation of the applicant with regards to the categories requested.

6.5.6. 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 substitution is scientifically impracticable: First, it should be noted that direct substitution of the lead, thus the dopant of barium silicate, is scientifically impossible as this impacts the phosphor's characteristics, thus, the characteristic of interest for the applications. Applying alternative phosphor, i.e. Ce-doped YPO, is the minimum, though unlikely as this phosphor does not exactly emits in right wavelengths with the needed efficiencies. Finally, research did not reveal appropriate LEDs, and arrays of LEDs have not been researched (for tanning equipment) or found unfeasible (for ECP therapy).

LED technology being the most promising under the generally poor alternatives could not be implemented on the short term, even if appropriate combinations of LEDs were found for the use in LED arrays. As medical and dermatological applications are concerned, medical trials are needed before a substitute could finally become relevant for the market. Therefore, if LED technology was found to be able to substitute lead-activated phosphor discharge lamps in the short term, a sufficient long transition time would be needed.

Overall, the consultant concludes that all three exemptions cannot be revoked and there is no indication to change the scope of none of the three exemptions with regards to the application in scope. The proposed EEE categories to which renewed exemptions should apply to according to the applicant do not change the product portfolio in scope of the exemptions but only more specifically addresses the application area. However, tidying up in the sense of grouping the two medical applications in one exemption, however, separating medical and non-medical uses of the same lead-activated barium silicate, is recommended. As a consequence of grouping Ex. 18(b)-I (Annex III) and Ex. 34 (Annex IV) and of keeping the maximum concentration of 1% lead by weight as specified in Ex. 18(b)-I, a concentration limit now applies for applications that formerly were covered by Ex. 34. Based on the explanation of the applicant (as cited in footnote 27, chapter 6.2.2) that the phosphor material in the lamps in scope of Ex. 34 contains ~0.7% lead as dopant, the consultant concludes that the concentration limit of 1% of lead by weight does not affect the applications.

It is concluded that the exemption for the respective lamps in medical application, currently under Annex III (18(b)-I) and Annex IV (34), should be placed in Annex III, the non-medical application, i.e. tanning (18(b)), should be kept in Annex III.

The consultant suggests the duration of the exemption to be five years for both, sun tanning und medical applications, even if a seven-year duration period is possible. As earlier mentioned, the function of lead and of the leaded phosphor in the lamp is identical for the two areas of applications. It should be envisaged to review the exemptions in parallel in the future. In case, a substitute was found for one of both uses of lead, or rather the leaded phosphor or the technology of discharge lamps, based on the similar function it is highly probable that this substitute could be implemented in both applications. Additional two years duration for the medical equipment would be an unnecessary delay of substitution.

6.6. Recommendation

It is recommended to group exemption 18(b)-I Annex III and exemption 34 Annex IV under a new item (18(b)-II) in Annex III. The proposed wording for the new item has no implications on the scope of existing exemptions 18(b)-I and Ex. 34.

It is further recommended to renew exemption 18(b) on lead as an activator of discharge lamps for tanning equipment.

Substitution is scientifically not practical.

It is recommended to grant the exemptions for five years with the following formulation:

Exemption formulation	Duration
	Expires on:
18(b) 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)	— 21 July 2026 for categories 5, 8 and 9; — 21 July 2023 for category 8 in vitro diagnostic medical devices; — 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.
New item: 18(b)-II: Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP ($BaSi_2O_5$:Pb) when used in medical phototherapy equipment, incl. extracorporeal photopheresis lamps	— 21 July 2026 for categories 5, 8 and 9

While for most categories exemption 18(b) is set to expire on 21 July 2021, for category 8 in vitro diagnostic medical devices it is valid until 21 July 2023, and for category 9 industrial monitoring and control instruments and category 11 EEE on 21 July 2024. The applicability of these recommendations to EEE in categories which benefit from the validity of Ex. 18(b) beyond July 2021 is not completely clear from a legal perspective. It should be envisaged to review the exemptions 18(b) and the new item 18(b)-II in parallel in the future. In case, a substitute was found for one of both uses of lead, it is highly probable that this substitute could be implemented in both applications. Thus, it is recommended to align all named categories in terms of the validity period. Also, this will be more pragmatic for market surveillance and will with time lower the administrative burden of stakeholders and the European Commission with regards to renewed exemption requests for the coexisting exemptions.

If for legal reasons, a transition period has to be set for exemption 18(b)-I Annex III and exemption 34 Annex IV, the shortest possible duration of 12 months should be set as the applications are covered by the new item, exemption 18(b)-II and ergo a transition period would not be needed.

In a late communication, LightingEurope stated that the first item of the exemption for sun-tanning lamps should be available to both Cat. 5 and Cat.11. Specific equipment making use of BSP lamps and falling under category 11 was not specified and it is not clear what types of equipment this part of the scope would refer to in practice. Earlier reference to category 11 equipment was not made, neither in the application for the exemption, nor in any of the communications that followed. This item of the exemption is in any case recommended to be available to Cat. 11 until July 2024. It could not be clarified whether this category would apply to equipment which would otherwise not be able to make use of the exemption. Should such equipment exist, the consultant would assume that stakeholders would apply for the renewal of the exemption towards the 2024 expiry date, specifying for what type of equipment the exemption was needed and why this would not be assumed to fall under Cat. 5.

6.7. References

Gensch, C.-O.; Baron, Y.; Blepp, M.; Moch, K.; Moritz, S. (2016): Study to assess renewal requests for 29 RoHS 2 Annex III exemptions [no. 1(a to e - lighting purpose), no. 1(f - special purpose), no. 2(a), no. 2(b)(3), no. 2(b)(4), no. 3, no. 4(a), no. 4(b), no. 4(c), no. 4(e), no. 4(f), no. 5(b), no. 6(a), no. 6(b), no. 6(c), no. 7(a), no. 7(c) - I, no. 7(c) - II, no. 7(c) - IV, no. 8(b), no. 9, no. 15, no. 18b, no. 21, no. 24, no. 29, no. 32, no. 34, no. 37] - Pack 9. http://rohs.exemptions.oeko.info/. In collaboration with Deubzer, O. and Gibbs, A., 2016.

Jüstel, T. (2016): Inkohaerente Lichtquellen, Leuchtstoffe. FH Münster, 2016. Online available at https://www.fh-muenster.de/ciw/downloads/personal/juestel/juestel/7-InkohaerenteLichtquellen-Leuchtstoffe.pdf, last accessed on 21 Sep 2021.

LightingEurope (2020): Application_LE RoHS Exemptions 18b and 34 - 20200120 - FINAL, 2020.

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LightingEurope (2021b): Answers to 2nd round of clarification questions, submitted 15.09.2021, 2021.

NARVA (2021a): 01_Answers to Consultation Questions regarding Ex 18b/18b-I (A III) and Ex. 34 (A IV), submitted 04.06.2021, 4 Jun 2021. Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_24/Exemptions/18b/Ex_18ab_34_Pack24_contribution_NARVA_20210604.pdf, last accessed on 9 Sep 2021.

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7. Exemption 24: "Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors"

Declaration

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

Acronyms and definitions

Ag	Silver
Au	Gold
$BaTiO_3$	Barium titanate
Be	Beryllium
Cu	Copper
CCTV	Closed-circuit Television
CTE	Coefficient of thermal expansion
Cu	Copper
EMI	Electro Magnetic Interference
HMP	High Melting Point
In	Indium
Knowles	Knowles Precision Devices
LMP	Low Melting Point
LHMPS	lead-containing high melting point solder(s)
MLCC	multi-layer ceramic capacitors
Ni	Nickel
Pb	Lead
Pd	Palladium

RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
Sn	Tin
TPLS	Transient Phase Liquid Sintering
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment

7.1. Background

7.1.1. Overview of the submitted exemption requests

Knowles Precision Devices (2020) (hereinafter Knowles) with support from other companies[34] requests the renewal of exemption 24 of Annex III of the ROHS Directive for:

"*Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors*"

The consultant notes that the current formulation of Ex. 7(a)[35] excludes applications covered by Ex. 24 of Annex III from its scope.

The exemption is requested for RoHS Annex I categories 1 to 10 and for the maximum duration applicable according to the Directive (5-7 years, depending on category). With regard to category 11, Knowles requests that the application is not processed earlier than the applicable latest application date foreseen in RoHS 2 (i.e. 18 months before the respective maximum validity periods), since the renewal request deadline set for this category is 20 January 2023.

7.1.2. History of the exemption

The exemption was not listed in the Annex of RoHS 1 when it was published in 2003. It was requested and reviewed in 2005/2006 (Gensch et al. 2006), and the Commission followed the reviewers' recommendation to grant the exemption with the same wording and scope as still valid in the current exemption. Since then, the exemption was assessed twice to establish its continuous justification (Gensch et al. 2009; Gensch et al. 2016). In both assessments it was concluded that the exemption was still justified as substitutes were not sufficiently reliable or technically viable.

[34] Knowles' names other industry stakeholders that support its application request in the document. They are WID Co., Ltd; Expantech Co., Ltd; Amphenol Canada Corp.; Amphenol Inc.; Glenair UK; Glenair Inc.; Filconn; Cordon Electronics Italia; Oxley Developments Co. Ltd.

[35] "Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)."

7.2. Technical description of the requested exemption

7.2.1. Short description of specific capacitors and relevant applications under this exemption

The specific component group under this exemption is "*through hole discoidal and planar array ceramic capacitors*". Discoidal and planar array capacitors are frequently used in electromagnetic interference (EMI) filters and EMI filtered connectors (s. Figure 7-2) to suppress electromagnetic interference on signal lines. Knowles as a component supplier is not aware of all applications where this product is used. But in general, such components are used for high end applications, where the elimination of electrical interference is critical and where performance is more important than cost. They are not generally used in low cost consumer electronics (Knowles Precision Devices 2020). Knowles Precision Devices (2020) specifies typical applications, for assemblies incorporating these components and covered by the RoHS Directive, to include: professional audio equipment, maritime monitoring (coastguard radar) and closed-circuit television (CCTV) systems.

Through hole ceramic capacitors are based on the technology of multi-layer chip capacitors (MLCC's) with modified internal architecture. The manufacture is similar to MLCC's in that layers of ceramic dielectric material interlaced with precious metal electrodes are built up to form the structure, but holes are then drilled in the ceramic to form contacts to the inner or hot electrodes (s. Figure 7-1). The outside is machined to shape and makes contact to the outer or cold electrodes. The capacitance is formed between the hole and the outside edge (Knowles 2020). Single hole components are usually referred to as discs (they are not necessarily circular) whilst multi hole components are referred to as planar arrays (s. examples in Figure 7-1). In the case of planar arrays capacitance is formed between each hole and the outside edge. Within limits, each hole can have different capacitance characteristics. The materials involved are typically $BaTiO_3$ ceramic dielectric with PdAg electrodes. Terminations are usually plated Au over Ni directly onto the ceramic surface, or sometimes PdAg based fritted glass solderable terminations (Knowles 2020).

Figure 7-1: Typical discoidal and planar array construction

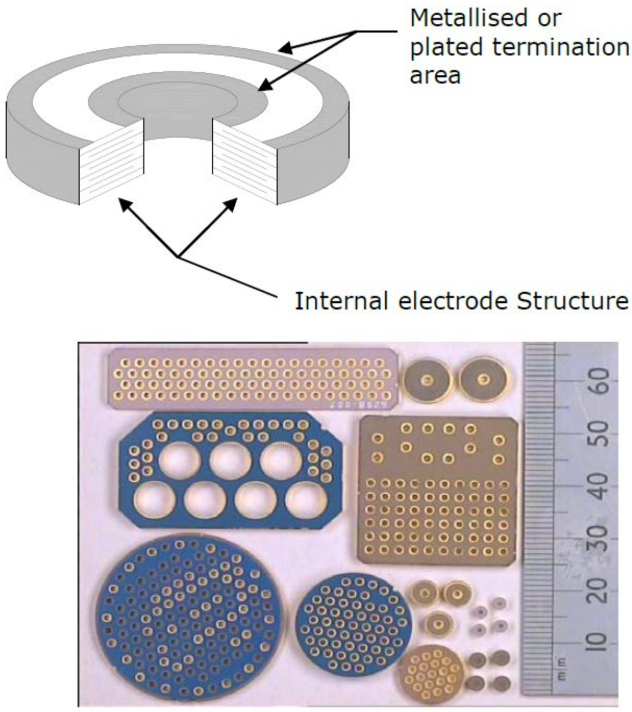


Fig 1

Typical Discoidal Construction

Fig 2

Examples of Discoidal and Planar Array Capacitors

Source: (Knowles 2020); Measuring unit is mm

Figure 7-2: Typical EMI Filter Construction and examples of EMI Filters

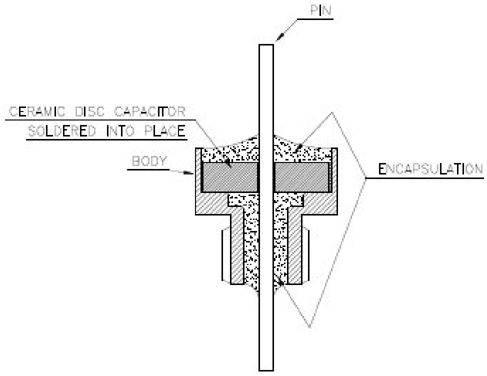


Fig 3

Typical Emi Filter Construction

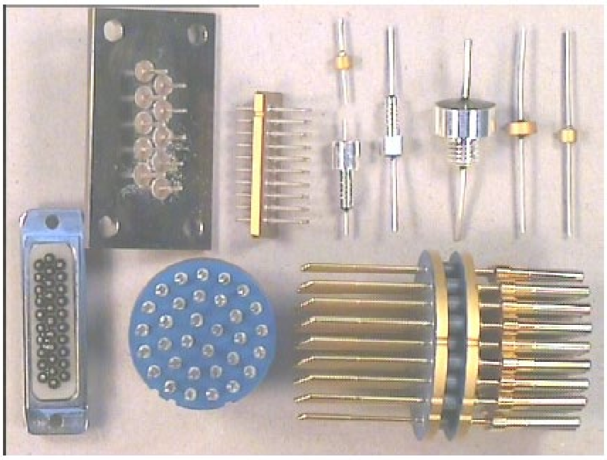


Fig 4

Examples of Emi Filters and Assemblies

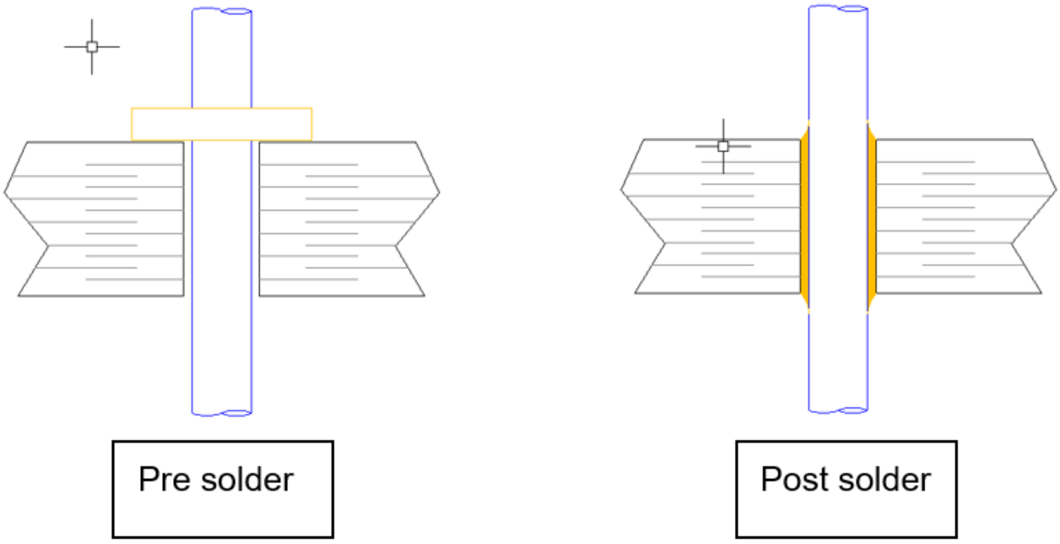
Source: (Knowles 2020)

7.2.2. Specific properties of lead and uses of lead

In relation to the lead containing solders used under this exemption, two cases need to be distinguished:

- Low melting point (LMP) solders:
  The typical solder used is InPb with lower lead content as compared to HMP (s. below), e.g. 50Pb/50In solder (Knowles Precision Devices 2021c). The solidus temperature of Pb50In50 is around 184 °C (Knowles Precision Devices 2021b). Signal carrying feedthrough pins (s. **Figure 7-2**; **Figure 7-3**) are passed through the ceramic element and connected to the internal bore to make a mechanical and electrical connection. The orange part in Figure 7-3 indicates the Pb-containing solders that connect the pin and the capacitor.

Figure 7-3: Pb-containing solder used in a ceramic discoidal capacitor



Source: (Knowles Precision Devices 2021b)

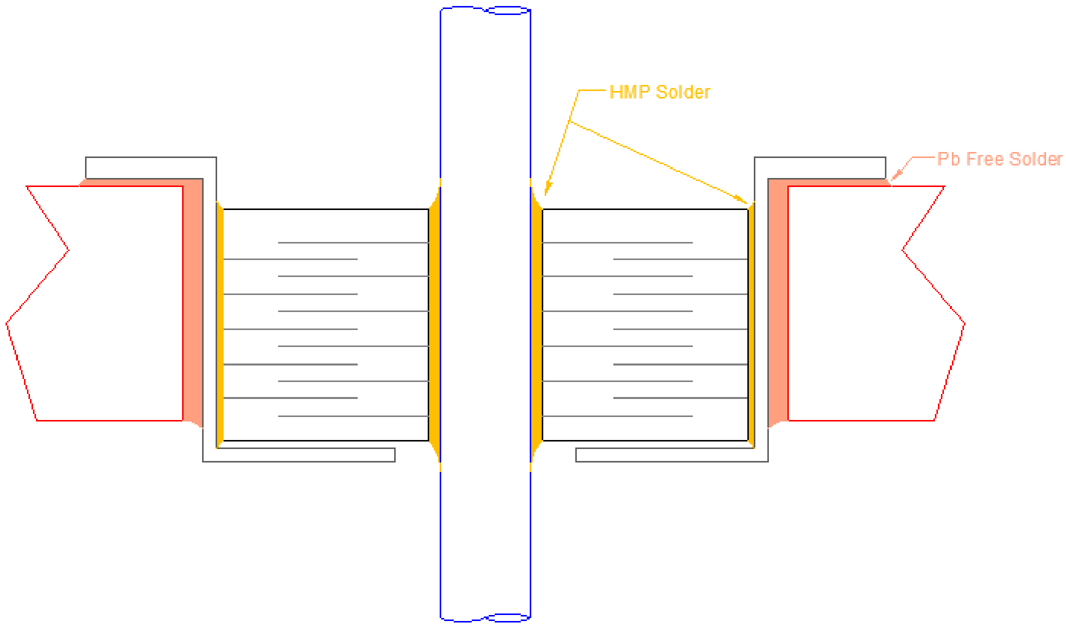
EMI filters/connectors soldered with 50In/50Pb are not further processed through soldering into place, but either through hand soldering (selective soldering) or by being mechanically mounted. Knowles Precision Devices (2021b) explains that signal line panel mount filters soldered with 50In/50Pb joints have screw thread bodies and will be mounted into metal bulkheads using nuts and washers. Some connectors (e.g. a hermetic device) may be selectively soldered (e.g. hand soldering) or welded (for example by laser welding) where the size of the connector, in conjuncttion with the internal design and the grounding / connection to the ceramic element protects the ceramic from thermal / mechanical stress that would result in component failure. Selective soldering will usually be undertaken where mechanical connection is not possible, but with the aim of using the lower lead content solder. EMI filters/connectors soldered with 50In/50Pb will not go into the further subsequent reflow soldering processes, where HMP (s. below) solders instead of LMP solders must be used.

- High melting point (HMP) solders:
  The typical solders used are PbSnAg (Knowles Precision Devices 2020), e.g, 95Pb/5In solder (typical melting point of 300°C/313°C) and 93.5Pb/5Sn/1.5Ag solder (typical melting point of 296°C/301°C) (Knowles Precision Devices 2021c; Knowles 2020). The HMP solders are only used where reflow is required at a lower temperature, commonly known as a "step soldering" process. As shown in Figure 7-4, HMP solders are used not only as solder joints between the pin and the inner bore, but also between the external diameter and places necessary to mount the discoidal or planar (Knowles Precision Devices 2021b). Filters which use HMP solders are designed to be mounted into a panel or bulkhead through reflow soldering with a minimum temperature of 260ºC. In applications with "step soldering", HMP solders cannot be replaced with low melting point solders (LMP),

according to Knowles Precision Devices (2021b). In the later communication, Knowles Precision Devices (2021b) adds that if the component is to be used at a high temperature, for example in excess of 150ºC, HMP solders will be used, since a low melting point alloy (e.g. 50In50Pb, solidus 184ºC) would present reliability concerns.

