Study to assess requests for a renewal of nine (-9-) exemptions 6(a), 6(a)-I, 6(b), 6(b)-I, 6(b)-II, 6(c), 7(a), 7(c)-I and 7 (c)-II of Annex III of Directive 2011/65/EU (Pack 22) – Final Report (Amended Version)

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.

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1. Executive summary – English

With contract No. 070201/2020/8358484/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 taking into account that exemptions falling under the enlarged scope of RoHS 2 can be applied for since the entry into force of the Directive (21.7.2011), the consultant carried out an assessment of sixteen requests for the renewal of nine 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 applicant concerned, as well as the final recommendation and proposed expiry date are summarised in the table below (Table 1-1). Sixteen requests for the renewal of nine exemptions listed in Annex III were included in the scope of this project. The reader is referred to the corresponding section 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.	Requested exemption wording	Applicant/s	Recommendation	Expiry date & scope
Annex III, 6(a) and 6(a)-I	*"Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight." and "Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight and in batch hot dip galvanised steel components containing up to 0,2 % lead by weight"*	RÖHM GmbH; The Umbrella Project	6(a): Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight and in galvanized steel containing up to 0,35 % lead by weight	— 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
			6(a)-I: Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight	Expires on 21 July 2024 for all categories
			6(a)-II: Lead in batch hot dip galvanised steel components containing up to 0,2 % lead by weight	Expires on 21 July 2026 for all categories
Annex III, 6(b)/6(b)-I	*"Lead as an alloying element in aluminium containing up to 0,4 % lead by weight"* and *"Lead as an alloying element in aluminium containing up to 0,4 % lead by weight, provided it stems from lead-bearing aluminium scrap recycling"*	European Aluminium; The Umbrella Project	6(b)-I: Lead as an alloying element in aluminium containing up to 0,4% lead by weight provided it stems from lead-bearing aluminium scrap recycling	Expires 12 months after the decision for all categories
			6(b)-III: Lead as an alloying element in aluminium casting alloys containing up to 0,3% lead by weight provided it stems from lead-bearing aluminium scrap recycling	Expires on 21 July 2026 for all categories

Ex. Req. No.	Requested exemption wording	Applicant/s	Recommendation	Expiry date & scope
Annex III, 6(b)-II	*"Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight"*	The Umbrella Project	6(b)-II: Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight.	Expires 18 months after the decision for all categories
			6(b)-IV: Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight in gas valves applied in category 1 EEE (large household appliances)	Expires on 31 December 2024
Annex III, 6(c)	*"Copper alloy containing up to 4 % lead by weight"*	Bourns Inc.; The Umbrella Project	6(c): Copper alloy containing up to 4 % lead by weight	Expires on 21 July 2026 for all categories
Annex III, 7(a)	*"Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)"*	Bourns Inc.; The Umbrella Project	Lead in high melting temperature type solders (i.e., lead-based alloys containing 85 % by weight or more lead) (excludes those in the scope of exemption 24)	For all categories except applications covered by point 24 of this Annex, expires on 21 July 2024.
			Lead in high melting temperature type solders (i.e., lead-based alloys containing 85 % by weight or more lead) when used for the following applications (excludes those in the scope of exemption 24): I) for internal interconnections for attaching die, or other components along with a die in semiconductor assembly with steady state or transient/impulse currents of 0.1 A or greater or blocking voltages beyond 10 V, or die edge sizes larger than 0.3 mm x 0.3 mm II) for integral (meaning internal and external) connections of die attach in electrical and electronic components, if the thermal conductivity of the cured/sintered die-attach material is >35W/(m*K) AND the electrical conductivity of the cured/sintered die-attach material shall be >4.7MS/m AND solidus melting temperature has to be above 260°C	Applies to all categories except applications covered by point 24 of this Annex, expires on 21 July 2026

Ex. Req. No.	Requested exemption wording	Applicant/s	Recommendation	Expiry date & scope
			III) In first level solder joints (internal or integral connections - meaning internal and external) for manufacturing components so that subsequent mounting of electronic components onto subassemblies (i.e., modules or sub-circuit boards or substrates or point to point soldering) with a secondary solder does not reflow the first level solder. This item excludes die attach applications and hermetic sealings IV) In second level solder joints for the attachment of components to printed circuit board or lead frames: 1. in solder balls for the attachment of ceramic ball-grid-array (BGA) 2. in high temperature plastic overmouldings (> 220 °C) V) as a hermetic sealing material between: 1. a ceramic package or plug and a metal case, 2. component terminations and an internal sub-part VI) for establishing electrical connections between lamp components in incandescent reflector lamps for infrared heating or high intensity discharge lamps or oven lamps VII) for audio transducers where the peak operating temperature exceeds 200°C	

Ex. Req. No.	Requested exemption wording	Applicant/s	Recommendation	Expiry date & scope
Annex III, 7(c)-I	*"Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in ca-pacitors, e.g. piezoelec-tronic devices, or in a glass or ceramic matrix compound"*	COCIR; SCHOTT AG; Bourns Inc.; Photonis Scientific, Inc.; Optical Fiber Packaging Ltd; The Umbrella Project	7(c)-I: 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	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
Annex III, 7(c)-II	*"Lead in dielectric ceramic in capacitors for a rated volt-age of 125 V AC or 250 V DC or higher"*	The Umbrella Project	7(c)-II: Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher	Does not apply to applications covered by point 7(c)-I and 7(c)-IV of this Annex. Expires on 21 July 2026 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

Avec le contrat n° 070201/2020/8358484/ENV.B.3 mettant en œuvre le contrat-cadre n° ENV.B.3/FRA/2019/0017, un consortium dirigé par Ramboll Deutschland GmbH, a été sollicité par la DG Environnement de la Commission européenne pour fournir un soutien technique et scientifique pour l'évaluation des demandes d'exemption dans le cadre du régime RoHS 2. Dans l'étude actuelle, le travail a été entrepris et revu par les pairs par Oeko-Institut.

2.1. Contexte et objectifs

La directive RoHS 2 2011/65/EU 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 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 á l'adaptation de ses annexes au progrès scientifique et technique. L'article 5(1), point a), détaille 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.
- 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 á 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), le consultant a procédé à l'évaluation de seize demandes de renouvellement de neuf exemptions dans le cadre de la présente mission.

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

Les demandes d'exemption couvertes par ce projet et le nom du demandeur concerné, ainsi que la recommandation finale et la date d'expiration proposée, sont résumées dans le tableau ci-dessous (Tableau 2-1). Seize demandes de renouvellement de neuf exemptions énumérées à l'annexe III ont été incluses dans le champ d'application de ce projet.

Le lecteur est invité à se reporter à la section correspondante du présent rapport pour plus de détails sur les résultats de l'évaluation.

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.

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

Numéro de la demande d'exemption	Texte de l'exemption demandée	Demandeur/s	Recommendation	Date d'expiration et champ d'application
Annex III, 6(a) et 6(a)-I	*"Le plomb en tant qu'élément d'alliage dans l'acier destiné à l'usinage contenant jusqu'à 0,35 % de plomb en poids" et "Le plomb en tant qu'élément d'alliage dans l'acier destiné à l'usinage contenant jusqu'à 0,35 % de plomb en poids et dans les composants en acier galvanisé à chaud par lots contenant jusqu'à 0,2 % de plomb en poids"*	RÖHM GmbH; The Umbrella Project	6(a) : Le plomb comme élément d'alliage dans l'acier destiné à l'usinage contenant jusqu'à 0,35 % de plomb en poids et dans l'acier galvanisé contenant jusqu'à 0,35 % de plomb en poids.	- 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
			6(a)-I : Plomb comme élément d'alliage dans l'acier destiné à l'usinage contenant jusqu'à 0,35 % de plomb en poids.	Expire le 21 juillet 2024 pour toutes les catégories
			6(a)-II : Plomb dans les composants en acier galvanisé à chaud par lots contenant jusqu'à 0,2 % de plomb en poids.	Expire le 21 juillet 2026 pour toutes les catégories
Annex III, 6(b)/6(b)-I	*"Le plomb en tant qu'élément d'alliage dans l'aluminium contenant jusqu'à 0,4 % de plomb en poids" et "Le plomb en tant qu'élément d'alliage dans l'aluminium contenant jusqu'à 0,4*	European Aluminium; The Umbrella Project	6(b)-I : Plomb en tant qu'élément d'alliage dans l'aluminium contenant jusqu'à 0,4 % de plomb en poids, à condition qu'il provienne du recyclage de débris d'aluminium contenant du plomb	Expire 12 mois après la décision pour toutes les catégories