These HMP solders are not covered in this case by Ex. 7(a) of annex III[36] which excludes applications covered by Ex. 24 from its scope.

Figure 7-4: HMP solder used for soldering pins to the internal bore and mounting capacitors into place



Source: (Knowles Precision Devices 2021b)

According to Knowles Precision Devices (2020), this connection must have low electrical resistance and inductance for optimum performance, as high resistance / inductance will inhibit the high frequency electrical path to ground through the filtering capacitor. The particular characteristics of Lead containing solders are (Knowles Precision Devices 2020):

- The solder must have good wetting action – it is not physically possible to apply the solder directly into the joint area, so the wetting action is vital for the solder to flow into the holes through capillary action. As illustrated in Figure 7-3 and Figure 7-4, the gap between the pin and the capacitor is too small to inject solder directly into the area to be soldered. Therefore, Knowles Precision Devices (2021b) relies on the wettability and flow characteristics of the solder to penetrate into the gap, where capillary action pulls the solder into place.

[36] Ex. 7(a), Annex III wording as of 16.3.2021: "Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)"

- The solder must have good ductility. This good ductility is retained also at low temperatures. Lead indium compounds used are the only alloys in the 'standard' melting temperature range that have the required ductility.
- Where secondary soldering operations are required (solder-mount filters) there is an additional requirement to maintain the ductility of the joint and have a high enough melting point alloy to allow the user to mount the filter by conventional reflow soldering techniques without the internal solder joint suffering secondary reflow. The only other alloys having appropriate ductility and associated high melting points are lead containing HMP alloys.

Further detailed descriptions of the technical background can be found in the previous evaluation reports by Gensch et al. (2016) and Gensch et al. (2009)

7.2.3. Amount of lead used under the exemption

Knowles Precision Devices (2020) has no accurate data available to indicate the amount of lead entering the EU in this type of application. However, Knowles states that most applications of these components are not covered by the RoHS Directive. Knowles provides the following calculation steps and estimations of Pb placed on the global market (Knowles Precision Devices 2020; 2021a).

- **Calculation amount of Pb used in component sectors**

1) amount of Pb used in planar arrays for EMI filtered connectors:

- Knowles current annual manufacturing output is about 39 million holes capacitive holes, which account for ~70% of the global market. That means that the global market output is about 57 million capacitive holes per year. Knowles estimates that the share of non-capacitive (not soldered) components accounts for ~15% and 20% of the rest (i.e. 85%) use BeCu spring clips to make the contact. That means, the amount of soldered capacitive holes is 39 million (=57 million*(1-15%)*(1-20%)). In addition, Knowles estimate from client feedback that only around 10% of parts (39 million) are supplied into applications covered by the RoHS Directive, meaning ~3.9 million capacitive holes (=39 million*10%). Other equipment is out of scope such as aerospace and military applications. It is noted that the share of components covered by the RoHS Directive was 4% in 2016 evaluation phase, meaning an increment with a factor of 2.5 (=10%/4%) comparing current percentage with the value in 2016.
- Knowles Precision Devices (2020) explains that the amount of lead placed on the market through this exemption varies depending on filter design, but that typically 5 mg to 10 mg per solder joint, equating to ~1.0% of the total component weight (maximum) is needed. More complex designs such as filter connectors will be proportionally less than 1% of the total weight. Based on earlier calculations (Gensch et al. 2016) that each hole requires average 7.5 mg of lead in a typical solder joint, the total lead from EMI filtered connectors entering the EU through RoHS applications per annum is estimated at ~29 kg (=3.9 Million*7.5mg);

2) amount of Pb used in EMI single line filters:

around 19 kg of lead maximum was estimated in the last evaluation phase regarding EMI single line filters. Knowles states that they do not believe there has been any significant movement in the market from this position but have taken the stance to increase the percentage of sales into RoHS applications to 10% in line with the trend seen in EMI connectors as noted in 1). This gives an estimate of lead from EMI single line filters of ~48kg (=19kg*2.5) for 2019.

3) amount of Pb used for HMP soldering related to EMI filter market

   Knowles estimates that the market for HMP filters is the same as for LMP filters but will typically use 92.5% lead solder instead of 50% solder, which results in ~88 kg (=48kg/50%*92.5%) of lead placed on the market per annum.

- **Sum up**

Adding these three estimated quantities together gives the total estimate of 164 kg lead per annum supplied into applications covered by the RoHS Directive. Allowing for errors and assumptions, and applying the same ratio as previous exemption applications, Knowles estimates the total usage at **<250 kg lead per annum for the global market** under this exemption.

Based on the above values, **HMP** applications related to the soldering to through hole discoidal and planar array ceramic multilayer capacitors represent roughly **~53%** (= 88kg / 132.5kg) of the global lead (Pb) used, while **LMP** accounts for **~47%**.

7.3. Applicant’s justification for the requested exemption

Knowles Precision Devices (2020) argues the justification of the exemption on the basis of the lack of substitutes with sufficient technical reliability: Knowles currently sees no scope for replacing lead solder as the primary method of making electrical and mechanical connection for the capacitors, as at present there are no viable alternatives to lead containing alloys.

7.3.1. Substitution or elimination of Lead

Lead-free solders

Knowles Precision Devices (2020) explains that when lead-free solder is used to make the connection, the shrinkage of the solder and pin assembly within the bore exerts a tension force on the inside of the bore sufficient to form micro-cracks in the ceramic element. These cracks have a recognisable shape and form. If the crack propagates through the electrically active portion of the design, where electrodes of opposing polarities overlap each other, then the result can be a low resistance path or an electrical short circuit resulting in failure of the electrical system and potentially health and safety risks to operators. Alternative solder alloys, such as tin (Sn)-based lead-free alloys and SnPb alloys[37], do not have sufficient ductility to prevent stress damage to

37 From the consultant’s knowledge, SnPb alloys commonly used for electrical soldering include 60/40 Sn-Pb and 63/37 Sn-Pb, i.e. both with less than 50 % weight lead.

the ceramic and can represent a reliability / safety risk during the operating life of the component.

Additional information is given by Knowles on alternative solders in an annex (Knowles 2020) to the application, differentiating between cases with long bow crack (these usually lead to short circuit) and corner cracking (these can be eased by limiting the volume of solder in the meniscus or reducing the pad size. On very small size parts, it is common to remove the pad entirely). Test results with other solders are shown, where only 50Pb/50In solder, 95Pb/5In solder and 93.5Pb/5Sn/1.5Ag solder showed absence of cracks.

Where secondary soldering operations (i.e. reflow processes) are required, Knowles Precision Devices (2020) explains that the only other alloys having appropriate ductility and associated high melting points are Pb containing HMP alloys. Knowles was asked for the test results concerning several candidates for substitution of HMP. Knowles Precision Devices (2021b) states that lead-free solders with high indium contents are not suitable due to the low melting point. As for BiAgX system (Melting Temperatures (Solidus Line / Liquidus Line): 263 / 320°C), Knowles Precision Devices (2021b) claims that the solidus temperature of only 263ºC is considered way too low for a step soldering lead free alloy, since components to be used in lead free soldering processes need to withstand a reflow temperature of 260°C minimum for at least 30 seconds according to the standard J-STD-020[38]. In addition, Knowles Precision Devices (2021b) carried out some initial solder trials with Au80Sn20 solder alloy (melting point ≈280°C). The discussions with its customers indicated that the eutectic temperature of only 280ºC was not high enough for step soldering and would present reliability concerns.

Knowles (Knowles 2020) concludes that lead-free alloys performed worse of all solders under test due to induced cracks in the ceramic dielectric. In order to manufacture reliable safe capacitor assemblies, it is essential to use a ductile solder so as to prevent excessive force being transferred to the ceramic dielectric material. Ductile solders tend to be an alloy of lead and indium.

Gold and PdAg terminations with Pd-free solders

Experiments with lead free soldering to gold and PdAg terminations were conducted. Information on the experiments with gold and PdAg terminations used with Pb-free alloys is provided by Knowles as an annex of the application (Knowles 2020a). Analysis on gold terminations determined that the cracking occurred during the cooling cycle after soldering, although the gold-plated termination has a far greater adhesion to the ceramic. With respect to PdAg termination, although the ceramic does not crack in the same way as gold plated terminated parts do, the joint between the termination and the ceramic is compromised resulting in a parametric failure (i.e. unacceptable capacitance drop up to 83% of design capacitance). Leaching has been observed on PdAg terminated components with all Pb free alloys (s. Figure 7-5). This leaching also

[38] *Moisture/Reflow Sensitivity Classification for Nonhermetic Solid State Surface Mounted Devices*

has the effect of reducing the termination adhesion between the termination and the ceramic.

Knowles (2020a) describes that there is a conundrum – if the termination system provides a very good bond to the ceramic, then there is a risk of cracking the ceramic. If the termination system provides a weak bond to the ceramic, then there is a risk of parametric failure leading to loss of performance. The best option for reliable performance is to use a termination system that provides a very strong bond to the ceramic (e.g. gold) and introduce stress relief through the use of ductile solders containing lead and indium.

Knowles concludes that the PdAg terminations (due to unacceptable capacitance drop) and gold terminations (due to cracks induced within the ceramic) with lead-free solders are not acceptable. A summary of trials results is shown in Appendix 11.2.1.

Figure 7-5: Examples of PdAg-Termination leaching

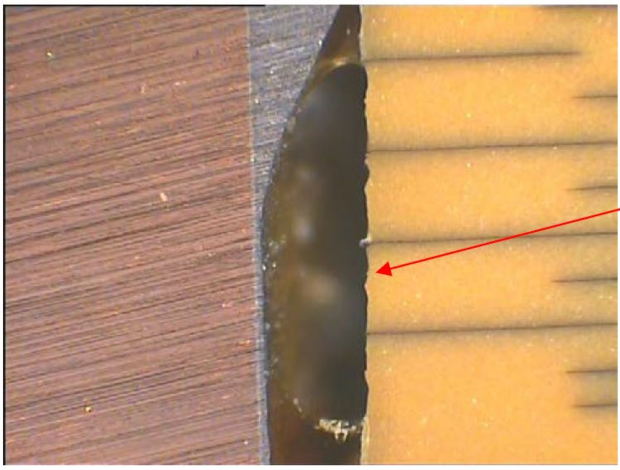


Fig 30

Termination leached away from this area.

These electrodes have lost contact and will result in a potential reduction in filtering performance.

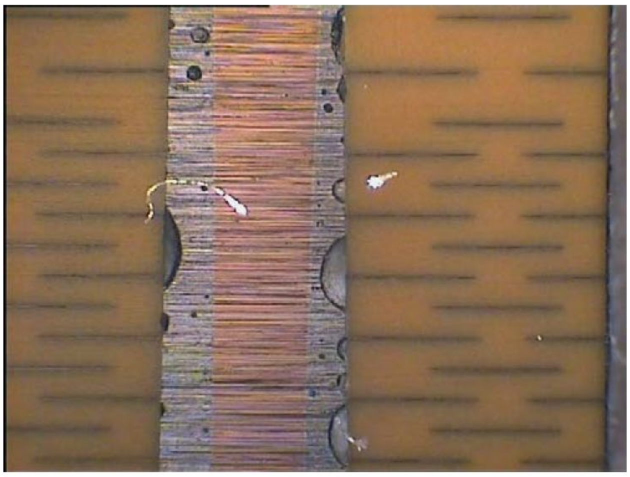


Fig 31

Further example of leaching and poor solder joint with PdAg termination.

Source: (Knowles 2020)

Selective soldering

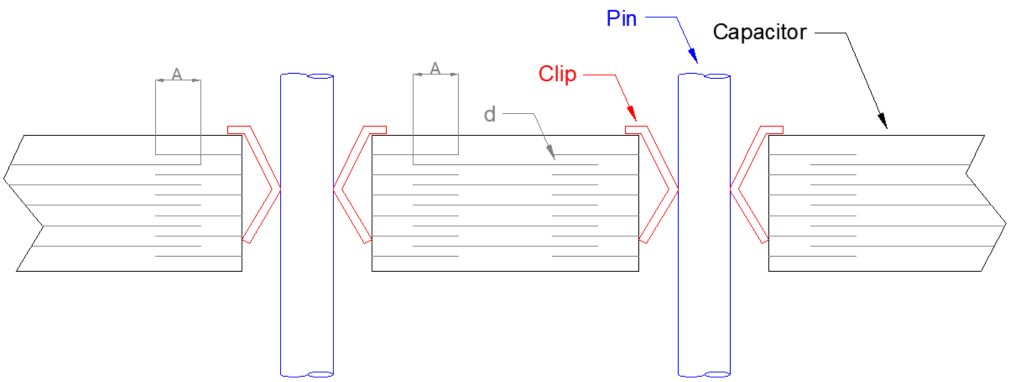
When referring to selective soldering, it means soldered manually or by standard solder reflow equipment (Knowles Precision Devices 2021b). Selective soldering is one of the bonding processes when LMP solders are used. Components using HMP solders are designed to be mounted into place through reflow soldering, not selective soldering. Knowles was asked why not all capacitors in the scope of exemption 24 can be soldered selectively, so that the use of HMP would be avoided. Knowles (Knowles Precision Devices 2021a) explains that selective soldering isn’t possible for all applications. Lead HMP solders are used to assemble components that are to be subsequently assembled into application through reflow soldering processes. During assembly the whole component will be elevated to a temperature in excess of the normal reflow temperature of conventional lead (Pb) free solders to ensure that the joints made are of a suitable quality and to avoid the issues of cold-solder joints. The use of a lower melting point solder to assemble the components would result in a full or partial reflow of the internal joints during installation, which in turn causes potential reliability concerns.

With respect to why some components must go through reflow processes, in which HMP solders are needed, Knowles Precision Devices (2021a) explains that these components are too small to allow for selective soldering and the metal piece parts used would conduct heat too efficiently to the internal solder joints. Knowles Precision Devices (2021b) details with help of Figure 7-4 that the HMP solder joints are positioned just the other side of a very thin (typically <0.5mm) thick brass wall from the Pb free joint that will be used to mount the part in place. The thin wall means that it would not be possible to solder the outside of the body without reflowing. The filter must go through a standard reflow profile and reach a minimum of 260ºC to ensure the quality and reliability of the Pb free joint.

Beryllium-copper (BeCu) spring clips

As a technological alterative, Knowles Precision Devices (2020) explains that beryllium-copper (BeCu) spring clips are used in some cases to make the contact, replacing solder. Knowles processes currently about 13 million holes per annum for applications which use BeCu spring clips to make the electrical and mechanical contact. An illustration of clips used in capacitors is shown in Figure 7-6.

Figure 7-6: Clips used in capacitors



Source: (Knowles Precision Devices 2021b)

However, the majority of applications cannot use this clip technique. The limitations of the clip technique can be concluded as below (Knowles Precision Devices 2020; 2021b):

- The BeCu clip takes up more physical space than a conventional solder joint (typical diameter of capacitive hole ~25% larger) due the mechanical requirements of the clip. It means that clips cannot be used on applications with a tight pin pitch, or small diameter, as there is no mechanical space available.
- Spring clips do have limitations in high bump and vibration applications, which can result in the clip becoming dislodged with possible loss of electrical connectivity.
- The increase in hole diameter reduces available capacitance and the electrical performance of the device. For this reason, the use is limited to larger size filtered connectors with wide contact pitch and lower filtering requirements. An equation was provided by Knowles Precision Devices (2021b) to explain the that capacitance is proportional to area (indicated as "A" in the Figure 7-6) and dielectric thickness (indicated as "d" in Figure 7-6).
- Clips cannot be used with connectors that require that a seal is made directly to the surface (for example epoxy encapsulation) as the liquid (epoxy) enters the connection cavity, isolating and insulating the clip from the connector pin, therefore resulting in the loss of electrical connectivity.
- The technique does not provide a 100% grounding ring (a 100% electrical contact through 360º between the conductor pin and the capacitor), so it can reduce EMI performance and allow high frequency noise to pass through.
- Some connectors that preclude the use of clips as the metal part of the clip protruding onto the surface of the capacitor (s. Figure 7-6) will either interfere with each other or reduce tracking distances (electrical isolation) to the point where electrical flashover can occur.

In addition, Knowles notes that BeCu is under consideration for inclusion in the RoHS Directive as a restricted material, but there are no known alternatives with the appropriate combination of mechanical resilience and electrical conductivity to replace this.

Transient Phase Liquid Sintering (TPLS)

Transient Phase Liquid Sintering (TPLS) is also mentioned as a possible candidate substitute for future applications, with improvements in this field of 'soldering' being monitored. TPLS theoretically allows reflow using lead free alloys to achieve a joint with a high secondary reflow temperature. Knowles Precision Devices (2021c) explains that TPLS for interconnects are generally indium(In)-silver(Ag) or copper(Cu)-tin(S) based. Trials have been undertaken with a number of TPLS materials and are ongoing as part of Knowles' work to replace LHMP solders currently covered by exemption 7(a) (Knowles Precision Devices 2021b). The results of these trials show that TPLS materials act more like conductive epoxies and do not flow and wet across the metallised surfaces as required. No samples provided by the manufactures has demonstrated suitable wetting and flow characteristics to allow the jointing material to fill the joint area. Knowles continues to monitor the market for direct material replacements of lead (Pb) based solders (Knowles Precision Devices 2021c).

Alternative pin material

In the last evaluation report (Gensch et al. 2016), it was documented that "*One possible approach could thus be to use a different material for the pin with a CTE closer to the other materials involved.*" At that time, Knowles stated that "*The pin materials are fixed as copper alloys by application. No other material is acceptable to the industry as offering the appropriate combination of physical and electrical characteristics*."

Knowles was asked this time to detail what type of characteristics an alternative pin material would need to fulfil to be considered as a possible alternative. Knowles Precision Devices (2021b) states no further investigation to their knowledge has been conducted. But they believe if a material with the machinability, wear resistance and electrical conductivity of copper, and a coefficient of thermal expansion (CTE) close to that of ceramic could be developed, it may alleviate the problem. Knowles Precision Devices (2021b) estimates that such a material would need to go through extensive qualification testing over many years.

7.3.2. Environmental arguments

Environmental arguments were not raised as the main justification for this exemption. As for the reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste, Knowles as a manufacturer of component level products states that they are not aware of the final disposition of EEE at EOL.

7.3.3. Socioeconomic impacts

Socioeconomic arguments were not raised as the main justification for this exemption.

7.3.4. Road map to substitution

There is no updated information regarding a road map in the application as compared to the last evaluation in 2015/2016. Similarly to the last evaluation report, Knowles Precision Devices (2020) states that Knowles continues to monitor the solder industry through web searches and in conjunction with their partner solder supplier Indium Corporation, but they claim no viable alternatives to lead containing alloys to be available at the present time.

In a later communication, Knowles Precision Devices (2021b) describes that it is investigating the use of TPLS as part of research into replacement for LHMP in exemption 7a. Knowles Precision Devices (2021b) details the various stages and the range of time needed for each stage as reproduced below. It is noted that the items in green are stages that are performed by Knowles.

Figure 7-7: Road map to substitution for Ex. 24

Stage (Knowles Stage and Gate)	Description	Timescales
Supplier development of alternative material	Solution to Exemption 24	Unknown to Knowles
Knowles	Idea Capture	0 to 3 months
Knowles	Project Definition and Planning	0 to 3 months
Knowles	Project planning and early results - preliminary design review	3 to 6 months
Knowles	Early product / process validation / Intermediate design review	6 to 24 months
Knowles	Product / Process sign off - Final design review.	Up to 6 months
Knowles	Knowles introduce technology to their customers at this stage	Up to 6 months
Customers application approval (Customers who wish to convert to alternative material/solution)	Qualification and approval of Knowles alternative material/solution in Knowles customer applications.	Knowles application engineers estimate 3 to 4 years for customer to perform their own application qualifications and approvals.

Source: (Knowles Precision Devices 2021b)

7.4. Stakeholder contributions

No contributions were made regarding this exemption as part of the stakeholder consultation held in the course of this study.

7.5. Critical review

7.5.1. REACH compliance – Relation to the REACH Regulation

See section 4.1 for details.