Numéro de la demande d'exemption	Texte de l'exemption demandée	Demandeur/s	Recommendation	Date d'expiration et champ d'application
	% de plomb en poids à condition qu'il provienne du recyclage de débris d'aluminium contenant du plomb"		6(b)-III : Plomb comme élément d'alliage dans les alliages de fonderie d'aluminium contenant jusqu'à 0,3 % de plomb en poids, à condition qu'il provienne du recyclage de débris d'aluminium contenant du plomb.	Expire le 21 juillet 2026 pour toutes les catégories
Annex III, 6(b)-II	"Le plomb en tant qu'élément d'alliage dans l'aluminium destiné à l'usinage contenant jusqu'à 0,4 % de plomb en poids"	The Umbrella Project	6(b)-II : Plomb en tant qu'élément d'alliage dans l'aluminium destiné à l'usinage contenant jusqu'à 0,4 % de plomb en poids.	Expire 18 mois après la décision pour toutes les catégories
			6(b)-IV : Plomb en tant qu'élément d'alliage dans l'aluminium à des fins d'usinage avec une teneur en plomb allant jusqu'à 0,4 % en poids dans les robinets à gaz utilisés dans les EEE de catégorie 1 (gros appareils ménagers).	Expire le 31 décembre 2024
Annex III, 6(c)	"L'alliage de cuivre contenant jusqu'à 4 % de plomb en poids"	Bourns Inc.; The Umbrella Project	6(c): L'alliage de cuivre contenant jusqu'à 4 % de plomb en poids.	Expire le 21 juillet 2026 pour toutes les catégories
Annex III, 7(a)	*"Le plomb dans les soudures à haute température de fusion (alliages de plomb contenant au moins 85 % de plomb en poids)"*	Bourns Inc.; The Umbrella Project	Plomb dans les soudures à haute température de fusion (alliages de plomb contenant au moins 85 % de plomb en poids) (à l'exclusion de celles relevant de l'exemption 24).	Pour toutes les catégories, à l'exception des demandes couvertes par le point 24 de la présente annexe, expire le 21 juillet 2024

Numéro de la demande d'exemption	Texte de l'exemption demandée	Demandeur/s	Recommendation	Date d'expiration et champ d'application
			Le plomb dans les soudures à haute température de fusion (alliages de plomb contenant au moins 85 % de plomb en poids) lorsqu'il est utilisé pour les applications suivantes (à l'exclusion de celles relevant de l'exemption 24) : I) pour les interconnexions internes destinées à fixer une puce, ou d'autres composants le long d'une puce dans un assemblage de semi-conducteurs avec des courants permanents ou transitoires/impulsifs de 0,1 A ou plus ou des tensions de blocage supérieures à 10 V, ou des tailles de bord de puce supérieures à 0,3 mm x 0,3 mm II) pour les connexions intégrales (internes et externes) de fixation de puce dans les composants électriques et électroniques, si la conductivité thermique du matériau de fixation de puce durci/fritté est >35W/(m*K) ET la conductivité électrique du matériau de fixation de puce durci/fritté doit être >4,7MS/m ET la température de fusion du solidus doit être supérieure à 260°C III) Dans les soudures de premier niveau (connexions internes ou intégrales - c'est-à-dire internes et externes) pour la fabrication de composants, de sorte que le montage ultérieur de composants électroniques sur des sous-ensembles (des modules ou des cartes de sous-circuits ou des substrats ou le soudage point à point) avec une soudure secondaire ne provoque	S'applique à toutes les catégories sauf aux demandes couvertes par le point 24 de la présente annexe, expire le 21 juillet 2026

Numéro de la demande d'exemption	Texte de l'exemption demandée	Demandeur/s	Recommendation	Date d'expiration et champ d'application
			pas la refusion de la soudure de premier niveau. Ce point exclut les applications de fixation de puce et les joints hermétiques. IV) Dans les brasures de deuxième niveau pour la fixation de composants sur des cartes de circuits imprimés ou des grilles de connexion : 1. dans les billes de soudure pour la fixation des grilles matricielles à billes en céramique (anglais : ball grid array BGA) 2. dans les surmoulages plastiques haute température (> 220 °C) V) comme matériau de scellement hermétique entre : 1. un boîtier ou une fiche en céramique et un boîtier métallique, 2. les terminaisons de composants et une sous-partie interne. VI) pour établir des connexions électriques entre les composants de lampes dans les lampes à réflecteur à incandescence pour le chauffage infrarouge ou les lampes à décharge à haute intensité ou les lampes de four VII) pour les transducteurs audio dont la température maximale de fonctionnement dépasse 200 °C.	

Numéro de la demande d'exemption	Texte de l'exemption demandée	Demandeur/s	Recommendation	Date d'expiration et champ d'application
Annex III, 7(c)-I	*"Les composants électriques et électroniques contenant du plomb dans du verre ou des matériaux céramiques autres que les céramiques diélectriques dans les condensateurs, (par exemple, les dispositifs piézoélectriques) ou dans une matrice en verre ou en céramique"*	COCIR; SCHOTT AG; Bourns Inc.; Photonis Scientific, Inc.; Optical Fiber Packaging Ltd; The Umbrella Project	7(c)-I : Les composants électriques et électroniques contenant du plomb dans un verre ou des matériaux céramiques autres que les céramiques diélectriques dans les condensateurs, (par exemple, les dispositifs piézo-électriques) ou dans une matrice en verre ou en céramique	Expire le 21 juillet 2024 pour toutes les catégories.
			7(c)-V : Composants électriques et électroniques contenant du plomb dans un verre ou un composé à matrice de verre qui remplit les fonctions suivantes : 1) protection et isolation électrique dans les perles de verre des diodes haute tension et dans les couches de verre pour plaquettes à base d'un corps en verre plomb-zinc-borate ou plomb-silice-borate*. 2) pour les scellements hermétiques entre des pièces en céramique, en métal et/ou en verre 3) à des fins de collage dans une fenêtre de para-mètres de processus pour < 500°C combiné avec une viscosité de $10^{13,3}$ dPas (appelée "température de transition du verre") 4) utilisés comme matériaux de résistance tels que l'encre, avec une gamme de résistivité de 1 Ohms/carré à 1 Méga Ohms/carré, à l'exception des potentiomètres de réglage**. 5) utilisés dans les surfaces en verre chimiquement modifiées pour les plaques à microcanaux (MCP), les multiplicateurs	Expire le 21 juillet 2026 pour toutes les catégories.

Numéro de la demande d’exemption	Texte de l’exemption demandée	Demandeur/s	Recommendation	Date d’expiration et champ d’application
			d'électrons à canaux (CEM) et les produits en verre résistif (RGP).	
			7(c)-VI : Composants électriques et électroniques contenant du plomb dans une céramique qui remplit les fonctions suivantes (à l'exclusion des articles couverts par les points 7(c)-II, 7(c)-III et 7(c)-IV de la présente annexe) : 1) céramiques piézoélectriques en titanate de plomb et de zirconium (PZT) 2) fournissant des céramiques à coefficient de température positif (CTP).	Expire le 21 juillet 2026 pour toutes les catégories
Annex III, 7(c)-II	*“Le plomb dans les céramiques diélectriques dans les condensateurs pour une tension nominale de 125 V CA ou 250 V CC ou plus”*	The Umbrella Project	7(c)-II : Plomb dans les céramiques diélectriques dans les condensateurs pour une tension nominale de 125 V CA ou 250 V CC ou plus	Ne s'applique pas aux demandes couvertes par le point 7(c)-I et 7(c)-IV de la présente annexe. Expire le 21 juillet 2026 pour toutes les catégories

Notez: 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 sixteen requests for the renewal of nine 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 23 December 2020 and was held for duration of ten weeks thus concluding 3 March 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 13.

Aspects related to REACH are detailed under Chapter 54.General arguments raised by stakeholders in relation to all exemptions are addressed under Chapter 5. Each of the chapters thereafter (0 through12) addresses a specific exemption (or in a few cases a number of exemptions evaluated jointly) evaluated in the course of this study. The information provided by the applicant 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 consultant 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]

3.2. Project set-up

Assignment of project tasks to Oeko-Institut, started in 28 October 2020. The overall study has been led by Yifaat Baron and is managed by Katja Moch.

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

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 State 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:

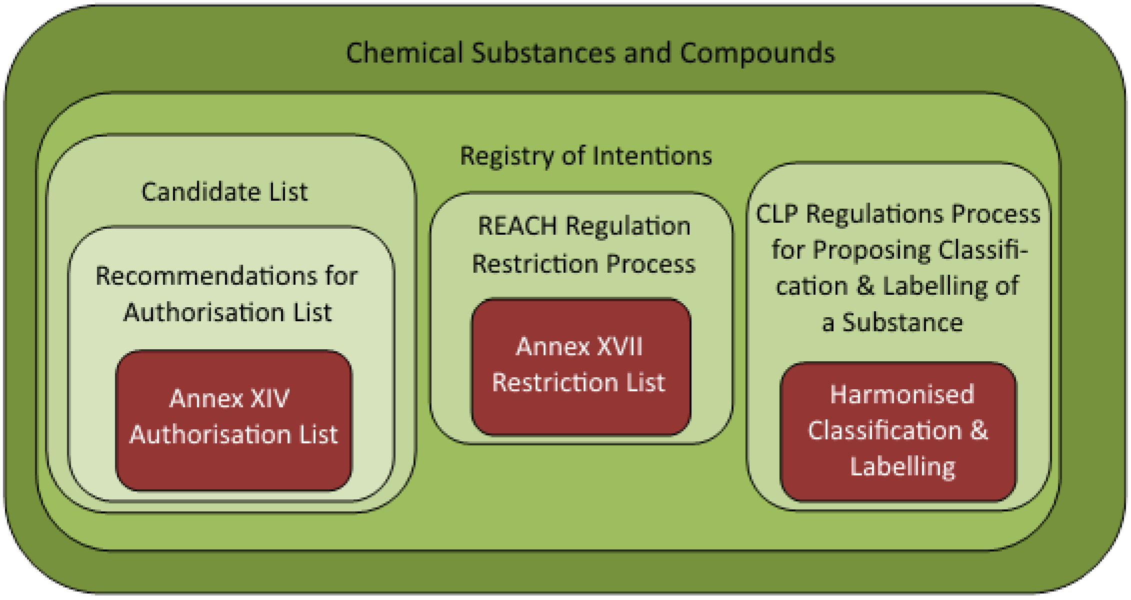
- on the list of substances of very high concern (SVHCs- the Candidate List);
- in the recommendations of substances for Annex XIV (recommended to be added to the Authorisation List);
- listed in REACH Annex XIV itself (the Authorisation List); or
- listed in REACH Annex XVII (the List of Restrictions).