7.5.2. Scientific and technical practicability of substitution

The applicant plausibly shows that lead-free solders currently cannot replace the lead-containing solders. Severe cracks were found in all assemblies manufactured with both conventional tin lead solders and the proposed lead-free alloys. With respect to terminations, both PdAg terminations (due to unacceptable capacitance drop, the so called "parametric failure", followed by "leaching" which reduces the termination adhesion between the termination and the ceramic) and gold (Au) terminations (due to cracks induced within the ceramic) do not provide acceptable results, whereas the use of 50Pb/50In solder, 95Pb/5In solder and 93.5Pb/5Sn/1.5Ag solder on gold terminations creates a reliable bond.

The selective soldering process, while not capable of complete substitution, is being considered as a way to avoid the use of HMP, which has a much higher lead content. Components still need lead due to the required performance characteristic of good wettability and ductility. In those cases, where selective soldering could be applied, only LMP would need to be used with the aim of lowering the total lead content used in solder. The applicant argues that selective soldering cannot be used for the applications, where secondary soldering operations in reflow processes are required. Lead-free solders are used to solder the components onto place in reflow processes. The physical space between the outside of the body and place to be soldered is so small, that it would not be possible to solder the outside of the body without reflowing. In addition, an inefficient thermal conductivity is also a limitation. Knowles (2021b) explains that selective soldering can be done manually or by standard solder reflow equipment. The consultant assumes this to mean that selective soldering by hand is difficult under the given circumstances, and also that the soldering time controlled manually could have an influence on the heat conductivity. However, why selective soldering by machine/equipment cannot reach the accuracy, quality and reliability that was not explained in the various communications on this aspect. Further clarification was not possible due to the limited timeframe of this study. This aspect should be clarified in the further review.

The applicant explained plausibly the limitations of the use of spring clips taking into consideration the physical space, any bump or vibration requirements in the operation, the filtering requirements of the connector such as capacitance and the electrical performance and reliability concerns. From the information provided by the applicant, it can however be understood that in some cases spring clips can be used, however not in most. Whether this can be considered in the scope of the exemption is discussed under section 8.5.4. The consultant however can follow that for most applications of Ex. 24 spring clips would not be a viable substitute in light of the limitations mentioned be the applicant (size, geometry, etc.). Knowles mentioned that BeCu is being considered for a RoHS restriction as a further reason why clips would not be considered a suitable substitute. However, from the consultant's knowledge, the assessment of beryllium and its compounds only raised consideration as to a possible restriction for "*beryllium-containing CuBe alloys used as sliding contact brushes in electric motors, which form part of consumers and professional EEE, such as vacuum cleaners and tools*". In the consultant's opinion, such a restriction would not apply to BeCu clips and thus cannot be considered as a justification not to apply BeCu as an alternative in this case.

Transient Phase Liquid Sintering (TPLS) as a potential lead-free solution is still under investigation and development. No samples have been found to demonstrate suitable wetting and flow characteristics to allow the jointing material to fill the joint area.

7.5.3. Environmental arguments and socioeconomic impacts

No environmental and socioeconomic arguments were raised as the main justification for this exemption.

7.5.4. Scope of the Exemption

The current scope of Exemption 24 covers HMP and LMP solders, thus allowing the use of high melting point solders with 85 % with more lead as well as other solders with lower lead contents. The current wording, however, does not differentiate between these two cases and could potentially allow misuse. As it can be understood that elements using HMP could always be applied, a manufacturer could choose to use only such components due to the simplified logistics (i.e. not needing to consider which parts to use in what applications and not needing to store multiple types). The current wording also does not provide certainly for market surveillance (or for that matter industrial actors) as to where HMP solders can be used in EEE and where LMP solders should be applied. Hence, the assessment tried to demarcate these two cases and specify the wording in a concrete way. Without a clear targeted wording, the implementation of market surveillance is very difficult.

The first initial proposals for specifying the scope of the exemption were provided by the consultant specified as follows (Knowles Precision Devices 2021a):

> *„Lead:*
>
> *I) in solders not exceeding 50 % by weight for soldering to machined through hole discoidal and planar array ceramic multilayer capacitors.*
>
> *II) in high melting point solders containing ≥ 85 % lead by weight for cases where a subsequent reflow process at a lower temperature is unavoidable.*"

Knowles Precision Devices (2021a) suggested the following minor changes as an acceptable solution to delimit between LMP & LHMP solders.

> *„Lead:*
>
> *I) in solders not exceeding 50% by weight (nominal) for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors.*
>
> *II) in high melting point solders containing ≥85 % lead by weight for cases where the component is designed to be installed using a reflow process at a lower temperature."*

The reason for adding „nominal" in item I by Knowles Precision Devices (2021a) is that there is obviously some natural variation in the lead (Pb) content due to manufacturing limits. Specifying the alloy as a nominal would prevent unnecessary hardship if the alloy used was found to have a variation in excess of 50% whilst maintaining the spirit of the Directive. Knowles was asked to detail what deviations there are in practice in the amount of lead in a soldering alloy and to specify the tolerance range. Knowles Precision Devices (2021b) states that they do not measure or investigate the content of lead in the solders they use, but as with any specification, there will always be a tolerance of accuracy that must be accepted. Knowles Precision Devices (2021b) provides an example of one supplier allowing a 1% tolerance in alloy ratio. Knowles Precision Devices (2021b) suggests the wording "nominal" to cover such cases where there could be small measured differences between the alloy used and the result measured, so as not to put undue burden on the manufacturer in the case that an alloy is determined to be very close to, but not exactly as stated. Knowles Precision Devices (2021b) suggests using either 50% nominal, or maximum 55% lead in the solder alloy. The consultant understands the concern. However, the need to introduce such a term "nominal" for solders has never been raised by stakeholders in the past and has never been introduced in other RoHS exemptions. The consultant assumes that in cases where market surveillance inspects the exact composition of the solder used that it would take into consideration tolerances that are considered acceptable in the branch. In other words, should such tolerances be relevant, the consultant would assume market surveillance to be aware of the admissible tolerance of accuracy as communicated in industry specifications and standards. A short search for reference of impurities in industry standards suggests that it is already addressed under the IPC J-STD-006C[39] "Requirements for Electronic Grade Solder Alloys and Fluxed and Non-Fluxed Solid Solders for Electronic Soldering Applications". Page 4 of this document specifies that the "tolerance & impurity levels of the alloy shall conform to the current version of J-STD-006, or equivalent".

In addition, the consultant disagrees strongly to the option of changing the threshold form 50% lead to 55% lead in the wording. Increasing the threshold from 50% to 55% does not solve the problem but rather refers to a soldering alloy of different composition. It would be interpreted that 55% lead can be used, with relevant tolerance or impurities. Hence, the consultant suggests retaining 50% in the wording without any changes.

In relation to the proposed addition to item II ("*where the component is designed to be installed")* Knowles Precision Devices (2021a) raises concern as to the exemption specifying that the application may only use LHMP where a subsequent reflow process

[39] https://www.ipc.org/TOC/IPC-J-STD-006C.pdf

at a lower temperature is unavoidable. Knowles states that this would put an unreasonable burden on the component supplier to determine if the application it is being sold into could use an alternative assembly method or not. If it is stated that the component is designed to be installed using a reflow process, then the burden of compliance remains with the component manufacturer.

The consultant understands Knowles' concern, to be that component suppliers would be given responsibility for the later assembly method, which they do not have control over. On the other side, in consultant's opinion, the wording "designed" will mean that compliance is given as long as the part was designed for the correct purpose, but how it is used in reality is irrelevant. This rather creates a loophole. In addition, it is not clear if market surveillance could distinguish between cases of misuse where components placed on the market as ones designed to be installed using a reflow process, were not needed as LMP would have been sufficient. The initial formulation, proposed by the consultant, referring to "unavoidable" is also difficult for market surveillance, since market surveillance cannot identify/detect which application is avoidable and which is unavoidable.

The consultant also tried to exclude applications where spring clips can be used through specifying performance thresholds. With respect to the clear-cut demarcation of clips-relevant applications, Knowles Precision Devices (2021b) states the use of spring clips to form electrical interconnections is dependent on each individual application. The decision is made by the designer of the connectors. Knowles explains plausibly the limitations of clips and complexity of the designs, which has been reproduced in section 8.3.1. Knowles Precision Devices (2021b) argues that a simple list of parameters that will cover every application or be in anyway exhaustive is not possible. Hence, Knowles can see no way to simplify the parameters to a set of rules that can define when clips are an acceptable option. In addition, the consultant proposed to modify *"Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors"* to *„Lead in alloys used for soldering pins to the internal bore of through hole discoidal capacitors and/or planar array ceramic multilayer capacitors"*, since the latter indicates explicitly where lead is used.

Knowles Precision Devices (2021b) does not agree to the inclusion of the term lead in alloys used for soldering pins to the internal bore of through hole discoidal capacitors, since lead is used not for solder joints to the inner bore but for the external diameter, necessary to mount the discoidal or planar in place.

Knowles Precision Devices (2021b) comments that these components are not specifically designed for and are very rarely installed in PCB's. They are more often installed in bulkheads or similar positions within electrical equipment. Knowles Precision Devices (2021b) together with partners and customers have also identified situations where filtered connectors are welded into metal bulkheads, but at a distance far enough from the internal solder joints so as to enable 50/50 solder to be used. Knowles Precision Devices (2021b) states that it is clear that jointing techniques other than soldering must be considered in the exemption wording. Further consideration is the operation temperature, as already explained in section 8.2.2.

After the clarification of these aspects, the consultant proposes a second reformulation. Knowles Precision Devices was asked to comment on what "machined" refers to in the current wording of the exemption and whether removal of "machined" would cause a misunderstanding or extend the scope of the exemption to applications for which it is not intended. Knowles Precision Devices (2021b) confirms that the term "machined" has caused some confusion and suggests deleting this term.

Knowles Precision Devices (2021b) strongly suggests that any change is deferred until the next round of exemption reviews. The reasons are reproduced in section 8.6.2. However, Knowles still provides a new proposal as specified below, if the suggestion is not acceptable. Knowles Precision Devices (2021b) feels that the following wording will cover most, but maybe not all applications.

> *„Lead in alloys used for soldering to through hole discoidal and/or planar array ceramic multilayer capacitors:*
>
> *I) Not exceeding 50% nominal by weight for applications where the components <u>are designed</u> to be mechanically mounted (e.g. by bolts, clips or screws) or by a selective soldering / welding process and the component will not exceed a temperature of 150ºC.*
>
> *II) In high melting point solders containing ≥ 85 % lead by weight for cases where the components <u>are designed</u> for mounting using an elevated temperature process (e.g. solder reflow, welding) or the component is rated to operate at a temperature of ≥150ºC.*

Knowles Precision Devices (2021b) explicitly expresses that this wording is given with the proviso that Knowles is very uncomfortable with adopting it.

As discussed previously, in the consultant's view, the wording "designed" is not just vague but actually produces a partial loophole. The consultant considers that an OEM has a responsibility to use a component that benefits from an exemption only in the application for which it is intended. Where the wording is not specific this creates uncertainties whereas the consultant's proposal aims to make it clear for both industry and market surveillance what is considered "intended". If the Directive indicates that a certain solder can only be used for some applications, then the OEM needs to make sure to purchase the correct components for their mode of bonding and not only LHMPS ones to use in both ways as this gives greater flexibility from a logistic perspective. In the consultant's opinion, the supplier of the component could use the exemption wording to specify in the component data sheet that it is compliant with the RoHS Directive only as long as it is applied in the specific bonding ways mentioned below. If the OEM does not purchase the component directly but rather a sub-assembly, then it could also use this specification to make sure that the sub-assembly also complies with this principal.

Interrelation with Exp. 7(a)

The current formulation of Exemption 7 (a) is: "Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)."

Exemption 7(a) currently covers the use of HMP (lead>85%) in electrical and electronic equipment so that there is a scope overlap with Exemption 24. However, the use of lead in the capacitors in the scope of Exemption 24 has already been excluded from the scope of Exemption 7(a) to avoid that the use of solders in these capacitors is covered by two different exemptions. In addition, Exemption 7(a) has a broad scope whereas the further demarcation of specific applications has been the focus of the last assessment that ran in part in parallel to this assessment. In the consultant's opinion, Exemption 24 should further remain as a separate exemption and should not be merged with Exemption 7(a), since Exemption 24 indicates a clear application and has a specific scope. Furthermore, in the course of a future scope refinement of Exemption 7, the HMP entry could be revoked, if the lead-content of the solder used under Exemption 24 could be reduced to a level below 50 %.

7.5.5. 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 lead-free solders are not sufficiently reliable. The applicants plausibly explain that lead-solders are required for soldering to through hole discoidal and/or planar array ceramic multilayer capacitors. Alternative approaches, such as selective soldering, spring clips, sintering, PdAg terminations, are either not technically viable or not suitable for all applications. Elimination of soldering via the use of spring clips is an option in some applications. As in the previous evaluation processes (Gensch et al. 2016; Gensch et al. 2009), the situation remains that it is still not possible to define a functional exemption wording with a clear-cut demarcation of applications where spring clips can be used due to multiple parameters.

Against this information, the exemption is concluded to be justified based on fulfilment of the first criteria, i.e. the elimination or substitution of lead used for soldering to through hole discoidal and/or planar array ceramic multilayer capacitors "via design changes or materials and components which do not require any of the materials or substances listed in Annex II" is considered to be scientifically or technically impracticable.

The current scope of Exemption 24 covers two cases (HMP and LMP), but without delimiting them. Though the use of low lead solders may be preferable from a process efficiency and economic point of view, it is understood not always to be possible. Nonetheless, the scope of the exemption should be targeted and focused on application fields and technologies as necessary. Though the consultants recommend splitting the exemption to address the HMP and LMP separately, data was not sufficiently available to allow a more detailed specification of application fields and technologies at this time. Such a specification however should be sought. This would ensure a higher certainty among companies and market surveillance as to when the exemption is used properly and when it is misused. Hence, in the consultants' opinion, demarcating these two cases is essential to ensure that HMP solders are only used where necessary and where no alternatives exist.

7.6. Recommendation

7.6.1. Wording of Exemption 24

The applicants plausibly explain that neither the elimination nor the substitution of lead is viable to a degree that would allow the revocation or the restricting of scope of Exemption 24. The information submitted by the stakeholders can be followed, showing that the substitution of lead in exemption 24 applications is technically impracticable. In the consultants' opinion the first criteria specified in RoHS Art. 5(1)(a) is fulfilled and a renewal of the exemption would be justified. It is recommended to renew the exemption for another five years but specifying the wordings to demarcate the use of lead HMP and LMP solders as specified below.

Exemption 24 formulation	Duration
Ex. 24 Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors	18-month transition period
New item Ex. 24 (a): Lead in alloys used for soldering to through hole discoidal and/or planar array ceramic multilayer capacitors I) Not exceeding 50% by weight for applications where the components are mechanically mounted (e.g. by bolts, clips or screws) or bonded by a selective soldering / welding process and where the component will not exceed a temperature of 150ºC. II) In high melting point solders containing ≥85 % lead by weight for cases where the components are mounted using an elevated temperature process (e.g. solder reflow, welding) at a temperature of ≥150°C or where the component is rated to operate at a temperature of ≥150° C.	21 July 2026 for categories 1-11

7.6.2. Applicant's objection concerning the split of Exemption 24

The applicant does not disagree with the splitting of the wording and provides contributions to reformulate the proposal. However, Knowles Precision Devices

(2021b) emphasises that they consider it very risky to business to consider changing the exemption wording at short notice without time to carry out due-diligence surveys of the industry to determine the full scope of applications demanding HMP solders. Knowles Precision Devices (2021b) strongly suggests that any change is deferred until the next round of exemption reviews to allow the situation to be properly assessed and for all stakeholders to have time to formulate a response.

The consultant can follow this concern and thus also recommended a transition period for the current exemption formulation as specified above.

7.6.3. Outlook: Further Specification of Exemption 24

The following aspects are summarised and recommended to be followed-up on in support of the future review of this exemption:

- More detailed information should be provided on what has been researched in the last 5 years, supported with clear evidence.
- Understanding the technical differences between selective soldering by equipment and reflow processes to clarify entirely why some components must be applied with a reflow processes.
- Investigation should be undertaken of how a clear-cut demarcation of applications where spring clips can be used, although there are multi factors to be considered. More concrete information on clip-relevant applications with clear detailed parameters should be obtained, to derive thresholds for the use cases of clips.

7.7. References

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8. Exemption 29: "Lead bound in crystal glass as defined in Directive 69/493/EEC (Cat.1, 2, 3, 4)"

Declaration

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

Acronyms and definitions

EEE	Electrical and Electronic Equipment
EDG	European Domestic Glass
LE	LightingEurope
LED	Light emitting diode
Pb	Lead
PbO	Lead oxide
Pb3O4	Lead tetroxide
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
SCIP	Substances of concern in articles as such or in complex products

8.1. Background of the exemption request

Ex. 29 was evaluated in 2009 and 2015/16 (Gensch et al. 2016). The past evaluation shows that there were no substitution substances available for lead in glass in terms of one-to-one replacements.

Lead in the form of lead oxide and lead tetroxide is used as raw material to produce lead bound in crystal glass. The crystal glass is a component of different lighting and decoration applications. In a combined application request, European Domestic Glass (EDG) and Lighting Europe (LE) thus request the renewal of Ex. 29 for (European Domestic Glass und Lighting Europe 2020):

> *Lead bound in crystal glass as defined in Directive 69/493/EEC (cat. 1, 2, 3, 4)*

The renewal is requested for EEE falling within the categories 3, 4, 5 and 11 set out in Annex I of the RoHS Directive for a duration of 10 years. The consultants note that Article 5 of the RoHS Directive specifies a maximum duration of 5 years for which exemptions can be granted for the categories referred to. Until now, the exemption covers all EEE Categories of Annex I.

8.2. Technical description of the requested exemption

8.2.1. Technical background

"By definition, glass is an amorphous, inorganic solid material made by fusing silica with basic oxides. Glass is called amorphous because it is neither a solid not a liquid but exists in a vitreous (or glassy) state. From a chemical point of view, glass is both a unique material and a material state respectively"" (European Domestic Glass und Lighting Europe 2020).

Within the silica layers, alkali as well as other cations such as Pb2+ form characteristic networks based on the molecular ratio: "*Inserted into the vitreous structure between the network formers as Si–O–Pb bonds, Pb does not form Pb–O–Pb clusters which are expected to be more easily leached. A part of Kalium (K) is located near Pb, forming mixed Si–O–(Pb,K) near the nonbridging oxygens. Pb is always released into the solution following a diffusion-controlled dissolution over various periods of time, at a rate between 1 and 2 orders of magnitude lower than the alkalis (K and Na). The preferential release of alkalis is followed by an in situ repolymerization of the silicate network. Pb is only depleted in the outermost part of the alteration layer. In the remaining part, it stays mainly surrounded by Si in a stable structural configuration similar to that of the pristine glass.*" (Angeli et al. 2016 cited by European Domestic Glass und Lighting Europe 2020).

Lead in the form of lead oxide (PbO) and lead tetroxide (Pb_3O_4) is used as a raw material to produce lead bound in crystal glass. According to Directive 69/493/EEC, lead (expressed as PbO) must be present in the glass at a minimum of 24 % for the glass to be declared 'lead crystal' (**Figure 8-1**); however, lead crystal glass does not contain PbO, as the compound has reacted during the production of the glass. The different categories of crystal glasses shown in **Figure 8-1** do differ in terms of the content of lead oxides (and other metal oxides) in the glass raw materials, even though the glass produced no longer contains PbO.

Directive 69/493/EEC specifies the following categories of lead crystal in its annex, clarifying the characteristics in terms of the amount of lead contained in the matrix and the properties that the glass needs to have.

Figure 8-1: List of crystal glass categories (Annex I of Directive 69/493/EEC)

ANNEX I

List of crystal glass categories

No	Description of category	Explanatory notes	Characteristics: Metal oxides (%)	Density	Refractive index	Surface hardness	Labelling: Shape of symbol	Remarks
—a—	—b—	—c—	—d—	—e—	—f—	—g—	—h—	—i—
1	CRISTAL SUPERIEUR 30% CRISTALLO SUPERIORE 30% HOCHBLEIKRISTALL 30% VOLLOODKRISTAL 30%	Description may be freely used, whatever the country of origin or the country of destination	PbO ≧ 30%	≧ 3·00	x		○	Round label. Colour: gold Ø ≧ 1 cm
2	CRISTAL AU PLOMP 24% CRISTALLO AL PIOMBO 24% BLEIKRISTALL 24% LOODKRISTAL 24%	The percentage figure refers to the lead oxide content	PbO ≧ 24%	≧ 2·90	x			
3	CRISTALLIN VETRO SONORO SUPERIORE KRISTALLGLAS KRISTALLIJNGLAS[1] SONOORGLAS[2]	Only the description in the language or languages of the country in which the goods are marketed may be used Exception: On the German market pressed glass containing 18% PbO and having a density of at least 2·70 may be sold under the description 'PRESSBLEIKRISTALL' or 'BLEIKRISTALL GEPRESST' (in capital letters)	ZnO BaO PbO K_2O singly or together ≧ 10%	≧ 2·45	nD ≧ 1·520		□	Square label. Colour: silver Side: ≧ 1 cm
4	VERRE SONORE VETRO SONORO KRISTALLGLAS SONOORGLAS		BaO PbO K_2O single or together ≧ 10%	≧ 2·40		Vickers — 550 ± 20	△	Label in the shape of an equilateral triangle. Colour: silver Side: ≧ 1 cm

x nD ≧ 1·545 as criterion for an additional non-destructive determination of the products (at the time of import).
1 In Belgium.
2 In the Netherlands.

Source: (Directive 69/493/EEC)

The applicants (European Domestic Glass und Lighting Europe 2020) describe the properties of lead crystal glass on the basis of the technical parameters listed below:

- *"The **refractive index** is defined as the ratio of the speed of light in a vacuum to a dimensionless number that describes how light propagates through a medium. The higher the refractive index, the more light effects (rainbow) occur.*
- *The **Abbe number** is a measure of the variation of refractive index with wavelength, so the refractive index of a glass with a low Abbe number varies less across the visible spectrum than a glass with a high Abbe number. Lead crystal glass has a low Abbe number, which reduces chromatic aberration while maintaining a high refractive index.*
- ***Dispersion** describes the phenomenon in which the phase velocity of a wave depends on its frequency. The bigger the dispersion, the greater the visible colour spectrum (rainbow).*
- *The **cooling time** is the time span between two viscosity states. Below and above this time span, glass cannot be shaped. The greater the cooling time, the more specific (longer, thinner and more complex) shapes can be made. This specificity increases the craftsman's ability to produce high quality products. Analogous to the cooling time, the working range indicates the temperature range with the same purpose as the cooling time, expressed in °C or Kelvin instead of time.*

- ***Vickers' Hardness** is a specific measure of the hardness of the material. The lower the hardness, the more possibilities there are for cutting and engraving complex artistic designs on unusual and prestigious objects that can only be achieved by handcrafting."*

The crystal glass is a component of different lighting and decoration applications. In this context, the applicants name the following applications and products (European Domestic Glass und Lighting Europe 2020):

- Fixed/portable luminaires
- Lamps
- Electrified mirrors
- Horology (clocks, watches etc.)
- Display cases
- Digital photo frames
- Tablet and smart phone docking stations
- Furniture and home décor items, if including electrical or electronic products (carrousel, tables, sofas, plumbing elements etc.)
- Building materials (illuminated bricks)

Accordingly, from the applicants' point of view, the products can be assigned to the following categories of Annex 1 of the RoHS Directive: 3. IT and telecommunications equipment, 4. Consumer equipment, 5. Lighting equipment, and 11. Other EEE not covered by any of the categories above. The applicants further state, that there is no use of lead bound in crystal glass in other categories (European Domestic Glass und Lighting Europe 2020).

8.2.2. Amount of lead used under the exemption

The applicants estimate that about 50 tons/year of Pb_3O_4 or PbO is used to produce lead bound in crystal glass for electrical and electronic items entering the EU market. The corresponding lead content in the lead oxides is calculated by the applicants to be 46 tonnes per year. The applicant states that the use remained stable within the last five years (European Domestic Glass und Lighting Europe 2020), same figures had been presented in the former assessment of Ex. 29 in 2016 (Gensch et al. 2016).

8.3. Applicant's justification for the requested exemption

The applicants justify the request for exemption essentially on the basis of technical aspects that are decisive for the fact that no adequate alternative substances are available that fulfil all the required properties. In addition, advantages of leaded crystal glass in terms of energy efficiency are presented and socio-economic impacts are detailed that relate to the case that an exemption renewal is not granted.

8.3.1. Substitution or elimination of lead in crystal glass

According to the applicant, lead in glass enables a higher energy efficiency of light transmission (lumen/watt) and the "*production of exceptional articles otherwise impossible to obtain'* based on an '*increased working time with the glass […], unique* *optical properties[40] […], unique mechanical process possibilities (cutting and polishing), unique refinement process possibilities, and decorative aspects."* (European Domestic Glass und Lighting Europe 2020)

According to the applicants, substitutes for these specific EEE applications have been sought for nearly two decades, but without success.[41] The applicants justify their doubts as to whether promising substitutes will ever be found with the fact that there are a limited number of elements in the periodic table available that can be combined to form some kinds of crystal glass in EEE applications (BaO, ZnO, SrO, CaO, MgO). Moreover, those combinations that exist form glasses only within relatively small composition ranges. The performance of alternative materials is inferior and does not allow the production of the same items from lead crystal glass. This is particularly due to the thermo-mechanical-optical properties, which are particularly important for the elaboration of the product. Moreover, alternatives provide insufficient performance in comparison to the processing time enabled by the lead oxide component.

Most of the machine-produced quality glass for domestic use has moved from lead crystal glass to alternatives. The remaining part, which is the subject of this request for exemption renewal is of highly specialised manufacture and requires a significant amount of handwork. Full Lead Crystal and Lead Crystal correspond to the categories with the highest density and refractive index in Directive 69/493/EEC (category 1 and 2 respectively, see annex I). These categories also have the highest PbO content of the crystal glass types addressed by Directive 69/493/EEC, namely ≥ 30 % and ≥ 24 % lead oxide, respectively. The applicant specifies these categories as the most relevant for applications benefiting from the exemption but cannot exclude the relevance of other categories (crystal glass using[42]).

In summary, the applicants assess the substitution situation to the effect that crystal glass without intentionally added lead does not meet the required combination of essential properties:

- Shorter cooling time/working range would not permit the production of complex items.
- Higher Vickers hardness will trigger musculo-skeletal disorders for the workers because the cutting difficulty will dramatically increase. In addition, quicker damage and need to replace industrial tools will drastically increase. It will become impossible to make very intricately engraved articles as employers are required to protect the health of their workers.
- The combination of optical properties (refractive index, Abbe number, dispersion) generated using lead bound in crystal glass are unique and unmatched by other

[40] *'High refractive index nd > 1.56 (responsible for brilliance), high dispersion nf – nc > 0.01, preferably 0.013 (responsible for the refraction and reflection performance), high light transmission (L > 98; -0.5 < a < 0; -0.5 < b < 0.5 (100 mm thickness immersion, light C, 2°, CIELAB), and no ‚grey' but sharp colour transition' European Domestic Glass und Lighting Europe (2020).*

[41] *'After two decades of intensive research, all possible combinations of elements have been prepared and evaluated, references are available upon request and upon confidentiality assurance.' European Domestic Glass und Lighting Europe (2020).*

[42] Exclusion from scope of Directive 69/493/EEC categories 3 and 4 would in any case not lead to a lower use of lead, as their use of various metal oxides such as PbO is lower than that of categories 1 and 2.

materials (the latter are unable to obtain the same low value of chromatic aberration).

To support this view, the applicant provides a comparison of lead crystal to soda lime and other crystal (non-leaded) shown in **Figure 8-2**.

Figure 8-2: Comparison of lead crystal to soda lime and non-leaded crystal glass

	lead crystal	sodalime glass	crystal glass 1 *	crystal glass 2 *	crystal glass 3 *	crystal glass 4 *	crystal glass 5 *	crystal glass 6 *	crystal glass 7 *	crystal glass 8 *
Refractive Index	1,56	1,52	1,55	1,55	1,55	1,52	1,52	1,51	1,52	1,54
	variation	-2%	0%	-1%	0%	-2%	-2%	-3%	-3%	-1%
Abbe Number	43,8	59,4	55,7	53,6	55,4	56,0	58,1	57,6	59,1	53,9
	variation	35%	27%	22%	26%	28%	32%	31%	35%	23%
Dispersion (656,27nm-768,2nm) (10E-3)	4,2	3,1	na	3,2	3,2	3,0	3,2	3,2	3,1	3,3
	variation	-27%		-24%	-24%	-29%	-25%	-26%	-27%	-23%
Dispersion (589,3nm-656,27nm) (10E-3)	3,7	2,6	na	2,7	2,7	2,6	2,7	2,7	2,6	2,8
	variation	-29%		-26%	-26%	-31%	-27%	-27%	-29%	-25%
Dispersion (435,84nm-486,13nm) (10E-3)	7,3	4,8	na	5,1	5,1	4,7	5,0	4,9	4,8	5,2
	variation	-34%		-30%	-31%	-36%	-32%	-33%	-34%	-29%
Dispersion (404,66nm-435,84nm) (10E-3)	6,3	4,0	na	4,3	4,2	3,9	4,2	4,1	4,0	4,3
	variation	-36%		-32%	-32%	-38%	-34%	-34%	-36%	-31%
Working Range (T Log4 - T Log 7,65) (°C)	333	298	271	290	254	326,7	311,6	308,1	320,4	301,8
	variation	-10%	-19%	-13%	-24%	-2%	-6%	-8%	-4%	-9%
Cooling time (s)	130	100	106	113	104	111,1	117,4	144,8	118,9	109,6
	variation	-23%	-19%	-13%	-20%	-15%	-10%	11%	-9%	-16%
Vickers Hardness (MPa)	4799	5586	5319	5038	5431	5451,7	5197,1	4909,2	5332,9	5025,7
	variation	16%	11%	5%	13%	14%	8%	2%	11%	5%

Legend: Green < 5% discrepancy; yellow 5-10% discrepancy; red > 10% discrepancy.
Note: Crystal glass 1&2: formulations investigated during R&D works (thesis conducted by Baccarat until 2003); Crystal glass 3: US patent 2007/003237A1. Holder is Swarovski; Sodalime glass: commercial formulation used for tableware production.
Source: (European Domestic Glass und Lighting Europe 2020) (Directive 69/493/EEC)

8.3.2. Environmental arguments

Environmental arguments are provided as to the end-of-life and waste stage of lead crystal glass as well as to the energy efficiency enabled through lead.

As for the latter aspect, according to the applicants, the addition of lead oxide enables a better energy efficiency of light transmission. In support of this argument, the applicants have submitted a test report (PISEO SAS 2015). This report presents the test results for a series of measurements in which the transmission of light is measured with different diffusers at constant electrical power of an LED light source. On the basis of the test report, the applicants conclude that for the same light source (LED), the luminous flux transmitted through a lead crystal article is at least 10% greater compared to the luminous flux transmitted through the “same” article when produced in (lead-free) flint glass. The energy efficiency (lumens/watt) of lead crystal would therefore be much better than that of flint glass and in certain cases, the energy efficiency class of an electrical lighting fixture could change from category B (with flint glass) to category A (with lead crystal).

According to the applicant, there are no negative environmental impacts in the end-of-life stage of lead crystal glass containing EEE. This is based on the following arguments:

1. Waste prevention: The applicants state that lead bound in crystal EEE applications are '*prestigious und expensive items which are kept, transferred, inherited or resold.*' (European Domestic Glass und Lighting Europe 2020) Second-hand sales, repairs and replacement of spare parts is common, specialised companies to collect and recycle WEEE containing crystal glass exist[43], according to the applicant. Against this background, the volume of articles or parts of articles which might be discarded is seen to be negligible.
2. Low risk for leaching in landfill: A leaching test was provided in 2015/2016 when asked whether it could be excluded that the limit for acceptance as non-hazardous waste for landfilling with regard to lead (10 mg/kg dry matter[44]) is exceeded. In accordance with EN 12457-2[45], a crystal branch '*was crushed and sieved to a grain size between 0.5 and 4 mm. The result is that the Pb concentration is at 3.09 mg/kg. […] It is therefore assumed that the limit value could be exceeded if lead crystal glass would be very finely grounded at a lower particle size diameter. This case is totally unlikely since the lead crystal articles under the scope of the RoHS are eventually discarded by consumers, in debris of a larger size.*' (European Domestic Glass und Lighting Europe 2021)
3. Low risk for accumulation of lead in glass recycling: '*EDG confirms that there is no accumulation of lead since the lead oxides are fully transformed into a glass substance*' (European Domestic Glass und Lighting Europe 2021). '*Under REACH Regulation, glass is itself a substance*[46]*, […] articles made of lead crystal glass actually contain no elemental Pb or PbO as such*' (European Domestic Glass und Lighting Europe 2020). The applicant justifies the low risk for accumulation based on the fact that '*there is no obligation to submit a SCIP notification*' (European Domestic Glass und Lighting Europe 2021) based on the understanding that PbO/Pb_3O_4 fully react into the "glass substance" (ECHA 2020 cited by European Domestic Glass und Lighting Europe 2021)

8.3.3. Socioeconomic impacts

The applicants make clear that the crystal glass industry is already facing an economically challenging situation. EEE applications account for about one third of the turnover of some of them. If the exemption is not extended, this would have serious repercussions:

- Loss of economic wealth;

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43 http://www.metabel.com/site/en/electronicscrap.asp cited by European Domestic Glass und Lighting Europe (2020).

44 Annex to Council Decision 2003/33/EC establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC; Chapter 2.2 Criteria for landfills for non-hazardous waste

45 EN 12457-2:2002 Characterization of waste - Leaching; Compliance test for leaching of granular and sludges - Part 2: One stage batch test at a liquid to solid ratio of 10 l/kg with particle size below 4 mm

46 REACH Regulation, Annex V and Guidance for Annex V, Entry 11, pp. 38-39 cited by European Domestic Glass und Lighting Europe (2020).

- loss of European patrimonial wealth and cultural diversity;
- loss of ca. one third of turnover of related manufacturing companies and in the medium/long term, their disappearance; and
- 2,750 direct jobs lost and 6,950 indirect jobs in the glass industry in Europe.

8.3.4. Road map to substitution

When asked about the prospects of success of further research efforts on substitutes, the association explained the state of affairs as follows (European Domestic Glass und Lighting Europe 2021):

Though, members of EDG are '*actively involved in research projects*' for substitution, projects have reached a pilot phase which '*is still subject to an iterative process'* which '*will take some more years.' (European Domestic Glass und Lighting Europe 2021)* However, the applicant states that '*progress has been made'* which is not yet at a status that details on compositions or processes could be made public. (European Domestic Glass und Lighting Europe 2021)

Further, the applicant expects '*that in about 10 years' time, about half of the remaining lead crystal companies will have shifted to [non-leaded] crystal. 'Please note that the planned shift does not mean that a substitute will have been found to lead crystal glass, but that companies will abandon lead crystal glass for high quality [non-leaded] crystal glass whose production process* determination is still ongoing.' (European Domestic Glass und Lighting Europe 2021)

8.4. Stakeholder contributions

In total, 16 individual contributions have been submitted during the consultation period from 30 March 2021 to 08 June 2021.

- The contribution of the **Conseil départemental de Meurthe-et-Moselle**, France, support the request for renewal of the exemption. The argumentation covers two different aspects: With regards to socio-economic impacts, the Département states that in France, the crystal glass sector employs 1.800 persons directly and roughly 5.000 indirectly. In recent years, the sector entered a new market and started successfully to export to Asia and the Middle East. The enterprises in the sector were awarded '*enterprises of living heritage'*. In addition, the contribution refers to two different research projects at Cerfav (Centre européen de formation aux arts verriers) and Baccarat (a city within the Départment) on lead alternatives which were not successful today but continue their efforts. (Départemant Meurthe & Moselle 2021)
- Arguments brought forward by the **Institut National des Metiers d'Art** (INMA) and the **Conféderation Francaise des Métiers d'Art de l'excellence du luxe** (cfma), both in France, include processability aspects of crystal glass containing lead oxides (increased viscosity, refractive, dispersion and transmission indices, lower hardness), state that there has not been found any substitute for lead oxide with the same properties, and support the fact that '*crystal items that end up on waste disposal sites is negligible'*. They are luxury products that can and indeed will be repaired due to their economic value. (INMA 2021; cfma 2021)

- The **city of Baccarat,** France, supports the request for renewal of the exemption. They state that in the city 500 persons are employed in the crystal glass manufacture which is an important local market and attracts tourists. (Ville de Baccarat 2021)
- The association of local authorities in **Pays de Bitche,** France, supports the request for renewal of the exemption as well. Besides bringing forward several of the arguments stated in other contributions summarized above, it is said that the manufactures of crystal glass continue to be the most important employers as well as the most important touristic attraction in the region of Pay de Bitche. (Communauté de comunes Pays de Bitche 2021)
- In crystal glass manufacturing in the **Département de la Moselle**, France, 1426 employees are employed in 26 different manufacturing enterprises. On their territory, the worldwide known and European oldest manufacture of crystal glass is located (HERMES, Saint-Louis) employing 300 persons. (Département de la Moselle 2021)
- The **SCHMIDT-HAENSCH GmbH** focusses on lead in glass for faraday rods used in polarimeters. Such polarimeters are used in optical measurement devices. Schmidt-Haensch speak in favor of the exemption request. (Schmidt Haensch 2021). The consultant raised various clarification questions in order to understand the use of lead in the application and to identify whether Ex. 29 is applicable to this application, see the details under chapter 8.5.5.
- The **Association of Glass and Ceramic Industry of the Czech Republic** (ASKP) supports the renewal pointing out similar arguments than mentioned by the French stakeholders. A new aspect mentioned by ASKP focusses on socioeconomic aspects stating that 'the glass industry is located mostly in areas with higher unemployment […], many jobs are at risk as are the social, economic and cultural benefits that producers bring to their region.' (Association of the Glass and Ceramic Industry of the Czech Republic 2021)
- Besides the already summarized arguments, the contribution of **Ministry of Industry and Trade of the Czech Republic** includes the perspective that 'the restriction rules of the use of certain dangerous substances in EEE aim to contribute to the mitigation of problems at the end of life cycle'. And below it is said that 'EEE containing lead bound in crystal glass belong to certain niche product groups […] as their inclusion would bring negligible environmental or health benefits.' (Ministry of Industry and Trade of the Czech Repbulic 2021)
- The **Senate of France** emphasizes the importance of the crystal glass manufacturers for the reason of living heritage, it contribute the same numbers of employees in the French crystal glass sector than the conseil départemental de Meurthe-et-Moselle (see above). (Senat FR 2021)

Without providing further specific input but referring to the arguments raised by the majority of stakeholders as summarized above, the following stakeholders expressed their support for the renewal for the exemption:

- Mr. Thibault Bazin, representative of the Département Meurthe-et-Moselle in the Assemblée Nationale, France (Bazin 2021) ;
- Mr. Jean-Marie Mizzon, président des maires ruraux de la Moselle, France (Mizzon 2021);

- Bernard Brochard, representative of the Département Alpes-Maritime in the Assemblée Nationale, France (Brochand 2021);
- Philippe Huppé, representative of the Département de l'Hérault in the Assemblée Nationale, France (Huppé 2021);
- Region Grand Est, France (Region Grand Est 2021);
- Centre européen de recherches et de formation auxarts verriers (CERFAV) (Cerfav 2021).

8.5. Critical review

8.5.1. REACH compliance – Relation to the REACH Regulation

For exemption 29, a derogation was granted in entry 63 for crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC.

In addition to the information in relation to REACH compliance in section 5, additional exemption-specific aspects are of importance and are discussed in the following. Lead oxide (PbO) and lead tetroxide (Pb_3O_4) are substances of very high concern in accordance with Article 59(10) of the REACH Regulation (EC 1907/2006) for which specific provisions apply, among others Art. 33 of the REACH Regulation[47]. When asked whether improper disposal of crystal glass would lead to an accumulation of lead in the waste, i.e. container glass, the applicant explains that the lead oxides are not present in the final glass and that REACH Art. 33 is not applicable to leaded crystal glass (*"There is no accumulation of lead since the lead oxides are fully transformed into a 'glass substance'* [48]*."*) This is based on the understanding provided by ECHA that "*if the lead substance as such is not present in the final glass article, there is no obligation to submit a SCIP notification for that article, nor to communicate information down the supply chain under Art. 33 of REACH"* (ECHA 2020 as cited by European Domestic Glass und Lighting Europe 2021). Against this background, in crystal glass applications, lead oxides are understood to have an intermediate use when used in the manufacturing of leaded crystal glass.