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 inform interested parties of the substances for which the authorities intend 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

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 two separate sections: The Registry of SVHC intentions until outcome, available under: https://echa.europa.eu/de/registry-of-svhc-intentions and the Registry of restriction intentions until outcome, available under: https://echa.europa.eu/de/registry-of-restriction-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.

As of July 2021, the consolidated version of the REACH legal text, dated 05.07.2021, 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%3A02006R1907-20210705. 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-ethyl-hexyl) 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 in 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 22 concerns the use of lead the REACH compliance check focused on lead 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 metal alloys (steel, aluminium and copper) (exemptions 6(a), (b), (c)) or
- lead in special solders (high melting temperature type solders) (exemption 7(a)) or
- lead in a glass or ceramic or dielectric ceramic in a specific application (capacitors) (exemptions 7(c)-I and 7(c)-II).

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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

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 compounds as a substance, mixture or constituent of other mixtures to the general public. Rather lead is part of an article and as such, 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 exemptions 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*".

However, the Swedish Chemicals Agency KEMI (2021) in its contribution to the stakeholder consultation claimed for the metal alloy exemptions[15], that "*RoHS must be adapted to the corresponding level of protection to human health according to other regulations. The broad exemptions for lead in RoHS undermine the purpose of the REACH restriction. The protection for human health in RoHS must be at least equivalent to the one in REACH. For example, external parts in EEE for use by the general public with a risk of skin contact do not lead to a safe use when an exemption of lead is applied.*"

This view is also reflected in the Common Understanding Communication stating that "in those situations in which the RoHS restriction generally takes into account the protection of human health and the environment, at all stages, similarly to REACH restrictions, the latter should exclude EEE from their scope of application, indicating that the use of the substance in question in EEE is restricted by the RoHS Directive." In this sense, the consultant concludes that EEE do not benefit from an exclusion in general but rather on the basis that exemptions are expected to be granted (or renewed) only in cases where a similar level of protection is ensured.

Entry 63 restricts lead and its compounds in articles and their accessible parts with the aim of minimising children's lead exposure from articles supplied to the general public (ECHA 2020).. Due to their mouthing behaviour, children, especially those under 3 years may be repeatedly exposed to lead or lead compounds released from consumer articles. Children are especially sensitive to lead exposure as their central nervous system is still developing, which can result in severe and irreversible neurobehavioral and neurodevelopmental effects (ECHA 2020). As no threshold has been found for the harmful effects of lead on the central nervous system, and with a view to background exposure from diet and other environmental sources, any relevant lead exposure

[15] General comments on the exemption requests for 6a, 6a-I, 6b, 6b-I, 6b-II, 6c

should be avoided as a matter of principle (ECHA 2020). According to the ECHA Guideline on the scope of the Entry 63, it is clarified 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.*" (ECHA Guideline).

The restriction under REACH applies to articles and accessible parts of articles, which meet all the 3 following conditions:

a. are supplied to the general public and contain lead or lead compounds at concentrations of lead, expressed as metal, equal to or greater than 0.05 % by weight;
b. may be placed in the mouth by small children during normal or reasonably foreseeable conditions of use;
c. are not covered by a derogation.

EEE should in general be kept away from children especially under 3 years, thus it should not be placed in the mouth by small children during normal or reasonably foreseeable conditions of use. However, the consultant agrees to the Swedish Chemicals Agency KEMI (2021) that RoHS exemptions of lead undermines the purpose of the REACH restriction if the application is not specified. This is primarily because

- the concentration of lead in the alloys' exemption under RoHS are greater than the limits in entry 63 and
- no threshold has been found for the harmful effects of lead on the central nervous system.
- This means that any relevant lead exposure should be avoided as a matter of principle according to ECHA (2020).

It should be noted that KEMI (2021) even uses the wording "*external parts in EEE for use by the general public with a risk of skin contact do not lead to a safe use when an exemption of lead is applied*" to describe an equivalent level of protection under RoHS. However, the consultant rather proposes that the wording of REACH should be used if the applications of the RoHS exemptions are not sufficiently specified to a degree that allows to conclude that they are not applied in articles or accessible parts of an article that may be placed in the mouth by children.

The following table compiles the exemptions under review in this study and their assessed potential to address accessible components / parts.

Table 4-1: Assessment of the applicability of REACH Annex XVII entry 63 to the exemptions under assessment

Ex. Req. No.	Recommended exemption wording	Potential for application to be accessible or to contain accessible components / parts
Annex III, 6(a) and 6(a)-I		As an exhaustive list of applications has not been provided, the use of this exemption for components in external and potentially accessible parts cannot be ruled out. This is relevant for EEE categories 1-4, 6 and 7 and 11.

Ex. Req. No.	Recommended exemption wording	Potential for application to be accessible or to contain accessible components / parts
Annex III, 6(b)/6(b)-I		As an exhaustive list of applications has not been provided, the use of this exemption for components in external and potentially accessible parts cannot be ruled out. This is relevant for EEE categories 1-4, 6 and 7 and 11.
Annex III, 6(b)-II	*"Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight* - *for gas valves for category 1 (large household appliances)*	No, relevant components are understood to be larger than specified
Annex III, 6(c)	*"Copper alloy containing up to 4 % lead by weight"*	For components with electrical function, no accessibility is anticipated. Mechanical components are understood to be specific internal components. However, as an exhaustive list of applications has not been provided, the use of this exemption for components in external and potentially accessible parts cannot be ruled out. This is relevant for EEE categories 1-4, 6, 7 and 11.
Annex III, 7(a)	*"Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)"*	No potential. Lead-based high melting point solders are applied in internal electric components of EEE.
Annex III, 7(c)-I	*"Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in ca-pacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound"*	No potential. Lead is used in glass or ceramic components that are applied in internal electric components of EEE.
Annex III, 7(c)-II	*"Lead in dielectric ceramic in capacitors for a rated volt-age of 125 V AC or 250 V DC or higher"*	No potential. Lead is used in capacitors which are internal electric components of the EEE.

To conclude, in order to ensure the same level of protection to human health as provided by REACH the consultant proposes that the following phrase should be added for precautionary reasons to the exemption wording to exclude the use in:

"article or accessible part of an article that 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 except where it can be demonstrated that the rate of lead release from the accessible component /part, 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".

Alternatively, it could be added as a footnote to exemptions where this aspect is relevant.

It should be noted here, that other stakeholders whose products originally fall in scope of entry 63, such as the watches industry has already implemented this concept; e.g. Federation of the Swiss Watch Industry FH (2021a) states that "*the watch industry has already substituted a long time ago lead alloys in external watch components. For internal components of the watch movement, substitution is more challenging.*"

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 July 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 taking into account all consideration discussed above if other criteria of Art. 5(1)(a) apply.

5. The applicability of the Pack 22 exemption conclusions and recommendations to sub-Cat. 8 in-vitro, sub-Cat. 9 industrial and Cat. 11

The RoHS Directive makes a distinction between eleven EEE categories (from here on referred to as Cat.) which are named in Annex I of the Directive. Certain provisions address some of these Cat. in a different way than they do others. To begin with, Cat. 8, Cat. 9 and Cat. 11 came into the scope of the Directive at a later point in time than the other categories, meaning among others that the substance restrictions need to be complied with by EEE under these categories at a later time. This is referred to under Article 4(3), which states:

> "Paragraph 1 shall apply to medical devices [Cat. 8 - consultants addition] and monitoring and control instruments [Cat. 9 - consultants addition] which are placed on the market from 22 July 2014, to in vitro diagnostic medical devices ([Cat. 8 in-vitro - consultants addition] which are placed on the market from 22 July 2016, to industrial monitoring and control instruments [Cat. 9 industrial - consultants addition] which are placed on the market from 22 July 2017, and to all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market from 22 July 2019 [Cat. 11 - consultants addition]."

Respectively, Article 5(2), last paragraph specifies that:

> *"For the exemptions listed in Annex III as at 21 July 2011, unless a shorter period is specified, the maximum validity period, which may be renewed, shall be:*

(a) for categories 1 to 7 and category 10 of Annex I, 5 years from 21 July 2011;
(b) for categories 8 and 9 of Annex I, 7 years from the relevant dates laid down in Article 4(3); and
(c) for category 11 of Annex I, 5 years from 22 July 2019.