The consultant clarifies that this argumentation is not applicable to RoHS as the RoHS Directive defines that *"lead [in any form] in EEE is restricted if the weight concentration exceeds 0,1% in the homogenous material"*. Thus, the argumentation that lead does not accumulate *"since the lead oxides are fully transformed into a glass substance"* (European Domestic Glass und Lighting Europe 2021) is not correct under RoHS.

[47] *"Directly after a substance is included in the Candidate List, suppliers of articles which contain such a substance in a concentration above 0.1% (weight by weight) have to provide enough information to allow the safe use of the article to the recipients of the article. In this case, recipients are industrial or professional users and distributors, but not consumers. As a minimum the name of the substance in question has to be communicated. Consumers can request similar information. The supplier of the article has to provide this information within 45 days, free of charge."* ECHA (2021).

[48] *"Certain lead substances, e.g. lead oxide, included in the Candidate List may be involved in processes leading to the production of articles containing a 'glass' substance. In these processes, the lead substances may be first chemically transformed into a manufactured glass substance. The glass substance is subsequently processed into articles."* ECHA (2020).

The applicant rightly states that the lead oxides do not accumulate, but it is a different situation for Pb^{2+} in the glass. In this case, it is misleading to conclude from REACH to RoHS due to different scopes and objectives: The RoHS Directive addresses lead and its compounds as a group and does not differentiate between compounds. This means that if lead oxides (PbO and Pb_3O_4) are used in the manufacturing process and lead is bounded in the amorphous glass matrix (e.g. as Pb^{2+}) in a concentration of >0,1% in the homogenous material, the use of this material in EEE is restricted under RoHS except if an exemption is granted.

8.5.2. Scientific and technical practicability of substitution

EDG and LE have requested the renewal of Ex. 29 to allow the use of lead in crystal glass when used in EEE. The main argumentation of the applicants is that no alternatives are available to achieve the complex shaping and machinability of crystal glass in combination with optical properties (refractive index and the dispersion of light).

The manufacture of lead crystal glass items involves a large degree of hand crafting in manufacturing (blowing and pressing) and in the later stages of cold processing (such as cutting and polishing). It is understood that the ability to perform the various steps of hand crafting requires certain properties of the material, and that substitutes would not allow creating articles of the same complexity. Particularly, the lead in the glass matrix increases the time of viscosity in which complex geometries can be grinded. The consultant acknowledges the lubricating effect that is attributed to lead in glass matrixes. The consultant further follows the explanation provided by the applicant that the thermal inertia enabled through lead allows longer time spans of an acceptable temperature range of the glass for manufacturing.

From the evaluation in 2015/2016, the consultant is aware that at least some lead crystal manufacturers were actively engaged in research and testing of lead crystal substitutes at the time of the last review. The argumentation of EDG and LE suggests that the results of these efforts was not as promising as initially expected. As to support this view, **Figure 8-2** was presented together with the exemption request in 2020. A comparable figure had been presented in the assessment in 2016 (Table 31-1, p.686 Gensch et al. 2016) which compared lead crystal to soda lime glass and three lead-free crystal glass formulations. In **Figure 8-2**, eight crystal glass formulations with no intentionally added lead are shown in comparison to lead crystal glass and soda lime glass. All substitutes (the three earlier presented as well as the new five formulations) show high discrepancy (above 10%) in Abbe Number and dispersion.

It is concluded that neither a one-to-one substitute exist to replace the lead, nor any lead-free glass formulations that have similar technical properties. These properties are understood to be important for the appearance, i.e. of aesthetic nature, thus being difficult to assess in technical terms, however, some data has been provided to show that should other types of glass be used to create articles of similar appearance, that the optical properties of importance for the aesthetic properties of the products would not be comparable on the crystal level. It is further concluded, that even though for the various EEE articles, in which lead crystal is used, various alternatives exist – e.g.

alternative luminaires – the consultants can follow that such articles would not provide a replacement in terms of the appearance of the products.

Irrespective of this special property profile of lead crystal glass, the applicants assume that in about 10 years about half of the remaining lead crystal companies will abandon their production of lead crystal glass in favour of high-quality (lead-free) crystal glass, even if the development of the production process required for this has not yet been completed at present. From the consultants' point of view, it can be concluded that high-quality substitutes are in prospect, at least for certain property profiles and applications.

8.5.3. Environmental arguments

The applicants, as well as various stakeholders, who participated in the consultation, explain that based on the fact that in lead crystal glass articles lead is encapsulated within the material (see technical background, chapter 8.2) the risk of emissions to the environment during the use and the end-of-life phases is not expected.

End-of-life / misthrow into container glass

The risk related to the end-of-life stage is stated to be negligible, claiming that practices of repair or replacement of the broken parts of these prestigious and expensive items (e.g. one branch or prism of a luminaire) prevents the discarding of the full EEE application at end-of-life. The applicant argues that the probability of lead crystal glass EEE articles to reach the waste stream is very small. Thus, emissions and exposure are claimed to tend to zero. A submitted leaching test of granular waste material and sludges (European Domestic Glass und Lighting Europe 2021) shows that the risk of lead emissions from such articles is negligible (see above section 8.5.3).

Even though no recent leaching test was provided in addition to the test provided already in the 2015/16 assessment, in the consultant’s view, the submitted test results sufficiently show that (under normal use/ environmental conditions) emissions from lead crystal during use and during end-of-life are not expected. As long as not treated with strong acids, the release of lead from the vitreous matrix would not be expected. The consultants can also follow that lead crystal articles would typically not reach the waste stream in light of their value.

However, in the following, the consultant assesses the concern that it cannot be excluded that the (e.g. accidently broken) glass is disposed of with other glass leading to a contamination of recycled (container) glass. This is of relevance due to the high concentrations of lead in leaded crystal glass and due to the high glass recycling rate (close to full circulation).

Regarding the **probability of a misthrow** the consultant follows the argumentation of the applicant, that due to the high price of crystal glass items, remanufacturing is more likely than (proper) disposal which is more likely than improper disposal. Only improper disposal would lead to a contamination of the waste container glass. However, in contrast to tableware, these EEE articles are less at risk to break during use, e.g. chandeliers and luminaires shall usually be fixed to walls and ceilings, etc.

However, in the case that leaded crystal glass is disposed with container class, what **concentrations of lead in recycled (container glass)** can be expected? The container glass waste accounts for 14.5 million tons of glass waste materials in the EU in 2018 (Eurostat 2021). The applicant refers to 46 tons per year of lead being introduced to the European market through this exemption. If hypothetically 10% of the crystal glass was introduced into the container glass recycling, the relation of Pb to glass would result in 1x10^(-7) to 3,2x10^(-7).

Studies on the **potential exposure** with lead leaching from crystal glass e.g. decanter into beverages have been performed with crystal glass according to Directive 69/493/EEC that has a minimum share of lead of 24%: Lead concentrations were found to be 89 µg/L and between 2,000 and 5,000 µg/L for port wine after two days storage and four months respectively (Health Canada 2002; GRAZIANO und Blum 1991), white wine doubled its lead content within an hour of storage and tripled it within four hours. After storage in lead crystal for over 5 years, some brandy contained around 20,000 µg lead per liter (GRAZIANO und Blum 1991; Altman 19 Feb 1991). Leaching of lead through citrus juices and other acidic drinks is comparable to the leaching through alcoholic beverages (Guadagnino et al. 2000; S.J. Barbee und L.A. Constantine 1994). Daily usage of lead crystal glass was found to add up to 14.5 µg of lead from drinking a 350ml cola beverage. However, these leaching experiments cannot be transferred to the case of contaminated of glass with a considerable lower lead contents of a magnitude of 10^(-7).

Thus, if leaded glass entered the glass material loop which is used to produce glass items used in food contact scenarios, it is unlikely that the lead contamination results in any leaching of lead into the beverages in the short term because the amount of Pb2+ ions in the glass matrix is too small. On the long term, it will depend on the amount of leaded crystal glass that enters the glass loop. It is questionable whether this is a relevant amount, however, it cannot be excluded that lead ions could be found in glass matrices used for food contact material. The existence of ISO 7086-1:2019-09[49] on test methods for the determination of lead (and Cd) in glass tableware proves that independent of leaded crystal glass in EEE, lead is a common contaminant in the glass loop.

It is concluded that as misthrow is unlikely, lead concentrations in container glass can be seen negligible (magnitude of 10^(-7)), thus, the lead content is too little to be leached to food and beverages effectively, and exposure with lead from other sources is considerably higher. This view is shared by the Ministry of Industry and Trade of the Czech Repbulic (2021) who state that *"EEE containing lead bound in crystal glass belong to certain niche product groups […] as their inclusion would bring negligible environmental or health benefits."*

Besides the argumentation brought forward by the applicant, the consultant assumes that leaded crystal glass does not affect recycling of container glass for packaging purposes because it would be sorted out by the optical separation techniques in the recycling process. According to information from recyclers, misthrows mainly consist

49 ISO 7086-1:2019-09: Glass hollowware in contact with food - Release of lead and cadmium - Part 1: Test method (https://www.beuth.de/de/norm/iso-7086-1/313796493)

of drinking glasses (composed of a different type of glass) as well as window or car glass and porcelain. These so-called "faulty cullets" are separated out by optical methods during the processing of used glass. If drinking glasses is reliably separated, the consultant expects that lead-containing crystal glass due to its high refractive index is also sorted out.

Energy savings during manufacture

As already explained in Gensch et al. (2016), it is understood that lead increases the working time of the glass during manufacture through its impact on the viscosity of the glass and its thermal properties. This facilitates the melting and forming of crystal articles in hot processing, and, more importantly, has an impact on the energy consumption related to these production stages, as the glass does not need to be reheated (re-melted) as frequently as in lead-free glass types, and as the temperature for reheating is significantly lower than for lead-free glass types.

Energy efficiency of light transmission

As justification for the renewal of the exemption request, the applicants have also cited the better energy efficiency in light transmission, cf. section 8.3.2. However, on closer examination of the data provided by the applicants from the relevant test report, it becomes clear that not only the glass material but also the design of the diffuser significantly determines the light transmission and energy efficiency. This means that with appropriate design, high energy efficiency can also be realized with lead-free glass. In this respect, the consultants can only partially follow the applicants' argumentation. In addition, other diffusers would also have to be included for a holistic view.

Figure 8-3: Influence of the diffuser on the energy efficiency of the luminaires

Object of investigation	Efficiency (+/- 3%)	Unit	Relative efficiency
Luminaire without diffuser	30,9%	lm/W	100%
Luminaire with plain diffuser, cristal glass	27,4%		89%
Luminaire with diffuser design 1, cristal glass	21,3%		69%
Luminaire with diffuser design 2, cristal glass	20,0%		65%
Luminaire with plain diffuser, flint glass	24,5%		79%
Luminaire with diffuser design 1, flint glass	19,2%		62%
Luminaire with diffuser design 2, flint glass	17,8%		58%

Source: Own representation based on data from (PISEO SAS 2015)

8.5.4. Socioeconomic impacts

The applicants and the various stakeholders who participated in the consultation argue that the production of hand-crafted lead crystal is considered a cultural heritage in various regions of the EU (e.g. in France and the Czech Republic) which '*is an important local market and attracts tourists'* (Ville de Baccarat 2021; Communauté de comunes Pays de Bitche 2021)

A further socioeconomic argument in favour of this glass type is that a relatively high number of individual workers and artists are employed in the sector, since the manufacture of lead crystal glass items involves much handicraft. Stakeholders estimate that app. 1.800 persons are employed directly and roughly 5.000 indirectly in the French crystal glass sector (Départemant Meurthe & Moselle 2021), 500 of which are employed in the crystal glass manufacture in the city of Baccarat (Ville de Baccarat 2021). In the Département de la Moselle, 1426 employees are employed in 26 different manufacturing enterprises. The globally recognized and oldest manufacture of crystal glass in Europe (HERMES, Saint-Louis), employing 300 persons, is located on this territory (Département de la Moselle 2021). Pointing out another aspect of the importance of employment in the sector, a contribution provided by ASKP (2021) states that '*the glass industry is located mostly in areas with higher unemployment […], many jobs are at risk as are the social, economic and cultural benefits that producers bring to their region*.'

The consultants can conclude that the artisan manufacture of lead crystal articles has great importance both as a cultural heritage and as a source of employment for many individuals.

8.5.5. Scope of the Exemption

While the possibility to differentiate automated and hand-crafted manufacturing was discussed under the assessment in 2015/16 with no implication for the scope of the Exemption, such discussion was not renewed under this assessment.

The renewal is requested for EEE falling under Categories 3, 4, 5 and 11 of Annex I of the RoHS Directive. So far, applications from all EEE Categories of Annex I are covered under this exemption. While the exemption expires in 2021 for categories 1-7 and 10 as well as for categories 8 and 9, other than in vitro diagnostic medical devices and industrial monitoring and control instruments, it remains valid until 21 July 2023 for category 8 in vitro diagnostic medical devices, and until 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11. Based on the statement of the applicant that there are '*no use in other categories'* (European Domestic Glass und Lighting Europe 2020) except for Cat. 3, 4, 5 and 11.

Information as to lead-containing glass rods applied in Faraday modulators in polarimeters was provided as a contribution to the stakeholder consultation by Schmidt-Haensch (2021). '*These polarimeters would no longer be manufacturable without Faraday rods. Prohibition of lead in glass would sustainably damage manufactures of optical measurement devices'*. Schmidt-Haensch explains that the polarimeters belong to EEE category 9. However, renewal of the exemption is only requested for Cat 3, 4, 5 and 11, and the exemption expires for Cat 9 other than industrial monitoring and control instruments. In view of the consultant, the glass used to produce rods applied in Faraday modulators does not fall under the crystal glass categories 1-4 as defined in Directive 69/493/EEC. Therefore, the lead-containing glass rods applied in Faraday modulators in polarimeters do not fall within the scope of Ex. 29. The consultant explained this view to the stakeholder. The consultant does not have enough information to consider whether the application is covered by an existing exemption (e.g. Ex. 13a, 13b or 7c-I) or whether based on the criteria set out in Article 5(1)(a) of the RoHS Directive, Schmidt-Haensch needs to seek a new exemption to be able to further place their product on the market. Furthermore, the consultant sees such assessment beyond its mandate from the Commission to assess the single exemption.

8.5.6. Conclusions

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

a) 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**;

b) the **reliability** of substitutes is not ensured;

c) 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 one-to-one substitutes for lead in crystal glass are currently not available. Though new formulations of glass have been tested and researched, it can be followed that at present such a substitute would limit both the complexity of articles that could be produced as well as resulting in a rise in energy consumption during manufacture. The consultant follows the explanation provided by the applicant that the thermal inertia enabled through lead allows longer time spans of an acceptable temperature of the glass for manufacturing. A substitution is not understood to provide comparable products in terms of their complex geometries resulting in specific optical properties which is of importance for the consumers interested in crystal glass EEE applications.

It could be argued that non-leaded articles, i.e. other luminaires from different shape, form and other types of (non-leaded) glass, could provide the same function. However, the function of a luminaire is not only to provide light but as well to provide a certain appearance: Based on a high refractive index, a high dispersion and transmission of light and sharp colour transitions, a different performance can be expected from lead crystal luminaires than from non-leaded glass luminaires. The upper named prolonged manufacturing time spans due to the thermal inertia enabled through lead give the possibility for highly complex items compared to other glass items.

From an environmental perspective, especially with regards to potential emissions of lead from use and end-of-life phase, it is concluded that the risk for lead emissions is negligible. This is based on the chemical structure of glass which allows the lead only to leach if grinded to dust or treated with strong acids as well as based on the high price of the items of interest. Therefore, such items have a high value on 2nd-hand-markets and end up in WEEE management only occasionally. If unintentionally disposed of in container glass recycling, no measurable impacts can be attributed to this source of lead for the container glass recycling, even if recycled to be used in food contact material. Leaching of lead to beverages takes place only at higher concentrations of lead in the glass than to be expected through this contamination route.

In addition to Article 5 criteria and based on the cultural heritage character of the business branch and the possibility to employ specialised workers in hand-crafting of glass in regions of characteristically higher unemployment, socio economic arguments speak in favour of a renewal of the exemption.

8.6. Recommendation

The justification for the renewal of Ex. 29 is based on the observation that alternative formulations of non-leaded crystal glass do not compare in terms technical properties resulting in the desired optical properties and complexity of design.

The information submitted by the applicants supported by stakeholders can be followed, showing that the substitution of lead in exemption 29 applications is technically impracticable.

It is additionally based on the expectation that items under Ex. 29 do represent a negligible source of lead in the WEEE stream. However, during the evaluation of the present application it has also become clear that about 46 t of lead per year enter the European market as a component of crystal glass in electrical products, without the exact whereabouts or disposal being known. Due to the comparatively large quantity of lead as a pollutant regulated under the RoHS Directive, it is particularly important that, if this exemption is reapplied for, the whereabouts or treatment of this waste is presented more precisely and as far as possible quantitatively. In particular, an attempt should be made to determine the quantity flows of lead-containing crystal glass (a) in residual waste and (b) as an interfering material in the glass recycling of container glass.

It is recommended to grant the exemption with the following formulation:

Exemption formulation	Duration
Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/ 493/EEC	Expires on — 21 July 2026 for categories 3, 4, 5 and 11; — 21 July 2023 for category 8 in vitro diagnostic medical devices; — 21 July 2024 for category 9 industrial monitoring and control instruments

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9. Exemption 32: "Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes"

Declaration

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

Acronyms and definitions

Ar	Argon
Kr	Krypton
Coherent	Coherent Inc.
CTE	Coefficient of Thermal Expansion
EEE	Electrical and Electronic Equipment
Lumentum	Lumentum Operations LLC
Pb	Lead
PbO	Lead Oxide
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment
SSL	Solid state laser(s)
UV	ultraviolet

9.1. Background

Lumentum Operations LLC (2020) applies for the renewal of Ex. 32 of Annex III of the RoHS Directive:

> *"Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes"*

Lumentum applies for the exemption in its current formulation and requests it to be renewed for 5 years for RoHS annex I categories 6, 8 and 9. In its application, it addresses only argon lasers, since Lumentum does not manufacture Krypton lasers.

The exemption was first reviewed in 2006 (Gensch et al. 2006), whereupon the Commission granted the exemption. The exemption was assessed again in 2010/2011 (Zangl et al. 2011) and in 2016 (Gensch et al. 2016) to establish its continuous justification. In both assessments it was concluded that the exemption was still justified, as substitution of lead was technically impracticable. Following this conclusion, the exemption was renewed without change.

Coherent, a manufacturer of krypton and/or argon lasers applied for the renewal of RoHS exemption 32 extension in the last evaluation process (2015/2016) but did not apply for the continuation this time. In the later communication with Coherent, it was clarified that Coherent still needs this exemption for argon and krypton lasers (Coherent 2021b). Coherent (2021b) confirmed that they also request the exemption for categories 6, 8 and 9 of RoHS Annex I.

9.2. Technical description of the requested exemption

9.2.1. Specific properties of lead and relevant applications under this exemption

Lead oxide is used in a solder glass frit as a vacuum seal in the manufacture of argon or krypton laser tube. This glass frit joins glass of a mirror to the laser metal tube without thermally damaging the complex coating layers (>30 layers) of the mirror. The lead-oxide glass material provides a critical thermo-mechanically-stable and vacuum-tight seal between the optics and laser tube in applications of relevance to this exemption (Lumentum Operations LLC 2020). Coherent (2021a) explains that argon and krypton lasers are merely vacuum tubes that are filled with a very low amount of gas (argon and/or krypton). The baseline components are comprised of a ceramic tube, a magnet, metallic inner components and optics.

Lumentum Operations LLC (2020) states that lead-oxide glass material has the following two main advantages:

- Lead oxide as a raw material lowers the melting temperature of the solder glass/glass frit. The softening point of the lead oxide-based material occurs at a narrow temperature range around 420°C and does not thermally damage the nearby fragile components being joined.
- The material has a coefficient of thermal expansion (CTE) closely matched to the components (e.g. glass and metal) for stress-free sealing. The seal frit is required to have a thermal expansion coefficient at 7.0 to $8.0*10^{-6}$/K to match to the components for stress-free sealing.

Concerning the argon or krypton laser tubes, both Lumentum (2021a) and Coherent (2021a) explain that argon and krypton gases are not interchangeable for applications, as the gas (or gain medium) creates a different spectrum of photons which then dictates wavelength, power and beam specifications.

Coherent (2021b) details that argon creates higher power for UV lasers with optics optimized for 364.1 nm transmission. Krypton creates higher power for violet, cyan, yellow and other visible wavelengths whilst using optics optimized for the specific wavelengths requested (highest request is Violet at 413.1 nm). The wavelength will dictate penetration depth, power requirements and beam size. So, although Krypton does produce UV light, they would only produce < 1% of the power at 364.1 nm that an argon ion laser would produce.

Argon laser products are used as light sources in a broad range of critical applications, a majority of which are in research, bioinstrumentation and semiconductor manufacturing. This includes flow cytometers, DNA sequencers, and hematology equipment. Instruments are used all over the world by both government and private sector agencies for health care, drug discovery, and research applications. In semiconductor manufacturing, argon lasers are used in inspection equipment (Lumentum Operations LLC 2020). Lumentum (2021b) explains that krypton lasers cannot be used in spectroscopy or metrology applications requiring blue/green wavelengths.

Coherent (2021b) states that these lasers will continue to be utilized in critical beam applications in life sciences research, and are an integral component in nearly all OEM semiconductor manufacturing processes for the inspection of silicon wafers and LCD/LED manufacturing. Coherent (2021b) details the categories associated with its specific applications applied as below:

- Category 6. Electrical and Electronic Tools
  - Writing of Photomask for chip stacks, integrated circuits, CPU, GPU, etc.
  - LCD/LED Photomask Writing
- Category 8. Medical Devices
  - Research & Development instruments used in industry
- Category 9. Monitoring and control instruments including industrial monitoring and control instruments
  - Semi-Conductor inspection
  - Photomask inspection

Further technical details related to exemption 32 are available in the reports of the previous reviews (Gensch et al. 2006; Zangl et al. 2011; Gensch et al. 2016).

9.2.2. Amount of lead used under the exemption

The content of lead in the frit used for making window assemblies in argon lasers is >50% of the homogeneous material (% weight) based on Lumentum's application. Lumentum uses on average, about 200 grams of PbO per year in the sealing glass frits of argon lasers. However, only a fraction of that enters the EU. Based on Lumentum's direct shipments, only 17 grams of PbO enter the EU market in argon lasers annually. This amount has not changed since Lumentum's previous application for the renewal of RoHS exemption 32 in 2015. Based on molar masses[50], 17 grams of PbO can be converted into about 16 g Pb.

Coherent (2021b) estimates the quantity of lead which will be introduced into the EU annually to amount to between 0.5 grams to 1 gram. This would represent roughly 25-50 tubes per year entering the EU, nearly all of which will be returned to the US for

[50] Molar mass of PbO = 223.2 g/mol; Molar mass of Pb = 207.2 g/mol; The weight of Pb = 207.2*17g/223.2=16g

replacement. The amount of lead oxide per window assembly is roughly 0.02 grams (Coherent 2021b).

In the 2016 evaluation report (Gensch et al. 2016), it is documented that such ion lasers have been in steady decline for several years. Lumenten and Coherent were asked for an estimation on the current market development. Lumentum (2021b) explains that most low-power argon ion lasers are typically used in established laser tool technology or legacy applications, with demand being either steady or at a very gradual decline pace. Coherent (2021b) states that the demand for argon and krypton lasers has remained steady since 2019 for various reasons (e.g. the rise in the internet of things (IoT), advancements in automotive intelligence/chip requirements, and a global supply shortage of chips (post pandemic)). A discontinuation date for the use of such lasers is currently not planned, indicating that this market shall probably remain stable or shall further decline gradually.

It is understood that both estimated values of lead (≈ 16 g by Lumenten and 1 g by Coherent) represent only those companies' own products and not the whole market in the EU. Estimations concerning the total amount of lead used under this exemption are not available. The consultants assume that, owing to the stable market, as followed by the last evaluation report (Gensch et al. 2016), **less than 1 kg of lead** is used in the EU under this exemption per year.

9.3. Applicant's justification for the requested exemption

The particular characteristics of lead as a sealing material under this exemption are lowering the glass softening point to 420°C and providing a coefficient of thermal expansion (CTE) closely matched to the components for stress-free sealing. Lumentum has not identified lead-free glass that meets these requirements. Argon lasers cannot be manufactured without the use of lead oxide in seal frit of the window assembly. Moreover, without argon lasers many applications (healthcare, research, bioinstrumentation, semiconductor manufacturing) would not be possible (Lumentum Operations LLC 2020).

Coherent (2021b) specifies that ion lasers are used for the writing and inspection of semiconductor silicon wafers and for critical life science research. Due to the tight tolerances and critical nature of these manufacturing processes, it is likely that there will be no suitable replacement for ion lasers for at least 5-10 years. The unique property of argon and krypton ion lasers is that they can produce a multitude of different wavelengths, which is impossible with solid state or more modern lasers. Most applications take place in wavelength ranges assigned to deep UV, UV and violet light. For all of these regimes, ion lasers are by far the most reliable devices, and, according to the applicants, it will be difficult to replace them in the next decade due to the nature of the industries.

9.3.1. Substitution or elimination of Lead

Bismuth-based glass frits

Commercially often investigated alternatives to the leaded glass sealing material (frits) are based on bismuth. Bismuth-based glasses have significantly higher (540°C) melting temperatures than the Pb-based frits. Lumentum has been searching for suitable bismuth-based frit alternatives for many years. Trial builds with bismuth oxide-based frits were performed at different temperatures starting at 480ºC. A good melting, per visual inspection, was only obtained starting from 540ºC (Lumentum Operations LLC 2021). In Lumentum's trial builds, the bismuth-based glass frit did not produce a consistent good flow of the frit material (see illustration photos in application and in (Gensch et al. 2016)). The bismuth-based material did not flow to provide a complete seal as Pb-based material does. To further substantiate this, Lumentum provides a comparison of the coefficients of thermal expansion and sealing temperature of leaded and bismuth-based lead-free sealing glass and sealed components in the argon lasers in Table 1 of the application (Lumentum Operations LLC 2020). Lumentum argues that the coating fabrication process of optics only allows for stabilization of the key optical properties to 500°C. Processing at temperatures above 500°C will cause failure of the coatings. The consultants understand this to mean that use of bismuth-based glass frit, which requires higher temperatures, would damage the optic coatings and lead to failures of the laser.

Lumentum concludes that the bismuth oxide-based material (frit) is not considered a viable alternative at this time, since Lumentum's optics are not designed to be subjected to temperatures beyond 500°C.

Bismuth-free glass frits

Lumentum was asked to provide more details for other bismuth-free frit materials to further show the lack of suitable alternatives. Lumentum Operations LLC (2021) states that bismuth-based frits are typically used as a replacement for leaded frits due to their lower melting temperatures compared to other type of glass material. Bismuth-free frits are used by the industry for other types of application, however, their sintering or firing temperatures are already above 700°C, and their actual melting point is even above 900°C (Lumentum Operations LLC 2021). Two research papers were given as examples by Lumentum as evidence for the high temperatures of other bismuth-free frits.

Phosphorus-based glasses were mentioned in the past evaluation reports (Gensch et al. 2006; Gensch et al. 2016). Lumentum and Coherent were asked to comment on the development of such alternatives. Lumentum (2021b) explains that the melting temperature of phosphate glasses exceeds 500°C, and their thermal expansion coefficient is above $8.0*10^{-6}$/K based on the two research papers as referenced by Lumentum. Therefore, phosphate glass is not a viable alternative for Lumentum's argon lasers. Coherent (2021b) states that this alternative was not sustainable without providing any concrete reasons. However, Coherent is developing another solution (s. below).

Alternative sealing mechanism using malleable metals

Coherent (2021a) states that they have begun qualifying an alternative sealing mechanism using malleable metals in lieu of a fritted material. Coherent (2021b) further explains that the replacement would be a metal seal between the two crystalline media, which will not require extensive qualification for new material in the internal assembly, since plasma is VERY sensitive to material changes. However, impacts resulting from the COVID pandemic affect the availability of the metal as well as testing the new technology due to manufacturing constraints and local/federal limitations. Coherent thus needs further time for testing.

Solid state lasers (SSL)

Solid state lasers (SSL) were described in the last evaluation report in 2016 (Gensch et al. 2016). It was documented that solid-state sources may not be available for specific wavelengths or groups of wavelengths combined with narrow linewidth or are otherwise unreliable. Substituting solid-state sources for these applications would require several SSL in place of a single gas laser. To perform the same analyses with SSL would thus significantly increase the use of natural resources and the environmental impact of the equipment manufacturing. Lumentum and Coherent were asked to provide more details as to any new development or progresses in SSL technology that have been made since the last evaluation.

Lumentum Operations LLC; Lumentum (2021) states that no industry progress has been made to satisfactorily replace argon ion laser technology in active gas laser applications, installed in existing instrumentation models, since the last evaluation. SSL are usually well suited for instrumentation designed specifically to accommodate their characteristic electrical and optical performance. For some current applications, SSL do not provide the required optical characteristics necessary to achieve required results, including wavelengths, linewidth, coherence, power, beam characteristics etc. Trying to build an equivalent SSL to replace argon and/or krypton lasers would be extremely resource-intensive, costly, and inefficient (10x), which is why the market has not yet succeeded and argon ion lasers have not yet been replaced. Lumentum argues that it is impractical and inefficient to update instrumentation previously designed to operate with gas lasers with modern SSL. Lumentum (2021b) later stresses that this is technically not feasible. There are still low-power argon ion lasers in applications where SSL do not yet offer necessary performance on spectral or beam characteristics, comparable size and mounting.

Coherent (2021a) describes that SSL have made great progress in the last five years, however, there are several other factors that prevent the immediate transfer to solid state from ion. Coherent raises similar arguments to those raised by Lumentum. Coherent also specifies that the unique properties of argon and krypton lasers combined with the fact that many applications are "copy-exactly[51]" results in a very

[51] The "copy-exactly" practice is common in the semiconductor sector. In this approach, once a fabrication facility has been designed in detail and successfully implemented in one location, the same design is replicated in other locations (sometimes making small modifications to adapt to local zoning and building rules). The design includes not just the facility buildings but the detailed plan of all manufacturing installations and emissions control measures. In this context, it is assumed that, as the lasers are applied in some cases in such designs in specific equipment, replacing of the specific laser is

slow transition. This is due to each application wavelength needing to be specifically qualified by the customer and then to be adopted by the end user. Lastly, some of the critical to manufacture lasers do not have an equivalent SSL that can replace the ion laser yet. Coherent estimates that it will take at least another 10 years until ion lasers will become available.

Coherent (2021b) states that the transition to solid state lasers is slowed due to many reasons (pandemic, resistance to change in semiconductor industry, failed R&D projects). This should be seen as temporary, with a 10% decline in demand forecasted year over year for the next 5 years. Coherent (2021b) expects some penetration of solid state lasers to supplant ion lasers over the next 2 years, with a stronger ramp to occur after 2025.

Other laser technologies

Lumentum and Coherent were asked to comment on other laser technologies that the consultant found through a review of publicly available information[52], and that seem to have comparable application areas to those of argon or krypton lasers. The examples are listed as below:

- DPSS laser series: Diode-pumped solid-state laser (Fields of Application: Microscopy; Holography; Raman Spectroscopy; Flow Cytometry)
- LDM-XT laser series: Next generation laser diode modules (Fields of Application: Microscopy; DNA Sequencing; Digital Imaging; Flow Cytometry)
- He-Ne laser series: (Fields of Application: Microscopy; Holography; FTIR Spectroscopy; Raman Spectroscopy; Digital Imaging; Gas Sensing; Fabry Perot Interferometry)
- Others, such as diode lasers, fiber lasers, CO_2 lasers.

Lumentum (2021a) expressed that, as regards DPSS and LDM-XT lasers, they are suitable for some spectroscopy applications, but not all, given that they do not produce the wavelengths, linewidths, coherence, laser power and other optical characteristics required by some spectroscopy applications. It would also not be efficient to redesign the instrumentation around these lasers. Coherent (2021a) describes that DPSS lasers are likely to have the best near-term chance of replacing some of the ion laser applications, as this is the type of laser which is supplanting the low-power UV ion laser. However, 85% of the ion laser installed base do not have a suitable replacement planned for the next 3 years (although qualification road maps exist), and ion lasers will continue to see critical service requirements for a minimum of 10 years. As for LDM-XT laser series, Coherent (2021b) estimates that the beam TEM00[53] power level could only provide 1/16th of the lowest power argon or krypton ion application. Coherent states that there may be a future for this technology, but

more complex, as it needs to be ensured whether the replacement would require further adjustments in the fabrication system.

52 https://www.lasos.com/products/lasos-he-ne-laser-series, last accessed on 24.06.2021

53 TEM00 is a measurement of the beam quality, more specifically the mode. A beam is considered TEM00 when a spectral scan of the beam yields most (90+%) of the beam power being centered in the beam. A beam can also be TEM01 or TEM10, which would indicate a hole in the centre of the beam and most of the power being in the “ring” of the beam. This is not desirable for most applications with ion lasers (Coherent (2021b).

that the latter cannot replace ion technologies with the current laser output specifications.

As for He-Ne lasers, Coherent (2021a) states that He-Ne lasers are typically used more for alignment and actually represent a vacuum tube technology akin to ion lasers (the gain medium being He). Both Coherent (2021a) and Lumentum (2021a) indicate that He-Ne lasers are not suitable as a replacement for argon/krypton ion laser applications, since He-Ne lasers cannot produce the wavelength spectra, higher power and performance necessary for applications.
Lumentum (2021a) concludes that these lasers are different technologies with different characteristics that cannot replace argon ion lasers in the current applications and instrumentation.

9.3.2. Environmental arguments

Environmental arguments were not raised by the applicant as the main justification for this exemption, though the applicants refer among others to the options for replacing argon and/or krypton lasers with SSL as being "extremely resource-intensive, costly, and inefficient (10x)". Lumentum states that the environmental and health impacts are negligible due to the small amount of PbO used. As for the reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste, Lumentum states that Lumentum's customers in the EU have a legal obligation under the WEEE Directive to provide appropriate treatment to the EEE waste, however, Lumentum as a component manufacturer does not have a visibility of these processes (Lumentum Operations LLC 2020).

Coherent (2021b) states additionally that nearly all laser tubes entering the EU will be returned to the US for replacement. This is due to the nature of the business, as the plasma tube is a consumable and is shipped back to Coherent for repair or replacement. However, this only equates to a small quantity or even none at all of the lead oxide physically being disposed of in the EU.

9.3.3. Socioeconomic impacts

Socioeconomic arguments were not raised as the main justification for this exemption ad in this sense, detailed socio-economic data was not specified in the application of the exemption and in other documents.

9.3.4. Road map to substitution

In the last four years Lumentum continued test build trials with different lead-free glass frit materials, but none of the lead-free alternatives produced satisfactory results (Lumentum Operations LLC 2020). Lumentum (2021b) periodically reviews the lead-free frit material availability with a melting temperature below 500°C, and a thermal expansion from 7.0 to $8.0*10^{-6}$/K on the market. The next review cycle is scheduled for the second quarter of 2022. Lumentum (2021b) describes the extensive qualification steps which must be conducted once a potential alternative material is identified. The internal qualification process may take 24 months. The qualification process by the customers may take an additional 6 months. Coherent (2021b) argues that the development of Ar/Kr ion replacements is ongoing, with this development occurring outside the sphere of influence of Coherent. It many cases it is not directly dictated by its customers (manufacturer of OEM tools) either, but by end user acceptance of a drastic change in the light source. This dramatically slows down development, since life tests typically require at least half of the expected lifetime, which for these types of lasers is more than 2 years. After 2 years of life testing, customers (tool manufacturers) will require 2 further years of testing the laser alternatives within the tools before they can be deployed in the field. The cascading of these qualifications leads to delays in end user acceptance and ultimately a life expectancy of ion lasers potentially beyond the decade mark (dependent on success rate).

Coherent (2021b) is researching the alternative sealing mechanism using malleable metals. Coherent expects to completely substitute the leaded frit for a mechanical seal (metal) by 2025. Coherent further specifies that the 4 years will allow for Coherent to fully qualify the process and perform several life tests on the new assembly and allow their customers to adopt the new assembly as well.

9.4. Stakeholder contributions

No contributions were submitted to the stakeholder consultation regarding this exemption.

9.5. Critical review

9.5.1. REACH compliance – Relation to the REACH Regulation

See section 4.1 for details.

9.5.2. Scientific and technical practicability of substitution

The information submitted to the consultant suggests that lead cannot be substituted in the seal frit used for making window assemblies for argon and krypton laser tubes.

Bismuth-based or other glass frit materials do not provide the melting temperature required nor reliable thermal expansion behaviour comparable to that of lead oxide glass, which ensures a stress-free sealing without potential damage to the components, primarily the optics.

Concerning solid state lasers, Lumentum and Coherent argue that SSL do not provide the required optical characteristics necessary to achieve required results, including wavelengths, linewidth, coherence, power, beam characteristics etc. Hence, the immediate transfer to solid state form ion is still not possible. For some time now, solid state lasers have been replacing a very small amount of ion lasers for very low-power UV applications (less than 0.2 W). Alternative UV and deep UV lasers which produce up to 40 W and can maintain the beam profile either do not exist or have not been verified as a suitable replacement as of yet (Coherent 2021a).

Other laser technologies such as DPSS (Diode-pumped solid-state) lasers and LDM-XT (next generation laser diode modules) lasers series could replace some argon/krypton laser applications, but not all. Available information did not permit a clarification if certain parts of the application range could be specified for such alternatives.

One promising substitute would be alternative sealing mechanisms using malleable metals described by Coherent. Coherent confirmed that the use of malleable metals will be investigated in the coming years to allow the substitution of PbO-based frit materials. Coherent believes that the malleable metal substitution will be fully qualified by 2025 and expects to completely substitute the leaded frit for a mechanical seal (metal) by 2025 (Coherent 2021b). As to the question whether this potential substitute could also be used for krypton lasers, if the reliability and practicality is ensured in the argon lasers, or vice versa, Coherent (2021b) confirms that both of these lasers use the exact same bill of materials with the only difference being the gas within the laser. Hence, the substitute would potentially be relevant for both gas type lasers.

9.5.3. Environmental arguments and socioeconomic impacts

Though some environmental aspects were raised in relation to argon and krypton lasers, these are not considered pertinent to the justification of the exemption and are not discussed further.

It was mentioned that an equivalent solid-state laser would be extremely resource-intensive, costly and inefficient. The applicant also states that not all lasers will move to solid state over the next 10 years due to the high change over cost and low return on investment (Coherent 2021b). This was not substantiated with further data and is thus not considered further, seeing that the main justification for the exemption is not based on socio-economic aspects.

9.5.4. Scope of the Exemption

The current wording of Ex. 32 is "*Lead oxide in seal frit used for making window assemblies for Argon **and** Krypton laser tubes*". The available information suggests that laser tubes benefiting from this exemption use either argon or krypton but not both. Lumenten and Coherent were thus asked to comment on whether a reformulation with an "OR" or "AND/OR" instead of the current "AND" would not ensure coherence of the wording.

Lumentum's gas laser tubes contain only one gas, which is Argon. As described previously, Lumentum manufactures low-power argon ion lasers and does not manufacture krypton laser tubes. Hence, the formulation with "AND/OR" is not relevant for Lumentum products, for which the "OR" relation is sufficient. Lumentum (2021b) further points out that a mixing of gases adds unnecessary lasing wavelengths and reduces argon ion lasing efficiency, which cannot be used by Lumentum's customers.

Coherent (2021b; 2021a) recommends using AND/OR, since the gases can be mixed and used in a single laser. Coherent explains that the mixed gas laser (or Purelight/ Sabre Light) is still in production and used in research industries, even though in very small quantities. The mixture of the two gases can produce more than 18 usable wavelengths. These wavelengths can then be separated through the use of external prisms or optics which only transmit a small bandwidth. This allows a customer to purchase one laser instead of purchasing 18 lasers, which would otherwise have been necessary. There are multiple customers in the EU (mostly universities in France) that still utilize this type of laser, though the last order to the EU of such a laser was shipped in 2019 (Coherent 2021b).

Since applications of the mixture of the two gases exist in practice according to Coherent, the term "AND/OR" is recommended to characterize the different gain mediums.

Furthermore, in consultants' view, adding the term "as a sealing material" in the current formulation would bring more clarity with regard to differentiating Ex. 32 from other exemptions with respect to the differing functions of lead. Lumentum (2021b) agrees with the proposed new wording "as a sealing material".

In addition to considerations on the wording, the potential overlaps with the following exemptions were examined:

- Regarding Ex. 7(c)-I of Annex III: "*Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezo-electronic devices, or in a glass or ceramic matrix compound*"

  The consultant agrees that Ex. 32 deals with lead in a glass material that could be considered to fall under the scope of the current Ex. 7(c)-I. However, the consultant considers that the formulation of the current scope of Exp. 32 refers to a specific component and material, and in doing so facilitates a clear understanding of the scope of the Ex. for industry as well as for market surveillance. This direction was also considered in the recent evaluation of Ex. 7(c)-I in an attempt to specify the exemption wording. Though measures should be taken to ensure that there is no overlap (exclusion of Ex. 32 for the scope of Ex. 7(c)-I), merging Ex. 32 into that exemption is considered counterproductive and is not recommended.