> *For the exemptions listed in Annex IV as at 21 July 2011, the maximum validity period, which may be renewed, shall be 7 years from the relevant dates laid down in Article 4(3), unless a shorter period is specified."*

Whereas the exemptions under assessment in this study are set to expire for Cat. 1-10 by 21 July 2021, later expiration dates apply to three categories as specified below:

- For Cat. 8 in-vitro EEE the exemption is specified to expire on 21 July 2023;
- For Cat. 9 industrial and Cat. 11 the exemption is specified to expire on 21 July 2024.

There has thus been uncertainty as to whether the current assessment shall also concern these categories and whether its recommendations should apply to these categories in the same way that they do to others. This is reflected both in the requests of applicants as also in a few of the contributions made to the stakeholder consultation, which are summarised in the next section.

5.1. Applicant and Stakeholder views

The “RoHS Umbrella Industry Project” (hereafter Umbrella Project or UP) who has submitted requests for all of the exemptions under assessment in this study initially requested the renewal of the exemptions for Cat. 1-10 (see for example (Umbrella Project 2020e)). After further consideration, a set of applications almost identical in content were submitted for the same exemptions, requesting also the renewal for Cat. 11 (see for example (Umbrella Project 2020g)). It can be understood that the Umbrella Project members have deemed it necessary to submit this second set of applications for reasons of legal certainty for their products. The Commission accepted the applications and included Cat. 11 in the current assessment.

SEMI EUROPE (2021b) is understood to represent among others manufacturers of equipment for the manufacture of semiconductors, which they explain to fall under Cat. 11. SEMI EUROPE (2021b) explains that it expects the current studies to only be “*related to exemptions which expire shortly (e.g., July of 2021), and that no reduction will be made to the later expiry dates or the categories of equipment they cover*”. SEMI (2021b) explains that many parts used in Semiconductor-Manufacturing (and Related) Equipment (SMRE) rely on some of the exemptions currently under review. Even in the case that a change in an exemption does not require a redesign of the part, i.e. the exemption formulation remains the same but the expiry dates changes, SEMI explains such changes to result in a cost: “*Even in the simplest scenario, the new RoHS-compliant part that does not depend on the exemption will have to be given a new part number, and the ‘where-used’ assemblies and related drawings and bill of materials will also have to be revised as an engineering action. Even one such simple change could require 8 to 32 or more hours of engineering time (depending on the project management and review systems in place for the SMRE manufacturer), which, when realistically distributed into a normal work schedule in parallel with other projects, could require one to three weeks of real calendar time*”. This is understood to illustrate the cost of needing to change the documentation of a part which no longer needs to refer to a certain exemption, resulting in a net cost of 8-32 person hours, which however could require up to 3 calendar weeks for implementation. If a requalification of the part is needed “*to demonstrate there is no significant impact to customer processes. Such requalification projects can in, the best case, require many weeks of planning an analysis and potentially tens of thousands of dollars in machine time, employee time, and test work-piece costs*.”

SEMI EUROPE (2021b) provides a table, listing parts it has identified that depend on exemptions covered under the current study. The detailed table can be found in the contribution. In summary, the number of parts specified in relation to each of the exemptions under review is as follows:

Table 5-1: Estimation of the number of SMRE parts relying on specific exemptions listed in RoHS Annex III

Ex. No.	6a	6b	6c	7(a)	7(c)-I	7(c)-II
No. of parts estimated	24	16	148	12	30	2

Source: SEMI EUROPE (2021b)

The Test and Measurement Coalition (Test & Measurement Coalition 2021) provide similar argumentation. On the exemptions currently under review, TMC states "*We understand that certain exemption applications include uses relevant to category 9 industrial monitoring and control equipment […]industrial monitoring and control producers have extended validity periods of their exemptions until 21 July 2024 due to the complexity of our products; the scale of our portfolios; and the length and breadth of our supply chain. We would like reiterate the critical importance of Annex III exemptions for category 9 industrial and to stress the need to retain each exemption as originally published in both definition and expiry date for our sector* […] *The legally established expiry dates for Category 9 industrial monitoring and control equipment shall be respected in order to guarantee legal certainly and predictability and avoid undesirable socioeconomic impacts*. […] Questioning of the initial validity period of RoHS exemptions could be envisaged only in case of proven scientific progress which makes earlier successful substitution possible for the specific product category.

Test & Measurement Coalition (2021) states that "*any additional and unforeseen disruption, such as premature shortening of exemption validity periods will be extremely detrimental to our sector and will result in negative socio-economic impact. Unforeseen workload will divert workforce from product development and slow down innovation*". As for possible socio-economic impacts of such so-called premature change of the exemptions for sub-Cat. 9-industrial, TMC provides two examples, explaining that both are considered to introduce additional risk to compliance with no perceivable benefit:

- Data management and Enterprise Resource Planning (ERP[16]) Solution re-engineering to segregate existing supplier declarations from those of the new Exemption takes IT investment, time and resources and is open to error;
- Separating and managing suppliers' declarations when schemas are in transition adds huge complexity where the same exemption number exists with a different description;

TMC was asked to elaborate as to how RoHS exemptions are referred to in supplier declarations (declaration of conformity) in order to allow understanding what types of changes may require updates of such documentation. TMC (2021) explains:

[16] In a later communication TMC (2021) explains ERP examples to be "*offerings from Oracle, SAP, 3DX Enovia, etc. Such tools are configured to manage all aspects of product configuration and engineering information through to customer orders. For business in our sector, the complexities of both product and portfolio require the use of such solutions to manage our businesses. Data relating to part compliance state links to any applied exemption numbering. Changes cause a massive IT effort to reconfigure and re-collect data. Justifiable for planned changes, unacceptable for changes triggered by other sectors that should not impact Industrial Cat 9 conformity*".

"EEE producers must decide whether exemptions stated by component producers are applicable to the category of equipment they market. These must then be collectively "rolled-up" to cover all components on the EEE bill of materials to declare the relevant Exemptions applied at the finished equipment level. Given the complexity of equipment produced by T&M Coalition members, this necessitates the use of ERP solutions to manage such activities. Such solutions must be configured to recognize acceptable and valid exemptions as well as be capable of importing component data via international schema. There is a significant range of data on exemptions presented by component manufacturers.

- *In many cases, it is simply an exemption number,*
- *Some provide the exemption description: Some describe if full, others only provide selected text,*
- *Next to no information is provided on applicability by sector or expiry date since this is not the responsibility of the component producers,*
- *Some provide no statement at all on whether an exemption has been applied or not, simply stating the component is "RoHS Compliant",*
- *Declarations provided at many different levels (part, family, business group, corporation)".*

From their contribution it can be understood that Fresenius Kabi (2021) manufactures instruments that fall under Cat. 8 and 9, of which at least some equipment would be categorised as sub-Cat. 8 in-vitro or sub-Cat. 9 industrial. Fresenius does not refer to the above aspect, but rather only specifies its support of the renewal of the various exemptions requested. In a few cases, its contribution refers to exemptions that are currently only available to Cat. 8, 9 and 11. In other cases, Fresenius refers to its agreement to include Cat. 8 and 9 in the exemptions addressed but does not mention aspects specific to sub-Cat. 8 in-vitro or sub-Cat. 9 industrial or Cat. 11.

5.2. Course of action of the assessment in relation to sub-Cat. 8 in-vitro, sub-Cat. 9 industrial and Cat. 11

Assessing whether sub-Cat. 8 in-vitro, sub-Cat. 9 industrial and Cat. 11 should be subject to this assessment and affected by its recommendations is beyond the mandate of this study. Nonetheless, the consultant would like to raise a few points of relevance to this issue.

Recital 19 of the Directive requires exemptions to "*be limited in their scope and duration*". To this end, over the years, the Oeko-Institut has sought to specify exemptions as needed so that they reflect the current state of science and technology. Along with this approach, considerations have also been included to merge exemptions where it could be clarified that the scopes of certain exemptions overlap or where parallel exemptions had been granted to similar applications of different technologies. This for example led in past assessments to a recommendation to split the original Annex III Ex. 18b for lead as an activator in BSP (BaSi2O5:Pb) sun tanning lamps into two items, one for sun-tanning lamps and one for medical therapy lamps. It was also recommended at the time to consider merging these exemptions with Annex IV Ex. 34 when the latter was due for assessment.

The consultant sees a benefit in merging exemptions or at least ensuring their proximity in the annexes through a mutual exemption number, when a similar technology or application is addressed and where the justification of the exemption is based on similar technical or scientific arguments. This approach increases the probability that when one exemption is under assessment, it is also reviewed whether overlaps exist with other exemptions that could create uncertainty in the implementation of the Directive and in some cases also loop-holes. To this end, merging categories under exemptions with a single expiration period is also considered to serve this purpose. It is also noted that this approach can be in conflict with the aim to specify exemptions in relation to specific applications. This is the case for some exemptions listed in the Directive and addressing a material which is widely applied for different purposes. To this end, where a specification and a narrowing of scope is sought, instead of merging exemptions, a proximity in the location in the annex could be sought through listing of specific application areas as sub-items of a certain exemption.

The consultant sought advice from the European Commission on this aspect in order to clarify whether to assess the exemptions for all categories or to exclude EEE where later dates apply. It was clarified that "the evaluation of all categories should be combined in one evaluation procedure, to be oriented at the closest expiry date of the categories it relates to". For this purpose, where it was aware of stakeholders representing such categories, Oeko-Institut informed representatives of this approach and requested information specific to their categories to try to get a broad picture of the state of substitution for the various types of EEE. As a general approach, where specific information was made available, this is relayed in the exemption specific reports and considered as in the assessment of the specific exemption. Where no specific data was provided, these categories are included into general recommendations.

6. Exemption 6(a) & 6(a)-I: Ex. 6(a) for "Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight", and Ex. 6(a)-I for „Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight and in batch hot dip galvanised steel components containing up to 0,2 % lead 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

Bi	Bismuth
11SMn30	Lead-free cutting steel containing high sulphur and also manganese
11SMn37	Same as 11SMn30 but with a higher Mn content
CoRAP	Community Rolling Action Plan
CRM	Critical Raw Material
EEE	Electrical and Electronic Equipment
EGGA	European General Galvanizers Association
EUROFER	European Steel Association
KEMI	Kemikalieninspektionen, Swedish Chemicals Agency
OEM	original equipment manufacturer
Pb	Lead
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment
SVHC	Substance of very high concern
TMC	Test and Measurement Coalition
UP	RoHS Umbrella Industry Project

6.1. Background

Regarding the history of the exemption, following an assessment held in 2009, exemption 6 was split into three exemptions 6a, 6b and 6c in order to cover steel, aluminium and copper alloy with a separate wording respectively. Exemption 6(a) covers different uses of lead: The use of lead added as an alloying element in steel for machining purposes and the presence of lead in galvanised steel. Ex. 6(a) was reviewed in 2015/16 (Gensch et al. 2016). The split of Ex. 6(a) and 6(a)-I was the consequence of specifying different thresholds for lead in galvanised steel components for categories 1-7 and 10 on the one hand (Ex. 6(a)-I) and categories 8 and 9 on the other hand (remaining Ex. 6(a)) as detailed below.

The renewal of exemption 6(a) & 6(a)-I was applied for by the RoHS Umbrella Industry Project (Umbrella Project 2020a), hereafter 'the Umbrella Project' or shortly the 'UP'. The Umbrella Project's Working Group on Exemption 6(a) and 6(a)-I is represented by EUROFER (the European Steel Association) and EGGA (the European General Galvanizers Association), who both applied individually for a renewal of exemptions 6(a) and 6(a)-I in 2015/16. Röhm GmbH has also requested a renewal of the exemption as explained below.

The UP's application (Umbrella Project 2020a) covers Ex. 6(a) and Ex. 6(a)-I that both allow the use of lead in steel for machining purposes and for lead in hot dip galvanised steel. The difference between the two exemptions is the content of lead in batch hot dip galvanised steel components and the applicability to different EEE categories. Based on the current listing in annex III of the Directive:

- 6(a) '[…] galvanised steel containing **up to 0,35 % lead by weight'**,
  - expires on 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;
  - on 21 July 2023 for category 8 in vitro diagnostic medical devices; and
  - on 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.
- 6(a)-I '[…] galvanised steel components containing **up to 0,2 % lead by weight'**,
  - expires on 21 July 2021 for categories 1-7 and 10.

The Umbrella Project (Umbrella Project 2020a) applies for a renewal of the exemptions 6(a) and 6(a)-I with regards to EEE categories 1-10. A second request addresses the renewal for Cat. 11 (Umbrella Project 2020b). The applicant proposes that all EEE categories covered under Ex. 6(a) would be merged into Ex. 6(a)-I in the future (then covering all EEE categories). The feasibility of this request in relation to Cat. 8 in-vitro diagnostic medical devices, Cat. 9 industrial monitoring and control instruments and Cat. 11 EEE is discussed in chapter 5.1 on the applicability of the Pack 22 exemption conclusions and recommendations to these categories of EEE.

UP refers to the wording of Ex. 6(a)-I as the requested wording and requests the maximum validity periods foreseen in the RoHS 2 Directive (which means 7 years for Cat. 8 and Cat. 9 EEE and 5 years for all other categories).

The second applicant, Röhm GmbH, applies for exemption 6(a) (Röhm GmbH 2020). As the applicant clarified to apply only for category 6 and not for other categories, the consultant has concluded that the application relates to Ex. 6(a)-I with regards to lead in steel for machining purposes. The applicant has not provided any alternative wording for the exemption, however, lead in steel for hot dip galvanized steel is not addressed by the Röhm application. The requested duration of the exemption is 5 years.

As the wording of the exemption refers to two different application areas, that is two different groups of uses of lead, the following chapters are divided into two subchapters referring each to one of these groups.

6.2. Leaded steel for machining purposes

6.2.1. Technical description for leaded steel for machining purposes

According to the applications and information provided by British Steel (2021) during the stakeholder consultation, lead in steel provides a lubricant effect to the host material that results in a good chip crack performance, stability and smooth surface. For machining processes, this allows a higher cutting speed, a higher stability (a lower spindle stress) and a longer tool life. The steel is used in a '*diverse range of final applications within EEE including finished products and fixed installation of which an exhaustive list is not feasible*', states the UP application. (Umbrella Project 2020a)

The different relevant types of low carbon steel where lead is used for machining purposes are according to the Umbrella Project (2021c):

- **Free-cutting steel:** the primary requirement is machinability. Such alloys are typically used for manufacturing where part of the material is removed to obtain machined parts. Therefore, besides lead, these steels also contain >0.1% sulphur to enhance machining performance along with other elements such as, oxygen and phosphor. In 2018, 89% of the total supply of low carbon free-cutting steel of a European steel manufacturer was the leaded version in contrast to the non-leaded version;
- **Steel for quenching and tempering/ heat treatable steel:** the primary requirement is the ability to maintain or achieve a certain combination of mechanical properties after thermal treatment, and '*machinability is enhanced primarily through the additions of low levels of sulphur (<0.1%) and, in some grades, Ca, Bi or Pb. Typically, customers only require the highest levels of machinability (i.e., leaded variants) where particularly demanding machining operations, such as high tolerance deep hole drilling, are undertaken' (Umbrella Project 2020a)*;
- **Carburising steel** is applied when high toughness parts with hard surfaces are required. Machinability enhancers can be low levels of sulphur (<0.1%), Ca, Bi, Te or Pb; as is the case for quenching and tempering steel, leaded variants are also more common in use for carburising steel.

Low carbon steels are the most widely used steel grade. Amongst the low carbon steels, free-cutting steels are the most common use scenario of leaded-steel alloys. '*They are typically used for the manufacture of machined parts where the amount of material removed is high or machined tolerance specifications are demanding and where service conditions do not result in the application of high levels of stress*', states the UP (2021c). It is assumed that low carbon free-cutting steel is used in drill chucks for power tools, however, this was not confirmed by Röhm GmbH (Röhm GmbH 2021) despite being asked.

6.2.2. Amount of lead used under the exemption for leaded steel for machining purposes

In 2020, Röhm GmbH placed ~ 1.2 tons of lead as an alloy in steel for machining purposes on the market worldwide through their specific application, i.e. approx. 1.2 tons per year are placed on the global market (drill chucks, which are applied in power tools of EEE category 6 (Röhm GmbH 2021).

Based on the input of the Umbrella Project, it is understood that 146 to 255 tons per annum of lead are placed on the market through all types of leaded steel applications for machining purposes (all EEE categories, based on numbers from 2013). Thereof, EEE (in addition to automotive applications) is only a part and the Umbrella Project cannot specify the share of steel used in EEE compared to other applications. (Umbrella Project 2020a)

6.2.3. Applicants' justification for the requested exemption for leaded steel for machining purposes

This chapter provides the UP's as well as Röhm GmbH's justifications for the requested exemption.

Substitution or elimination of lead

With regards to substitution, the UP refers to study results that were already presented in the exemption's review process in 2015/16. The application outlines the efforts taken by the EU steel industry with regards to alternatives to lead as machinability enhancer in steels. Machinability enhancing additives (lead, bismuth, increased sulfur, sulfuric tellurid, tin, phosphorus and calcium) were tested in three different steels (11SMn30, C45 and 16MnCr5) in a project in the early 2000s (European Commission 2005). Reynolds et al. showed that '*of the alternatives, bismuth is able to substitute for lead under certain conditions, although the cost of the addition may take it uneconomic, particularly for large-scale application. Calcium can also substitute in C45 steels for use at higher cutting speeds. Steels containing tin generally did not show good performance. The alternative grades generally showed equivalent fatigue performance to the leaded grades*'[17]. It is concluded that lead is preferred due to higher production rates, reduced cutting forces, lower tool wear rates, more finely broken chip morphology and improved surface finish. Bismuth being the best available substitute so far does not show the same hot workability, or hot ductility, which makes it only a theoretical substitute. The aspect of 'hot workability' is most important according to the UP (2020a), e.g. to roll the steel. Details on the reliability of bismuth, calcium and sulphur as alternative machinability enhancing additives are outlined by explaining the disadvantages of these substances.