- Regarding Ex. 25 of Annex III: "*Lead oxide in surface conduction electron emitter displays (SED) used in structural elements, notably in the seal frit and frit ring*"

  The consultant understands the exemption to cover components in display applications as opposed to the laser applications of Ex. 32 and thus concludes that there is no overlap.

- Regarding Ex. 4 of Annex IV: "*Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons*."

  Lumentum Operations LLC (2021; Lumentum 2021a) and Coherent (2021a) both consider that the partial formulation of "*Lead in glass frit binder for assembly of gas lasers"* under Ex. 4 of Annex IV seems to be suitable to cover their application. The latter exemption is however limited to Cat. 8 and Cat. 9 EEE, as it is listed in Annex IV which is dedicated to exemptions for these categories. Hence, it should be considered to exclude articles covered under Ex. 32 from Ex. 4 of Annex IV in the future so as to eliminate possible overlaps.

Finally, Lumentum and Coherent both specified that the exemption was only needed for categories 6, 8 and 9. Other stakeholders did not provide information to suggest that it may be needed for other categories. It is thus suggested to limit the scope to these three categories.

9.5.5. 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 no substitute has been found to be scientifically or technically practicable. SSL can replace a very small amount of ion lasers for very low power UV applications. The replacement has already begun according to Coherent (2021a). As for the alternative sealing mechanism using malleable metals, Coherent expects to completely substitute the leaded frit with mechanical metal seal by 2025 (Coherent 2021b).

Against this information, the exemption is concluded to be justified based on fulfilment of the first criteria, i.e. the elimination or substitution of lead in argon and/or krypton lasers "via design changes or materials and components which do not require any of the materials or substances listed in Annex II" is considered to be scientifically or technically impracticable.

Furthermore, Lumentum and Coherent plausibly explain that for technical and economic reasons, argon and krypton lasers are only used where their unique properties are required. Though it could not be confirmed that this is the case for every individual application, the very low market volume of Pb placed on the market through this application suggests that such articles are not in extensive use. The past declines in Pb amounts and the various statements also suggest that such applications were in decline in the past and may continue to decline in the future, possibly as alternatives become available for specific application areas. Though an effort could be made to determine an exact range of applications to which the exemption could be limited, the low amounts of lead and the general decline suggest that the exemption is not misused. As a candidate had been identified which may allow substitution in 2025 already, and in light of the limited time for the assessment, such a specification was not further pursued.

As explained in earlier sections, there is concern as to possible overlaps of Ex. 32 with other exemptions, and it is thus deemed necessary to ensure that Ex. 32 applications are excluded from the scope of other exemptions.

9.6. Recommendation

The information submitted by the stakeholders can be followed, showing that the substitution of lead in exemption 32 applications is technically impracticable.

In the consultants' opinion, the first criteria specified in RoHS Art. 5(1)(a) is fulfilled and a renewal of the exemption would be justified. It is recommended to renew the exemption for another five years, limiting it to the categories specified by Lumentum and Coherent and making slight modifications to the wording as specified below.

It is recommended to grant an exemption with the following formulation and duration. Though some small differences have been introduced in the recommended formulation, these are understood to ensure clarity and comprehension and not to limit the applications that will benefit from the exemption. In this sense, the consultants do not see a need to introduce a new item but just to amend the current formulation as the new formulation is not expected to limit the scope of the exemption. Regarding Cat. 11 applications, the applicant has not mentioned Cat. 11 as an EEE category where krypton and/or argon lasers are applied. Nonetheless, the current exemption is still valid for this category until 21 July 2024. To ensure that the amendment of the exemption does not result in an accidental revoke of the exemption for possible applications in this category, the exemption is thus also recommended for Cat. 11 for a limited duration. Should this category make actual use of the exemption, stakeholders would still have sufficient time to request an exemption renewal beyond July 2024, provided they can show that the exemption is justified in such applications.

Exemption formulation	Duration
Lead oxide in glass frit used as a sealing material for making window assemblies for argon and/or krypton laser tubes	21 July 2024 for category 11 21 July 2026 for categories 6, 8 and 9

It is also recommended to exclude applications covered by the above exemption from the scope of Ex. 7(c)-I of Annex III and from Ex. 4 of Annex IV.

The following aspects are summarised and recommended to be followed up on in support of the future review of this exemption:

- The status of development of a mechanical seal (metal) alternative as proposed by Coherent,
- Examine whether other laser technologies, such as DPSS (Diode-pumped solid-state) lasers and LDM-XT (next generation laser diode modules) lasers series, could replace some argon/krypton laser applications, when not all,
- Observing the market development concerning penetration of SSL to supplant ion lasers.

9.7. References

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Coherent (2021b): 2nd Clarification Questionnaire Exemption Ex. No. 32, 14 Sep 2021.

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10. Exemption 34: “Lead in cermet-based trimmer potentiometer elements”

Declaration

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

Acronyms and definitions

Cermet	Heat resistant material made of ceramic and sintered metal (an acronym of CERamic and METal); here the electrically resistive layer and the ceramic body onto which it is sintered
EEE	Electrical and Electronic Equipment
GE	General Electric
Pb	Lead
PbO	Lead-oxide
PWB	Printed wiring board (Printed circuit board)
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
UP	RoHS Umbrella Industry Project

10.1. Background of the exemption request

General Electric (GE), on behalf of the participants in the RoHS Umbrella Industry Project, applies for the renewal of Ex. 34 of Annex III of the RoHS Directive:

> *“Lead in cermet-based trimmer potentiometer elements”*

UP submitted two renewal requests (RoHS Umbrella Industry Project 2020b; 2020a), one applying for the exemption renewal for categories 1-10 and a second exemption request for category 11. UP applies for the renewal of exemption 34 for the maximum duration applicable for each category (5-7 years).

10.2. Technical description of the requested exemption

10.2.1. Technical background

The applicant explained that lead is used in glass-based resistive inks to fabricate a resistive layer – the cermet - that exhibits a specific set of electrical, thermal, and mechanical characteristics, which are required to form a functional element in trimmer potentiometers. Potentiometers are electronic components whose resistance can be repeatedly changed by the user during the use of EEE by a mechanical movement (e.g. by turning a rotary wiper contact). Trimmer potentiometers allow a suitable voltage point to be set within an electronic circuit before it is used or in the event of maintenance. These components contain a resistive track made of an electrically conductive material layer (the cermet) and a sliding contact that is moved across the cermet surface to vary the component's electrical resistance at the output terminal. (RoHS Umbrella Industry Project 2020)

(COCIR 2021b) offers the following definition for the categorisation of variable resistors:

- Trimmer: a variable resistance used to tune voltage in electronic device to get a good working function.
- Panel potentiometer: a variable resistor used as a machine interface. The variation of resistance due to shaft rotation generates a variation of voltage which is used as a reference by the electronic control system.

Figure 10-1: Examples of cermet based trimmer potentiometers

Source: (RoHS Umbrella Industry Project 2020)

From the applicant's explanations as well as information provided to the consultant during previous exemption evaluations (Oeko-Institut e.V. 2007), it can be inferred that the cermet layer is produced by partially coating a ceramic body with a paste-like ink consisting of a suspension of glass, containing 40-50% by weight lead oxide (PbO) in the homogeneous material of the cermet layer. Other constituents of the cermet are silver, ruthenium-oxide and boron trioxide, according to the information established during the 2016 exemption evaluation (Oeko-Institut 2016).

The printed thick film is then heated to sinter the ink into a solid cermet layer. The consultant notes the applicant`s point of view that the cermet is neither to be considered ceramic (because it does not consist of a crystalline substructure) nor does it meet the definition of glass (amorphous material). The cermet consists of a composite material containing ceramic particles dispersed in a glass matrix. Hence, the cermet-based potentiometers have not been considered to fall within Ex. 7(c)-I.

10.2.2. History of the exemption

Ex. 34 was first requested in 2006 and then reviewed in 2007 for a first and 2016 for a second time. The scope of the Ex. 34 has not changed since 2006 when it was formulated to complement Ex. 5 and Ex. 7, which (at that time) covered the use of lead in glasses and ceramic parts. These previous exemptions 5 and 7 have meanwhile been merged into Ex. 7(c)-I, which now covers certain glasses and ceramics that contain lead.

10.2.3. Scope of the exemption 34

The current formulation of the exemption covers "cermet-based trimmer potentiometer elements". These electrical components are a subset of a larger group of variable resistors called potentiometers. The term "trimmer" refers to a special type of variable resistors, usually mounted on a printed wiring board (PWB) as a part of electronic circuits. Trimmers act as voltage dividers and allow the voltage level within a circuit to be adjusted so that other electronic components (such as operational amplifiers) operate within their intended range (Bourns Trimpot undated).

Trimmers are used in a wide range of products covering the eleven EEE categories of RoHS. The current scope of Ex- 34 distinguishes the EEE categories according to their expiry dates:

- Categories 1-7 and 10: 21 July 2021
- Categories 8 and 9 (except for in-vitro diagnostic medical devices and industrial monitoring & control instruments): 21 July 2021
- Category 8 in-vitro diagnostic medical devices: 21 July 2023
- Category 9 industrial monitoring & control instruments; Category 11: 21 July 2024

At the Commission's request, the current assessment addresses all eleven EEE categories, including those with a later expiry date.

10.2.4. Amount of lead used under the exemption

The RoHS Umbrella Industry Project (2020) explains that the content of lead-oxide (PbO) in the homogenous material (glass) is 40-50%. Regarding the amount of Pb placed on the market in the EU as a constituent of EEE, the Umbrella Project states that it is not possible to give an exact figure for the amount of lead contained in glass and ceramic components for EEE in the EU (ibid). According to (Umbrella Project 2021), the component manufacturer Vishay uses less than 10 kg of Pb metal per year in potentiometers and trimmers of the "*Sfernice*" product line in the form of lead monoxide as a constituent of glass frit-based inks. UP also indicates that the components addressed by Ex. 34 are used in a wide range of final EEE products and markets, including all EEE categories 1 to 11.

The present renewal requests for Ex. 34 do not provide a concrete quantity nor any estimation of quantity range for lead that is placed on the EU market in form of trimmers. To fill this data gap, applicant and stakeholders were requested to provide verifiable data on the quantities of Pb placed on the EU market under Ex. 34. However, from the responses received,[54] it is not possible to derive even a rough estimate of the amounts of Pb used in trimmers. In the last assessment of Ex. 34 in 2016, the total amount of lead placed on the world market was estimated at about 1,500 kg of lead per year (Oeko-Institut 2016). No further information was provided to demonstrate whether progress has been made on lead substitution since the last review in 2016. From the applicant`s explanation that "no suitable substance for substituting lead has been identified" it can be concluded that the quantities of lead placed on the market in the form of trimmers have not been reduced.

Another reason for the difficulty in quantifying the amount of Pb used in cermet-based trimmers under Ex. 34 is the ambiguous definition of the scope. As discussed above, trimmer potentiometers represent a subset of a broader range of variable resistors, and some manufacturers appear to classify their products as Ex 7(c)-I rather than Ex 34. Bourns Inc. for example, stated that Ex. 34 was not used by that company and that "*many parts not classified as trimming potentiometers [...] use lead in glass portion of the thick film cermet ink [...] but not all are considered potentiometers* (Bourns Inc, 2021).

[54] When asked by the consultant about the estimated total amount of Pb placed on the EU market each year due to Ex 34, the UP responded with an individual example (see above mentioned Sfernice Potentiometers) that does not allow extrapolation to the total amount (Umbrella Project 2021). Upon repeated request, COCIR (2021a) states that "*it is not possible for the companies in the Umbrella Program (UP) to provide an estimation of the quantity imported or placed on the EU market*", because "*manufacturers of finished EEE have no information on the number of potentiometers incorporated on the parts they buy, sometimes not even if they are used.*"

10.3. Applicant's justification for the requested exemption

The applicant refers to the justification that was also brought forward by the Umbrella Project in its renewal request for the exemption 7(c)-I for "Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectric devices, or in a glass or ceramic matrix compound". (Umbrella Project 2020). There, the UP argues that that substitution of lead in glass and ceramics used in a variety of EEE components (except trimmer potentiometers) is not currently feasible because no substitute materials have yet been developed that meet all performance requirements of lead-containing materials.

For trimmer potentiometers, the RoHS Umbrella Industry Project (2020) asserts that cermet trimmer potentiometer elements additionally require high mechanical abrasion resistance and constant electrical contact resistance. These critical performance requirements of resistive cermet thick films can only be met by the addition of lead.

The list below specifies the functional characteristics of lead-based cermet trimmers for which the exemption 34 is needed, according to (RoHS Umbrella Industry Project 2020):

- Long lifetime, typically up to 50,000 rotation cycles;
- Low temperature coefficient (TC) - 50 ppm/°C which is lower than other types of potentiometer;
- High level of heat dissipation [not further specified];
- Wide operating temperature range, -55 °C to +125 °C;
- Higher wattage rating, e.g. 3 watts;
- Low reactance at high maximum frequency;
- Good resolution (resolution is the smallest possible change in resistance ratio);
- Low electrical noise when resistance is adjusted;
- Small size enabling use in high density microelectronic circuits.

When looking for possible replacement solutions for lead-containing cermet trimmers, the following aspects must also be considered (RoHS Umbrella Industry Project 2020):

- Can be of a very small size, unlike all other types (of potentiometers);
- are not sensitive to Electrostatic Discharge (ESD), unlike some other types (of potentiometers);
- do not need reverse polarity or surge protection, unlike other types (of potentiometers);
- can work at high temperature without Ohm-value drift.

The main parameters determining the quality of a potentiometer are as follows (Umbrella Project 2021):

- Total resistance drift percentage,
- wiper-track contact resistance variation percentage, and
- percentage of the maximum wiper-track contact resistance.

10.3.1. Substitution of lead in thick-film inks for cermet production

RoHS Umbrella Industry Project (2020) states that despite extensive research, no suitable material for substituting Pb has been identified. Identically to the previous exemption renewal request from 2015, the applicant mentions boron, phosphorus, zinc, tin, bismuth, etc. as potential principal lead-free alternatives for substituting Pb in cermet-based variable resistors (General Electric et al. 2015). However, these potential substitutes give inferior chemical stability and mechanical strength of the glasses compared with lead-containing glasses and do therefore not meet the required functionality. This inferior performance results in significantly shorter lifetimes.

According to RoHS Umbrella Industry Project (2020), the surface roughness of the cermet is the critical disadvantage of lead-free thick-films, which quickly degrades the sliding contact (wiper) or creates electrical noise, which is unacceptable for most applications. The applicant explains that preliminary tests with lead-free inks seem to show that the addition of a lubricant on the surface of the cermet shall be necessary in order to compensate for the disadvantages of lead-free thick-film materials. Even with using a lubricant, the applicant does not expect to achieve the same performance with all ohmic values.

RoHS Umbrella Industry Project (2020) explains that alternative types of potentiometer have different technical performance and are also larger, making them unsuitable in applications where cermet trimmer potentiometers are used. There are many types of potentiometers (variable resistors) on the market, but each type has a unique combination of performance criteria which determines when they are suitable. A comparison of these properties for various potentiometer types (conductive plastic, carbon and wire wound) provided by RoHS Umbrella Industry Project (2020) shows how the combination of performance of cermet's is different to all other types of potentiometer. So, one type of potentiometer cannot be substituted by another to achieve the same performance.

The cermet type provides a performance with no drift for hundreds of hours at 150°C. With Bakelite (carbon) inks for example, there are several %-points of drift for every 96 hours of testing at 125°C. Cermet is robust enough to withstand the force of the wiper. Particularly in miniature devices, accurate, repetitive determination of the force of the wiper is difficult. For cermet -based units, a wiper force from 10cN up to 150cN can be used. Bakelite pots are of a poorer quality than Cermet. The wear of the inks used on Bakelite is quicker than the Cermet ones. Cermet potentiometers can work up to 125°C, and can work up to 210°C under defined circumstances.

Additional alternative technologies to cermet trimmer/ potentiometers are mentioned, however without giving more detail (ibid):

- Conductive plastic inks;
- other technology (optic, magnetic, digital).

(COCIR 2021b) states that "more than 15 suppliers of resistive pastes have been contacted to find an alternative without lead. Some samples of the different potential solution have been evaluated unsuccessfully."

10.3.2. Environmental arguments

Environmental arguments were not raised as a justification for this exemption.

10.3.3. Socioeconomic impacts

RoHS Umbrella Industry Project (2020) states that deletion of this exemption would prevent the sale of thousands of types of electrical equipment into the EU. These types of equipment will include essential medical devices, test equipment, IT, telecoms, industrial controls etc., that are essential for health, environmental protection and manufacturing businesses in the EU.

10.3.4. Road map to substitution

The applicant states that no progress has been made in the development of lead-free substitutes for cermet-based trimmers. According to (COCIR 2021b), component manufacturers steadily survey and evaluate the cermet ink pastes offered by suppliers in order to identify new lead-free substitution pastes. Any lead-free cermet trimmer potentiometers provided by suppliers did not fulfil the required performance parameters.

The applicant states, that "there are currently no prospects of alternative technology. If an alternative were found, which is not currently foreseen, a possible time frame would be at least 3 years: one for evaluation, one for internal qualification, one for qualification at customers especially for specific applications. Additional validation time would be required in categories 8 & 9" (RoHS Umbrella Industry Project 2020). In the case of medical devices, the redesign with lead free components can take 10 years; for other categories, a period of 5 – 6 years is to be expected, as the applicant states.

10.4. Stakeholder contributions

There were no contributions received during the consultation period from 30 March 2021 to 08 June 2021.

The following information was provided by stakeholders after the deadline for submission of the consultation period:

- A Huawei representative (Andrae 2021) supports the exemption request based on the justification that available substitution materials exhibit an overall higher environmental impact than lead during the mineral extraction and refining life cycle phase.
- (Bourns Inc. 2021) states in a personal communication, that the company has not used Ex. 34 due to its specific scope on cermet-based trimming potentiometers. Bourns` product portfolio encompasses many parts that contain lead in the glass substrate of the thick film cermet ink but are not classified as trimming potentiometers. Examples are resistors such chip resistor/arrays, resistor networks, power resistors, some sensors etc. Bourns sees it as these components use lead in the glass portion of the inks, so they fall within 7(c)-I.
- A communication was received from (Siemens Healthcare GmbH 2021), supporting the renewal request for Ex. 34 for Category 8 in-vitro diagnostic applications. The contribution explains that Ex. 34 is needed for some in-vitro (IVD) diagnostic devices.

10.5. Critical review

10.5.1. REACH compliance – Relation to the REACH Regulation

See section 4.1 for details.

10.5.2. Scientific and technical practicability of substitution

The applicants assert that the possible substitution materials (e.g. boron, phosphorus, zinc, tin, bismuth, etc., conductive plastics (e.g. Bakelite), carbon layer and wire wound potentiometers) that have been explored so far have not been proven to fulfil all of the performance requirements (see section 10.3). The Umbrella Project (2020) points out that "manufacturers have been looking for new potential alternative inks, however, none have become available that give satisfactory performance." Information from the Umbrella Project (2020) and stakeholder input indicates that no progress has been made on lead substitution in trimmer potentiometers since the last evaluation of Ex. 34 in 2016, and even since the first evaluation in 2007. Although earlier scientific research and developments on lead-free thick-film resistors have been reported in the literature, such as (Maeder et al. 2009), these efforts do not seem to have been pursued in recent years. The current renewal request (RoHS Umbrella Industry Project 2020) basically repeats the rationale of the 2015 renewal request (Umbrella Project 2015) and provides little new evidence for proactive substitution research. Regarding the efforts to evaluate substitute materials, the applicant states that several different lead-free cermet inks were procured from different manufacturers and their performance was measured through qualification tests. Also stakeholders declare that they regularly monitor the EEE components market for newly appearing offers of lead-free trimmers. (COCIR 2021a) assures that "some samples of the different potential solution have been evaluated unsuccessfully." Although surveys and assessments are constantly being carried out to identify new substitute pastes, suppliers have not offered alternative technologies without lead. COCIR also says that "unless a valid alternative is identified, there is no other viable solution" to the continued use of lead-containing cermet trimmers (ibid). From all stakeholder information received, the consultant concludes that the EEE industry is currently not carrying out own research and development work. Instead of proactively initiating research projects, the industry surveys developments in the supply chain and tests cermet precursors available on the market. Thus, as long as suppliers do not bring viable lead-free solutions for resistive ink to the market, manufacturers see no alternative to the continued use of lead-containing material. (ibid)

However, the consultant cannot follow the justifications regarding some of the technical requirements of trimmer potentiometers, put forward by the applicants and stakeholders. The consultant assumes that the technical requirements for trimmer potentiometers described in section 10.3, are necessary for rather exceptional applications of trimmers, whereas most EEE does not require such demanding characteristics.