[17] Link specified in UP (2021c) as: https://op.europa.eu/en/publicationdetail/-/publication/6b46dd1c-5944-48d7-8c4c-e009d62ca1ba (last accessed on 13.08.2021)

Röhm GmbH provides information on two different steel alternatives (11SMn30 & 11SMn30-EM + C) that have been tested in 2019 (Röhm GmbH 2020). On the former it was concluded that substitution would technically not be feasible with regards to the required characteristics for the application of drill chucks. The latter shows some technical difficulties in tests (chip fracture behaviour, machine stability, life-time), but the main concerns remain with regards to availability and reliability given that the applicant claims to remain as last producer of the drill chucks in Europe. In a later communication, Röhm explains that there is only one supplier on the market of this alternative lead-free steel, the market acceptance with regards to product quality and price is unclear. '*If this supplier decide to stop the production or delivery problems occur, we […] could not produce the needed volume if we switch to this source*' (Röhm GmbH 2021). It was also clarified that for performing the same process, a tool with components from lead-free steel (in comparison with one with leaded-steel) needs more rotations per minute, resulting in consumption of more energy, with impacts on the lifetime of the tool and its components. Röhm GmbH specifies that more technical tests must be carried out once the lead-free material reaches a comparable quality to that of leaded steel and is available on the market from more than one supplier. When asked as to the lead-free alternative 11SMn30-EM + C presented by Röhm GmbH, the UP states that it could not conclude as to its suitability due to a lack of information.

Since leaded steels are more expensive than non-leaded versions, according to UP, the manufacturers of parts from steel use leaded steels only where it is economically feasible and where '*significant improvements in machining performance are required*'. (Umbrella Project 2021c)

Environmental arguments

The UP application considers environmental implications of bismuth by providing the following references:

- An LCA provided by the UP (referenced in UP (2020a) as Nuss and Eckelman (2014)) comparing cradle-to-gate impacts at the life cycle stages mining, purification, and refining of different metals is provided to support the argumentation against bismuth in favour of lead. In all five categories evaluated, the impact of bismuth was found higher than the impact of lead: Factors of higher impacts for bismuth are 10, 37, 14, 45, and 2 for Freshwater eutrophication [kgP-eq/kg], cumulative energy demand [MJ-eq/kg], terrestrial acidification [kg SO_2 eq/kg], global warming potential [kg CO_2 eq/kg] and human toxicity [CTUh/kg][18], respectively.
- Furthermore, an LCA on environmental impacts of leaded and non-leaded low carbon free-cutting steels including energy used during machining was provided as an Annex to the application (Umbrella Project 2020c; Coleman et al. 2015). The system boundaries include raw material extraction and production, steel manufacturing, component machining and electricity production. The study concludes

[18] As to this impact category, Nuss and Eckelman write, that 'while USEtox [the chosen method] is recommended as the latest model for modeling human toxicity in LCA, metals are included only with interim characterization factors with high uncertainties (several orders of magnitude). The results of Figure 3d [human toxicity comparison] should therefore be treated as a first indication of potential impacts to human toxicity.'

that '*for the part considered in the machining trials the global warming potential of the final part was ~9% lower for the leaded steel compared to a non-leaded steel'*. Thus, in general, lead-free steels require less energy mainly in component machining, no quantified conclusions can be drawn for steel objects that have not been tested.

The UP (Umbrella Project 2020c) concludes, that '*since lead additions result in lower cutting forces, the energy required to machine leaded steels should be lower than that required to machine the equivalent steels without lead additions*'. Thus, the effect described by Coleman et al. (2015), lower energy consumption during machining becomes especially relevant when a lot of steel has to be removed until a part is manufactured.

Socioeconomic impacts

No specific information has been submitted on socio-economic effects of substitution by Röhm GmbH or the Umbrella Project. As for general economic impacts, the UP emphasizes that bismuth is considered one of the 30 critical raw materials which are limited in supply (European Commission 2020a). '*This is the main reason why bismuth can't replace lead for the whole global production of free-cutting steels and engineering steels with improved machinability*' (Umbrella Project 2021c). Moreover, bismuth is produced as a by-product of lead, '*if the usage of lead were to decline in the future, production rates of bismuth would be proportionately impacted*.' (Umbrella Project 2020a)

6.2.4. Stakeholder contributions

In total, eight individual contributions have been submitted during the consultation period from 23 December 2020 to 03 March 2021.

Specifically in relation to exemption 6(a)/6(a)-I, British Steel has expressed its views: **British Steel** supports the renewal of the exemption, as they "*do not believe viable alternatives exist that would provide up 75 % higher cutting speed and also assure more than a 2 times higher tool life*". The consultants are unable to understand the applicability of these numbers as it is unclear what is being compared to what. As to the function of lead in steel, British Steel explains that '*lead in steel provides a lubrication function and aids machining and processing of steel reducing power requirements during machining. This also allow up 73% higher cutting speed'.* It is expected that leaded steel is compared to non-leaded steel, however, no concrete information as to this comparison is detailed by British Steel. '*The use of lead in steel promotes: 1. Lower energy costs and a reduction in CO_2 emissions during machining, 2. Lower manufacturing cycle times, 3. Long machine tool life, 4. Improved surface finish, 5. Promotes chip breaking during the machining process*.' (British Steel 2021)

Another seven contributions were submitted addressing all exemptions or the alloy exemptions under assessment in this study.

- The **Federation of the Swiss Watch Industry FH** (2021a) supports the UP's request for renewal of 6(a)/6(a)-I (as well as 6(b)-II and 6(c)). They explain their view based on specific material requirements in watches. '*The watch industry has* *already substituted a long time ago lead alloys in external watch components. For internal components of the watch movement, substitution is more challenging […]'* Projects exist as to the substitution of lead-containing internal brass components of watches. For details of this specific application example, please refer to the contribution provided by the Federation of the Swiss Watch Industry FH (2021a).

- The **Swedish Chemicals Agency** KEMI (2021) addresses in a general comment all alloy exemptions under review (6b, 6b-I, 6b-II, 6c) and also exemption 6(a) and 6(a)-I. KEMI claims that the exemptions should be adapted to the corresponding level of the REACH restriction entry 63 (for further information see section 4.1). Furthermore, KEMI states that the exemption formulation should specify both the material or component and the specific applications. With regards to the hot dip galvanisation, KEMI refers to a conflict of interests with regards to energy savings by recycling of metals containing lead compared to the production of lead-free virgin metal on the one hand side, and placing hazardous substances (here: lead) on the market as long as recycling of the lead-containing metal continues. In KEMI's view, neither is preferred over the other, rather it is said that "*one way to get around this in the long run could be to recycle metals containing lead in one loop while metals without lead is recycled in another loop so as not to contaminate all recycled metals.'*
- The **Norwegian Environment Agency** (2021) expresses similar arguments to the Swedish Chemicals Agency: Based on Recital (19) of the RoHS Directive (2011/65/EU) that '*exemptions from restrictions for certain specific materials or component should be limited in their scope'*, it is put forward that '*the material or component and the specific application need to be defined in the description of an exemption*'. Thus, the exemptions should be '*narrowed down to a scope*'.
- **Test and Measurement Coalition** (2021), see chapter 5.1
- **SEMI Europe** (2021b), see chapter 5.1
- **Fresenius Kabi** (2021), see chapter 5.1
- The contribution of **Huawei** (Andrae 2020) consists of a paper of A. S. G. Andrae (2020) on the analysis of environmental implications of RoHS exemptions 4f, 6a, 6b, 6c, 7a, 8b, 15(a), 15 and 34 of Annex III. As for leaded steel, the work compares four proxies of environmental impact (e.g. abundance in earth's crust and in the oceans) only to the point of the alloy composition. Impacts at other life-cycle stages or aspects such as e.g. different machining properties of the alloys are not considered.

In addition, eighteen organisations have expressed their support of the request for renewal of this exemption but did not provide any further detail: Arco Armaturenfabrik Obrigheim KG; Swiss Steel Group (Swiss Steel AG, Steeltec GmbH and Steltec AG); Trautwein Präzisionsdrehteile GmbH; Hacker-Feinmechanik; CARL DILLENIUS METALLWAREN GmbH & Co. KG; STERO GmbH & Co. KG; HEINRICH MUELLER GMBH; HUGO KARRENBERG & SOHN GMBH & CO. KG; Wilhelm Schauerte GmbH & Co. KG; Julius Klinke GmbH & Co. KG; Carl Leipold GmbH; wafi Walter Fischer GmbH & Co. KG; Heinrichs & Co. KG; Güntert Präzisionstechnik GmbH; Eisenhardt Metallteile GmbH; Paul Weber GmbH & Co.KG; Maier GmbH & Co. KG Präzisionstechnik; Fischer Automaten-Drehteile GmbH & Co. KG.

6.2.5. Critical Review for leaded steel for machining purposes

REACH compliance – Relation to the REACH Regulation

See section 4.1 for details.

Scientific and technical practicability of substitution

Based on the information provided through the two applications, possible alternatives are a one-to-one substitution in the alloy composition of lead through bismuth, and a shift from leaded free-cutting steels to another type of free-cutting steel which is lead-free, i.e. 11SMn30-EM + C, at least for some applications which are however not further detailed by providing e.g. examples.

Regarding other types of free cutting steel, the contribution of British Steel (2021) to the stakeholder consultation supports a renewal of the exemption with regards to lead in steel for machining purposes. British Steel '*does not believe 11SMn30-EM + C is a viable alternative to leaded steel grades*', however there is no evidence provided to support this statement. British Steel states that they '*routinely investigate improvements in steel making techniques including the use and alternatives to alloying elements*.' No additional information was provided as to concrete activities, nor when alternatives to lead as an alloying element could be expected on the market. The consultant understands that a one-to-one substitution will not provide the mentioned improvements with regards to phase-out of lead in steel for machining purposes as British Steel also mentions that '*all [alternative alloying elements] provide poorer results in terms of benefits for machinability and tool wear*'.

Regarding bismuth as substitute, the UP explained that in specific cases (which are not detailed), bismuth could technically be used as a machinability enhancer: '*Bismuth has been able to substitute for lead under certain conditions, although the reduced hot ductility and the increased cost of Bi additions may make it uneconomic*' (Umbrella Project 2021c). The UP relativized the statement '*that the applicant is aware of examples of successful substitution using bismuth and that those examples are only hindered by economics*.' (Umbrella Project 2021j) by explaining that this was a misunderstanding, instead '*there may be certain conditions under which the (downstream) machinability of bismuth steels in final application can be viable, but the adverse impacts of reduced hot ductility during the rolling processes carried out by the (upstream) steelmaker make the substitution by bismuth steels non-viable due to significantly lower material efficiency within the supply chain.*' (Umbrella Project 2021j). To conclude, though the UP mentioned bismuth as a substitute for lead in steel. However, additional clarifications provided in September 2021 revealed that bismuth technically has no potential at all for substituting lead due to upstream technical needs regarding hot ductility in steel manufacture. Despite the fact that substituting lead through bismuth is technically not practical, the UP still discusses adverse environmental and socioeconomic impacts of bismuth.

In the earlier evaluation in 2015/16, various stakeholders provided insights on their developments towards lead-free steel, e.g. resulfurised steel by Nippon Steel and Sumitomo Metal Corporation (NSSMC). At that time, NSSMC supplied material in the Asian market, but not in Europe. It is assumed that this has not changed since they did not contribute during the current review of Ex. 6(a). In 2015/16, PennEngineering stated that they had started to test rephosphorised and resulfurised lead-free free-cutting steel in 2012 but did not reveal details of the technical changes in order to protect the '*significant investment in preparing for the eventual removal of RoHS Exemption 6a*' (Gensch et al. 2016). PennEngineering (2021a) affirmed that they "*no longer use leaded steel for any product machined from steel bar. We no longer use exemption 6a and would have no issue if it were not renewed.*" PennEngineering is a manufacturer of specialty fasteners. "*The lead-free steel fasteners are made possible by applying new materials, processes, and tool technologies without compromising fastener quality and performance*."[19] PennEngineering did not reveal the identity of the substitute but pointed out that is not bismuth based (PennEngineering 2021b).

Besides the fact that very little information on possible substitutes for lead in steel for machining purposes was provided by the applicants or stakeholders, the consultant identifies three main gaps and shortcomings:

(1) The applications did not specify any efforts to reduce lead levels in steels for certain applications. Compared to the previous review for a renewal of this exemption in 2015/16, the applicants did not show any new studies or projects to work towards reducing or substituting lead. The progress of initiatives of lead-free steel by NSSMC also remains unclear.

(2) Additionally, the explanations and argumentation provided by the UP's application stay generic in nature. As Röhm GmbH only applies for a renewal of the exemption for a very specific application, i.e. drill chucks, provided arguments relate to this application of leaded steel specifically, in contrast to the UP's application which does not detail any information for specific applications.

(3) The UP proposes bismuth as a substitute based on similar machining performances in the machining of final steel parts (supply chain tier 2), however, also explains that bismuth has no potential to technically substitute lead due to limitations in hot ductility needed for the steel making (tier 1), esp. in rolling. In the opinion of the consultant, this would suggest that industry does not continue to research bismuth as a potential substitute.

The Swedish Chemicals Agency KEMI supported by the Norwegian Environment Agency does not agree to the broad scope of the exemption: '*Article 5 in the RoHS directive (2011/65/EC) stipulates that exemptions can be included in Annexes III and IV for materials and components of EEE for specific applications. Our interpretation is that both the material or component and the specific applications need to be defined in the description of an exemption. Otherwise, the need for an exemption cannot be assessed*.' (KEMI 2021; Norwegian Environment Agency 2021)

In this review process, neither the applicants, and specifically the UP, nor any other stakeholders provided enough information to allow concluding as to the developments of lead-free steels, roadmaps towards a reduction of lead, single applications where lead could be substituted through bismuth or the like. In 2016, Gensch et al. concluded that machining companies might be the right stakeholders for providing more

[19] https://www.pemnet.com/pennengineering-announces-expanded-lead-free-initiative-promoting-environmental-sustainability-and-marketplace-objectives/#more-26274

precise information. These supply machined parts to EEE manufacturers. Both, EEE manufacturers[20] as well as machining companies[21], are members of the Umbrella Project. Though this may explain why they did not participate in the stakeholder consultation separately, the consultant cannot identify any reflections of EEE manufacturers in this direction in the application. At this point of time, the consultant concludes that there is not enough information available to be able to narrow down the scope of the exemption which is viewed as very wide.

The consultant sees the European Commission's intention to monitor more closely substances such as critical raw materials (CRMs), substances of very high concern (SVHC) in articles, and other listed substances, e.g. within the activities of the Community Rolling Action Plan (CoRAP). More explicitly, EEE manufacturers are obliged from 05.01.2021 onwards to report to the SCIP database[22] if the application contains substances from the REACH candidate list. In addition, original equipment manufacturers (OEMs) are requested more and more to communicate along the supply chain. It is assumed that this is also true for UP members. The consultant recommends that the applicants prepare a more detailed list as to their products (and their lead content) based on such information which is expected to be available through their supply chain communication activities in the future. Against the background that the scope of the exemption is viewed as very wide, based on the above-mentioned list of different applications, industry should be able 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 the main areas of use. Otherwise it is not considered justifiable to keep the exemption's wording with regards to leaded steel for machining purposes in the next evaluation.

However, for drill chucks for which Röhm GmbH requests the renewal of the exemption, the consultant recognizes the applicant's concerns with regards to reliability and availability of the potential substitute (11SMn30-EM + C). As to the reliability in combination with environmental arguments, the consultant understands from Röhm's justification that a power tool with components from lead-free steel needs more rotations per minute, thus more energy, with additional impacts on the lifetime of tool and its components. As no measurement data was provided the consultant cannot not verify this claim. As to the aspect of availability, see socio-economic implications below.

Environmental arguments and socioeconomic impacts

Energy savings for machining leaded vs. non-leaded steal as well as general environmental impacts of lead vs. bismuth (separately from steel) are the two environmental aspects presented as relevant for this evaluation.

[20] For example: ZVEI German Electrical and Electronic Manufacturers' Association; EPTA European Power Tool Association; NECA Nippon Electric Control Equipment Industries; Digital Europe; etc.

[21] For example: EPCIA European Passive Components Industry Association; ESIA European Semiconductor Industry under the legal entity of European Electronic Component Manufacturers Association; FIM Fédération des Industries Méchaniques; WSM Wirtschaftsverband Stahl- und Metallverarbeitung e.V. etc.

[22] Database for information on Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive; https://echa.europa.eu/en/scip

The Umbrella Project (2020a) raises general environmental arguments, i.e. that '*lower energy consumption of machining leaded steels means that there is a potential benefit of reduced electricity consumption and CO_2 emissions in fabrication*'. This is supported by LCA studies provided that deal with the comparison of the manufacture of a leaded and non-leaded steel component (2015).

- Nuss and Eckelman (2014) compare impacts of extraction and refining of different metals, showing a preference for lead over bismuth in all of the evaluated impact categories which was found the best substitute for some applications from a technical perspective.
- The study provided by Huawai (Andrae 2020) as a contribution to the stakeholder consultation compares 11S30Mn (the most common type of free-cutting steel) with 0.35wt% Pb vs. 0.3wt% Bi with regards to cumulative energy demand, abundance and two economic impact categories[23]. Due to shortcomings in the description of the methodology, it is difficult to follow Andrae's conclusion: '*the increase is insignificant for energy demand and eco-cost but very high for relative resource scarcity (abundance) and potential for future sustainable production (EPS)*.' Both references indicate a preference for lead over bismuth. However, no cradle-to-grave LCA was provided that would have taken into account the end-of-life impacts of products containing lead, e.g. impacts on human health from releases of lead in the end-of-life, compared to non-toxic bismuth. As measures were deemed '*necessary to reduce the waste management problems associated with the heavy metals*' (Recital 7, RoHS 2 2011), the end-of-life is considered an important life-phase for a comprehensive comparison. The consultant cannot conclude whether the total negative environmental, health and consumer safety impacts caused by bismuth (higher at early life cycle stages compared to lead) are comparable to the total environmental, health and consumer safety impacts caused by lead (possibly higher at end-of-life compared to bismuth) or not.