The **technical specification** of lead-containing cermet-based trimmers (see section 10.2), and in particular the wide operating temperature range (-55 °C to +125 °C) as well as higher wattage rating, allows the use of leaded trimmers for EEE applications that **operate at high temperatures or have strong heat generation due to their**

wattage. However, for most trimmer applications, it is unlikely that high wattage and high temperature stability would be required. Since the applicant has not provided any insight into the actual development of lead-free trimmers, the consultant assumes that lead-containing trimmers might also be used in cases where their special performance parameters are not actually needed, for example on circuit boards whose trimmer potentiometers are set only once and which are not exposed to high temperatures. The consultant understands that a specification of the use conditions or for the type of equipment could be a way forward to narrow down the scope of the exemption in the future.

According to the (RoHS Umbrella Industry Project 2020), trimmer potentiometers falling within the scope of Ex. 34 must have a long service life, measured in the **number of mechanical rotation cycles.** The typical service life is given as up to 50 000 revolutions (see section 10.3). It is argued that the repeated movement of the sliding contact requires a high scratch resistance of the cermet surface. The applicant asserts, that "at present, no alternative solutions have similar (or acceptable) results compared to the leaded inks; especially in life tests. The critical point is the surface roughness of the ink after firing, which quickly degrades the sliding contact (wiper) or creates unacceptable electrical noise." Moreover, "all tests performed with lead-free inks utilising various wiper technologies across a range of contact forces did not offer the same product performance as with lead bearing inks" (ibid). In summary, the applicant argues that the use of lead-based cermet materials is indispensable, as only this material guarantees permanent abrasion resistance of the cermet surface and the sliding contact over 50 000 rotation cycles.

In the consultant's understanding, trimmer potentiometers falling within the scope of the of Ex. 34 are very unlikely to be rotated up to 50 000 times during the service life of EEE. As explained above, trimmer potentiometers are designed to be normally operated only a few times during EEE manufacturing and maintenance (apart from a limited number of exceptions). The high number of up to 50 000 rotation cycles would rather be expected to apply for panel potentiometers, which are outside the current scope of Ex. 34. The applicant did not provide information to explain why trimmers should be designed for such a high number of rotation cycles. From the consultant's point of view, this provides another option to narrow down the scope of the exemption to certain use conditions or certain type of equipment that needs a high scratch resistance.

The above considerations lead to the assumption that the current wording of Ex. 34 entices the use of Pb-containing cermet-based trimmer potentiometers in applications for which these components are not necessarily designed for. The consultant concludes that the scope of the current exemption is too wide and that there is potential to narrow down the scope. In this review process, neither the applicants, and specifically the UP, nor any other stakeholders provided information that would allow concluding on a specification of use conditions or of type of equipment.

The consultant expects industry to provide an overview in the future in order to justify the broad scope or where this is not possible to provide sufficient data for considering how the scope could be redefined according to use conditions or of type of equipment.

Otherwise, it is not considered justifiable to keep the exemption's wording in the next evaluation.

10.5.3. Environmental arguments

The replacement of lead in EE components under this exemption could lead to an increase in the consumption of other materials such as boron, phosphorus, zinc, tin and bismuth. This could increase the demand for critical raw materials[55] such as bismuth, which might have higher overall environmental impacts than lead during the mineral extraction and refinement. E.g. a Huawei representative (Andrae 2021) supports the exemption request based on the justification that available substitution materials exhibit an overall higher environmental impact than lead during the life cycle phases mineral extraction and refining. This work compares four indicators as proxies of environmental impact (e.g. abundance in earth's crust and in the Oceans) but only in regard to impact during raw-material acquisition, which represents only a subset of the whole life cycle of these materials in the context of their application in EEE. The economic criticality of raw materials is however not of relevance for the current assessment since this aspect is not addressed by the RoHS Directive.

10.5.4. Examination of the interrelation with other exemptions and the scope of the exemption

There are interrelations identified with Ex. 7(c)-I, as this exemption explicitly excludes cermet materials from its scope. Cermet materials can be understood to be a kind of glass or ceramic matrix compound. Ex. 34 was granted to accommodate applications of lead in cermet materials. Cermet materials are considered as a composite material consisting of oxide particles embedded in a matrix of PbO-containing glass, to form a reticular structure. Cermet materials are thus excluded from the scope of Ex. 7(c)-I. The current formulation of Exemptions 7(c)-I is: *„Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound".*

In the recent report on the study to assess among other exemptions also Ex. 7(c)-I (Oeko-Institut 2021), an adaptation was proposed so that in the future Ex. 34 can be taken up thereunder:

[55] Critical Raw Materials listed in the catalogue of EU (COM (2017) 490 final) have been identified as critical for the EU due to a risk of supply shortage (scarcity) and their high importance for the economy.

Figure 10-2: Recommendation given in Pack22 on Ex. 7(c)-I relevant parts highlighted in yellow

Ex. No	Exemption formulation	Duration
7(c)-I	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound	Expires on 21 July 2024 for all categories
7(c)-V	Electrical and electronic components containing lead in a glass or glass matrix compound that fulfils the following functions: 1) protection and electrical insulation in glass beads of high voltage diodes and glass layers for wafer on the basis of a lead-zinc-borate or a lead-silica-borate glass body,* 2) for hermetic sealings between ceramic, metal and/or glass parts 3) for bonding purposes in a process parameter window for < 500°C combined with a viscosity of $10^{13,3}$ dPas (so called "glass-transition temperature") 4) used as resistance materials such as ink, with a resistivity range from 1 Ohms/square to 1 Mega Ohms/square, excluding trimmer potentiometers** 5) used in chemically modified glass surfaces for Microchannel Plates (MCPs), Channel Electron Multipliers (CEMs) and Resistive Glass Products (RGPs).	Expires on 21 July 2026 for all categories
7(c)-VI	Electrical and electronic components containing lead in a ceramic that fulfils the following functions (excluding items covered under item 7(c)-II, 7(c)-III and 7(c)-IV of this annex): 1) piezoelectric lead zirconium titanate (PZT) ceramics 2) providing ceramics with a positive temperature coefficient (PTC)	Expires on 21 July 2026 for all categories

**Item 7(c)-V should be merged in the future with remaining applications covered by Ex. 37 should a renewal be requested of this exemption or of Ex. 7(a) for high voltage diodes with a zinc-borate glass body.*
*** The exclusion of trimmer potentiometers is under the assumption that Ex. 34 shall be renewed for a short period and covers these applications.*

Source: (Oeko-Institut 2021)

However, Ex. 34 is limited to the application of such cermet materials in a particular type of EEE-components: "cermet-based trimmer potentiometer elements". This includes all variants of components, which are used as adjustable resistors within the interior of electronic circuits. From the consultant`s understanding, the term trimmer refers to a subset of variable resistors that are broadly called potentiometers. In contrast to panel potentiometers (which are designed to be operated by the end-users of EEE as a user-machine interface), trimmers are usually not meant to be operated by the end-users of EEE. The physical design of trimmers is compact and they normally require a separate tool (e.g. a screwdriver) to be operated. Trimmers usually reside on printed wiring boards and serve the purpose of setting the required potential (voltage) working point within a circuit. Trimmers are usually designed for one-time operation in the course of the initial calibration of a product during manufacturing. They can also be operated several times in the event of maintenance / re-calibration of EEE). However, trimmers are normally not intended to be operated repeatedly during the use phase of EEE. For that purpose, panel potentiometers are used (e.g. as audio volume control dials).

However, the scope of Ex. 34 does not apply for cermet-based panel potentiometers since its current formulation specifies trimmer potentiometers. Likewise, the scope of Ex. 7(c)-I does not apply for cermet-based panel potentiometers since its scope is limited to glass or ceramic matrix compounds. However, the new wording proposal for 7(c)-I will solve this uncertainty.

10.5.5. 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.

Based on information provided by the applicant, stakeholders, and the publicly available literature, it appears that no suitable substitutes for lead-based cermet materials are available to date that meet all of the performance characteristics of lead-based thick-film materials for resistive cermets. This finding supports the first criterion: it is still scientifically or technically impractical to replace lead in cermet materials that are used in frequent operated variable resistors. However, as it is not likely that most trimmer potentiometers will be operated frequently enough to affect their reliability during their service life, the consultant concludes that the second criterion "reliability" applies only for a subset of trimmer potentiometers, notably those that are designed for frequent use. The exemption is only needed for lead-based resistive materials in cermet-based potentiometers, in particular for application purposes that involve frequent operation cycles. Thus, the consultant understands from the different information taken into account that lead-free substitutes for cermet-based trimmers could at least be used for some applications e.g. that are intended for infrequent operation and installation in low-power EEE. This possibility to narrow down the scope of the exemption should be followed up by e.g. supply chain surveys by the industry.

The third criterion, "*environmental, health and consumer safety impacts*" was not considered applicable since the applicant and stakeholders provided no relevant information in this respect.

To conclude, the exemption should be renewed only for a short period in order to point out to the industry that the information has to be updated and that active support in phasing out the exemption is expected. For this reason, it is recommended to renew the Ex. 34 for a short duration and not to immediately merge it in the revised formulation of 7(c)-I. A rapid merge is considered to bear the risk that the need to narrow down the scope of the current exemption or to specific uses or to specific type of equipment could get out of focus. Besides the proposed new item for 7(c)-I has a longer duration than proposed here for Ex. 34.

As for the categories, it was already noted that category 9 industrial monitoring and control instruments, and for category 11, Ex. 34 is anyway valid until 21 July 2024. The short duration for the renewal until 21 July 2024 allows to set one common expiry date. The earlier expiry date for category 8 in vitro diagnostic medical devices, where Ex. 34 expires 21 July 2023, is also recommended to be aligned with the other EEE categories. This common expiry date is recommended together with a request from industry to prepare technical information for a future review should the exemption renewal be necessary. This includes the provision of technical details as to the different applications addressed under this exemption and specify possibilities to narrow down the scope of the exemption.

10.6. Recommendation

It is recommended to grant the exemption for a period of 3 years and the expiry date should be set at 21 July 2024for all the EEE categories.

As explained above, an extension of Ex 34 until 21 July 2024 is recommended. This includes category 9 - industrial monitoring and control instruments – and category 11, which are valid until that date anyway. The short duration of the extension until 21 July 2024 makes it possible to set a common expiry date. For category 8 – in vitro diagnostic medical devices – the current expiry date is 21 July 2023. Here, an extension of one year until 21 July 2024 is recommended to align it with the other EEE categories.

It is recommended to grant the short extension of Ex 34 to a common expiry date and at the same time encourage the industry to compile input that would allow narrowing the scope of the exemption to specific use conditions or type of equipment.

It is recommended to renew the exemption 34 in Annex III with the current wording:

Exemption formulation	Duration
Lead in cermet-based trimmer potentiometer elements	21 July 2024 for all categories

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Umbrella Project (ed.) (2020): Umbrella Project. Exemption Request Form RoHS 7(c)-I "Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound", Revised version of application submitted 19 December 2019. In collaboration with Murata Electronics Europe B.V. and VISHAY BC components BEYSCHLAG GmbH. The RoHS Umbrella Project, 31 Jan 2020.

11. Appendix

11.1. Aspects relevant to the REACH Regulation

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

d) 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)
e) 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 A-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 A-1: Relevant entries from Annex XIV: List of substances subject to authorisation

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)	
4. Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	21 August 2013 (*)	21 February 2015 (**)	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/ 2004, Directive 2001/82/EC, and/or Directive 2001/83/EC
5. Benzyl butyl phthalate (BBP) EC No: 201-622-7 CAS No: 85-68-7	21 August 2013 (*)	21 February 2015 (**)	
6. Dibutyl phthalate (DBP) EC No: 201-557-4 CAS No: 84-74-2	21 August 2013 (*)	21 February 2015 (**)	
7. Diisobutyl phthalate (DiBP) EC No: 201-553-2 CAS No: 84-69-5	21 August 2013 (*)	21 February 2015 (**)	
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 (**)	-

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)	
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 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	21 Mar 2016 (*)	21 Sep 2017 (**)	-
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. Jul 2017 (*)	22 Jan 2019 (**)	
29. Strontium chromate EC No: 232-142-6 CAS CAS No: 7789-06-2	22 Jul 2017 (*)	22 Jan 2019 (**)	

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)	
30. Potassium hydroxyoctaoxodizincatedichromate EC No: 234-329-8 CAS No: 11103-86-9	22 Jul 2017 (*)	22 Jan 2019 (**)	
31. Pentazinc chromate octahydroxide EC No: 256-418-0 CAS No: 49663-84-5	22 Jul 2017 (*)	22 Jan 2019 (**)	

(*) 1 September 2019 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without that spare part, and for the use of the substance (on its own or in a mixture) for the repair of such articles where that substance on its own or in a mixture was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.

(**) 1 March 2021 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without those spare parts, and for the use of the substance (on its own or in a mixture) for the repair of such articles, where that substance was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.

For the substances currently restricted according to RoHS Annex II: cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls and polybrominated diphenyl ethers and their compounds, as well as bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DiBP), we have found that some relevant entries are listed in Annex XVII of the REACH Regulation. The conditions of restriction are presented in Table A-2 below.

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

Designation of the substance, group of substances, or 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 $2PbCO_3$-$Pb(OH)_2$ 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_xSO_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). 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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
23. Cadmium CAS No 7440-43-9 EC No 231-152-8 and its compounds	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 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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	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 or placed on the market in paints with codes [3208] [3209] in a concentration (expressed as Cd metal) equal to or greater than 0,01 % by weight. For paints with codes [3208] [3209] 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', — 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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	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 bookbinding [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) 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:

Designation of the substance, group of substances, or mixture	Conditions of restriction
	— 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.
28. Substances which are classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2, respectively.	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:

Designation of the substance, group of substances, or mixture	Conditions of restriction
29. Substances which are classified as germ cell mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 3 or Appendix 4, respectively. 30. Substances which are classified as reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or Appendix 6, respectively.	— 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.
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 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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	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.
51. The following phthalates (or other CAS and EC numbers covering the substance): Bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 EC No 204-211-0 Dibutyl phthalate (DBP) CAS No 84-74-2 EC No 201-557-4 Benzyl butyl phthalate (BBP) CAS No 85-68-7 EC No 201-622-7 Diisobutyl phthalate (DiBP) CAS No.: 84-69-5 EC No.: 201-553-2	1. Shall not be used as substances or in mixtures, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material, in toys and childcare articles. 2. Shall not be placed on the market in toys or childcare articles, individually or in any combination of the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material. In addition, DiBP shall not be placed on the market after 7 July 2020 in toys or childcare articles, individually or in any combination with the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material. 3. Shall not be placed on the market after 7 July 2020 in articles, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material in the article. 4. Paragraph 3 shall not apply to: (a) articles exclusively for industrial or agricultural use, or for use exclusively in the open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin; (b) aircraft, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft; (c) motor vehicles within the scope of Directive 2007/46/EC, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles;

Designation of the substance, group of substances, or mixture	Conditions of restriction
	(d) articles placed on the market before 7 July 2020; (e) measuring devices for laboratory use, or parts thereof; (f) materials and articles intended to come into contact with food within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EU) No 10/2011(*); (g) medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof; (h) electrical and electronic equipment within the scope of Directive 2011/65/EU; (i) the immediate packaging of medicinal products within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC; (j) toys and childcare articles covered by paragraphs 1 or 2. 5. For the purposes of paragraphs 1, 2, 3 and 4(a), (a) 'plasticised material' means any of the following homogeneous materials: — polyvinyl chloride (PVC), polyvinylidene chloride (PVDC),polyvinyl acetate (PVA), polyurethanes, — any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings, — surface coatings, non-slip coatings, finishes, decals, printed designs, — adhesives, sealants, paints and inks. (b) 'prolonged contact with human skin' means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day. (c) 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children. 6. For the purposes of paragraph 4(b), 'aircraft' means one of the following: (a) a civil aircraft produced in accordance with a type certificate issued under Regulation (EC) No 216/2008 or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation, signed on December 7, 1944, in Chicago; (b) a military aircraft. (*) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).'

Designation of the substance, group of substances, or mixture	Conditions of restriction
62. (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.
63. Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	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 (*);

Designation of the substance, group of substances, or mixture	Conditions of restriction
	(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, 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;

Designation of the substance, group of substances, or mixture	Conditions of restriction
	(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 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).
67. Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) CAS No 1163-19-5 EC No 214-604-9	1. Shall not be manufactured or placed on the market as a substance on its own after 2 March 2019. 2. Shall not be used in the production of, or placed on the market in: (a) another substance, as a constituent; (b) a mixture; (c) an article, or any part thereof, in a concentration equal to or greater than 0,1 % by weight, after 2 March 2019. 3. Paragraphs 1 and 2 shall not apply to a substance, constituent of another substance or mixture that is to be used, or is used: (a) in the production of an aircraft before 2 March 2027. (b) in the production of spare parts for either of the following: (i) an aircraft produced before 2 March 2027; (ii) motor vehicles within the scope of Directive 2007/46/EC, agricultural and forestry vehicles within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council (*) or machinery within the scope of Directive 2006/42/EC of the European Parliament and of the Council (**), produced before 2 March 2019 4. Subparagraph 2(c) shall not apply to any of the following:

Designation of the substance, group of substances, or mixture	Conditions of restriction
	(a) articles placed on the market before 2 March 2019; (b) aircraft produced in accordance with subparagraph 3(a); (c) spare parts of aircraft, vehicles or machines produced in accordance with subparagraph 3(b); (d) electrical and electronic equipment within the scope of Directive 2011/65/EU. 5. For the purposes of this entry 'aircraft' means one of the following: (a) a civil aircraft produced in accordance with a type certificate issued under Regulation (EU) No 216/2008 of the European Parliament and of the Council (***) or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation; (b) a military aircraft. (*) Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OL L 60, 2.3.2013, p. 1). (**) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24). (***) Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79 19.3.2008, p. 1).

As of October 2021, the REACH Regulation Candidate list includes various substances of relevance for RoHS. 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 revocations).

11.2. Exemption 24: „Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors "

11.2.1. Summary of the information from trials with respect to Gold and PdAg terminations

The following tables from the Knowles Precision Devices (2021) (reproduced as is):

Figure 11-1: Summary of the information from trials with respect to Gold and PdAg terminations

Reliability tests	Materials of terminations: Gold	Materials of terminations: PdAg
Lead-containing solders:	*50In/50Pb* *95Pb5In* *93.5Pb5Sn1.5Ag* *60Sn40Pb* *62Sn/36Pb/2Ag* *50In/50Pb, 95Pb5In &* *93.5Pb5Sn1.5Ag, also 92.5Pb5Sn2.5Ag (since approved for production) all gave suitable results when the cooling cycle was controlled* *60Sn40Pb & 62Sn/36Pb/2Ag produced excessive electrical failures and analysis identified cracks within the ceramic. It was determined that the cracking occurred during the cooling cycle after soldering and that undue stress was being placed on the ceramic.*	*50In50Pb* *50In/50Pb gave suitable results when the cooling cycle was controlled* *PdAg is now very rarely used in the industry due to the very high cost of Pd.*
Lead-free solders: 95.5Sn/3.8Ag/0.7Cu	Parts soldered with this alloy failed electrically and were unsuitable for use. Analysis determined that the cracking occurred during the cooling cycle after soldering and that undue stress was being placed on the ceramic	Parts soldered with this alloy had reduced incidences of cracking, but exhibited loss of capacitance reducing the electrical filtering performance to an unacceptably low level. Analysis identified loss of termination into the solder, a well-known issue with lead free alloys on PdAg terminations
Lead-free solders:	Parts soldered with this alloy failed electrically and were unsuitable for use.	

99.3Sn/0.7Cu	Analysis determined that the cracking occurred during the cooling cycle after soldering and that undue stress was being placed on the ceramic	
Lead-free solders: 95Sn 5Ag	Parts soldered with this alloy failed electrically and were unsuitable for use. Analysis determined that the cracking occurred during the cooling cycle after soldering and that undue stress was being placed on the ceramic	

Source: Knowles Precision Devices (2021)