In relation to the critical raw material character, which has been acknowledged by the EC[24], the consultant understands this to refer mainly to the risk of future supply. This is concluded as the applicants did not raise particular environmental aspect that have been taken into consideration in the analysis performed to identify bismuth as a CRM. The consultant considers the identification of bismuth as a CRM as a serious issue. Nonetheless, the economic aspects that are understood to contribute to the categorisation of a material as having supply risks do not relate to the three main criteria of Article 5(1)(a) but rather only to the secondary criteria of availability. The information provided furthermore does not allow to assess the severity of this risk and how it could affect the market in the future should bismuth be found beneficial as a substitute for lead in steel alloys in certain applications. In so far, the political relevance of the identification of bismuth as a CRM is not further investigated as it is considered to

[23] Environmental Priority Strategy (EPS); Steen B. Calculation of monetary values of environmental impacts from emissions and resource use—The case of using the EPS 2015d impact assessment method. J Sustain Dev **2016**; 9: 15. https://doi.org/10.5539/jsd.v9n6p15) & Endpoint modelling (Itsubo N, Murakami K, Kuriyama K, Yoshida K, Tokimatsu K, Inaba A. Development of weighting factors for G20 countries—explore the difference in environmental awareness between developed and emerging countries. Int J Life Cycle Assess **2018**; 23: 2311-2326. https://doi.org/10.1007/s11367-015-0881-z)

[24] See: https://ec.europa.eu/growth/sectors/raw-materials/specific-interest/critical_en

be beyond the mandate of this review which is based on the Article 5(1)(a) criteria for justifying exemptions.

Even though this cannot be brought forward as a main part of the argumentation, it is noted, that the presence of lead in steel is known for a long time. '*The steel industry has in place the appropriate practice and processes to ensure that metals like lead are recovered and made available for recycling and reuse'* (Umbrella Project 2020a). Industrial emissions e.g. from steel manufacture are controlled through the corresponding legislation (Industry Emissions Directive), and it can be assumed that workers' health measures are in place, at least in the EU.

As to the aspect of availability of the potential substitute (11SMn30-EM + C) provided by Röhm GmbH, i.e. that there is only one supplier on the market, and market acceptance with regards to product quality and price is unclear, such arguments are not applicable for justifying RoHS exemption evaluations according to the Article (5)(1)(a) criteria, i.e. the primary criteria. However, in addition to these primary criteria, '*decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account the availability of substitutes and the socioeconomic impact of substitution.*' (RoHS 2 2011) Information to conclude on the aspect of availability is only partially available. The consultant wonders whether this substitute has limited availability due to low market uptake, seeing as it is relatively unknown and the UP members could not provide any information as to this steel ('*UP Exemption #6a WG Participants do not have enough information on this alternative so far, so we cannot conclude if it can be used for <u>all</u> specific applications*' (Umbrella Project 2021c)). The consultant recommends that industry consider this alternative steel and the identification of those applications where it could be used in the next few years. Should this prove a viable alternative in some applications, it would not only allow reducing the total amount of lead used in steel alloys, but could also contribute to an increase in the demand for this material and subsequently also in its supply in the future.

It should be noted, that it is not expected that a one-fits-all solution will be found for lead in steel alloys used in machined parts but rather that different substitutes can be applied to different groups of applications which thus can be separated from each other. A distinction between future substitute candidates and their range of application may become relevant in the future, and for this purpose industry should investigate how certain applications could be grouped in terms of the different properties of the lead alloy required for machining or different properties required for the operation of the EEE component parts made of such alloys.

<u>Scope of the Exemption</u>

In steel, where it is used for machinability, lead is intentionally added to the alloy. In machinability applications, the lead reduction potential is lower compared to hot dip galvanisation. The consultant does not see a possibility to reduce the threshold with regards to lead in steel for machinability based on the information provided by the Umbrella Project (see above), however, it is definitely necessary for the industry to support the exemption evaluation through close collaboration on identifying those applications, sectors and EEE categories, for which this exemption is essentially needed. The example of PennEngineering shows that substitution is basically possible but needs adaptations in machining processes and tools.

As the consultant does not see a possibility for narrowing down the scope of the exemption in this evaluation, the consultant concludes that the exemption should only be renewed to allow EEE manufacturers to compile the information in order to specify the applications where they need leaded steel for machining purposes. In order to put higher pressure on the members of the UP’s consortium for this collaboration, the consultant concludes that an exemption for lead in steel for machining purposes should only be granted for a short period of time.

6.2.6. Conclusion for leaded steel for machining purposes

With regards to lead in steel for machining purposes, it is claimed that bismuth and other types of non-leaded machinability enhancers in steel are technically unsuitable in the majority of cases. However, no example was provided where substitution may be technically possible. The consultant emphasizes that no progress at all has been made compared to the last evaluation. Compared to the evaluation in 2015/16, hardly any new information (e.g., pictures, statistics, etc.) have been presented to support this claim. Furthermore, despite the fact that only at a late stage of the evaluation it became clear that Bi technically has no potential to substitute lead due to its disadvantageous hot ductility, from the available information it is additionally not possible to conclude as to the best environmental option when comparing the bismuth with lead. As to the type of non-leaded steel provided as an alternative by Röhm GmbH, this type of steel is understood to have not been rejected for use in drill chucks from a technical point of view (figures, statistics, etc., were not provided in this respect), but rather in light of availability concerns. The UP was not able to conclude as to the suitability of this substitute. Substitution with bismuth may also be constrained from a technical as well as an availability perspective due to bismuth being identified as a critical raw material by the European Commission[25]. The current formulation of the exemption is considered to be too wide as it could be used both when substitutes are available as well as when they are not. The example of PennEngineering shows that substitution is possible.

Nonetheless, stakeholders did not provide sufficient data to allow a reformulation. This situation is very similar to the state of the exemption in the last review performed in 2015/2016 by Oeko-Institute (Gensch et al. 2016).

Revoking the exemption is not considered pragmatic as it would *de facto* require a transition in a very short time and is likely to result in withdraw of products where substitutes still need to be developed, where a design adjustments must be made and/or where the availability of substitutes is not sufficient to allow a quick transition of the whole EEE sector. Nonetheless the current Directive does not provide for a longer transition period. A short-termed exemption is therefore considered necessary.

Should industry fail to provide sufficient and relevant data in the next assessment, than it would be recommended to withdraw the exemption, possibly allowing a longer

[25] See “**Fourth list of CRMs”** published in 2020 in a European Commission communication on critical raw materials, COM(2020) 474 final

transition period that would be sufficient for implementing a phase-out where it is possible, but also for identifying application areas where this is not the case and for applying for new and specific exemptions. A short-termed exemption shall allow industry to gather information as to lead content and EEE components that need the exemption for leaded steel for machinability purposes based on supply chain communication which is expected to exist anyway. This may include an analysis of the SCIP Database. The consultant expects from an application for renewal for this exemption that it clearly elaborates the supply chain from sourcing of raw materials to machined parts, and that the technical practicability and reliability of presented alternatives to the RoHS substance is comprehensively discussed for the various steps of the supply chain. Initial results provided by the industry working group or associations shall trigger individual industry stakeholders, such as machining companies, to specifically comment and complement the list of applications (see also the final conclusion and recommendation, i.e. chapters 6.4 and 6.5, including expected tasks to be fulfilled during this shortened extension of the exemption). In light of the information presented during the evaluation of the exemption request in 2015/16, e.g. photos, technical characteristics of steel components with different lead contents, more detailed listing of different steel compositions etc., and seeing that the conclusion of the evaluation report in 2016 states that '*the current scope is not justified*' and suggesting to '*conduct a survey amongst EEE component manufacturers 'in order to narrow the scope of the exemption to a comprehensive list of applications'* (Gensch et al. 2016), it is crucial that data of relevance is provided which allows the consultant to draw evidence-based conclusions that are in line with the targets of the RoHS Directive.

In the last evaluation, it was already recommended to split the exemption and separate an item for lead in steel for machining purposes which was not followed by the European Commission. The split is urgently recommended again because it would allow to better focus on the substitution needs of relevant applications. For lead in steel for machining purposes, industry is urged to generate input that would allow narrowing the scope of the exemption to a comprehensive list of applications.

6.2.7. Recommendation for leaded steel for machining purposes

It is recommended to split the two applications covered by Exemption 6(a) and 6(a)-I. It is further recommended in order to avoid future co-existence of several sub-items with slightly different scopes to align all categories in terms of the validity period, seeing as stakeholders did not provide information to show that technical differences exist between categories regarding the substitution of lead in steel. For further details on this view, see chapter 6.5.

As for leaded steel for machining purposes, all EEE Categories should be covered by an exemption item dedicated to this application group to be listed in the Directive in the future:

	Exemption formulation	Duration
6(a)-I	Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight	Expires on 21 July 2024 for all categories

6.3. Hot dip galvanised steel

6.3.1. Technical description for hot dip galvanised steel

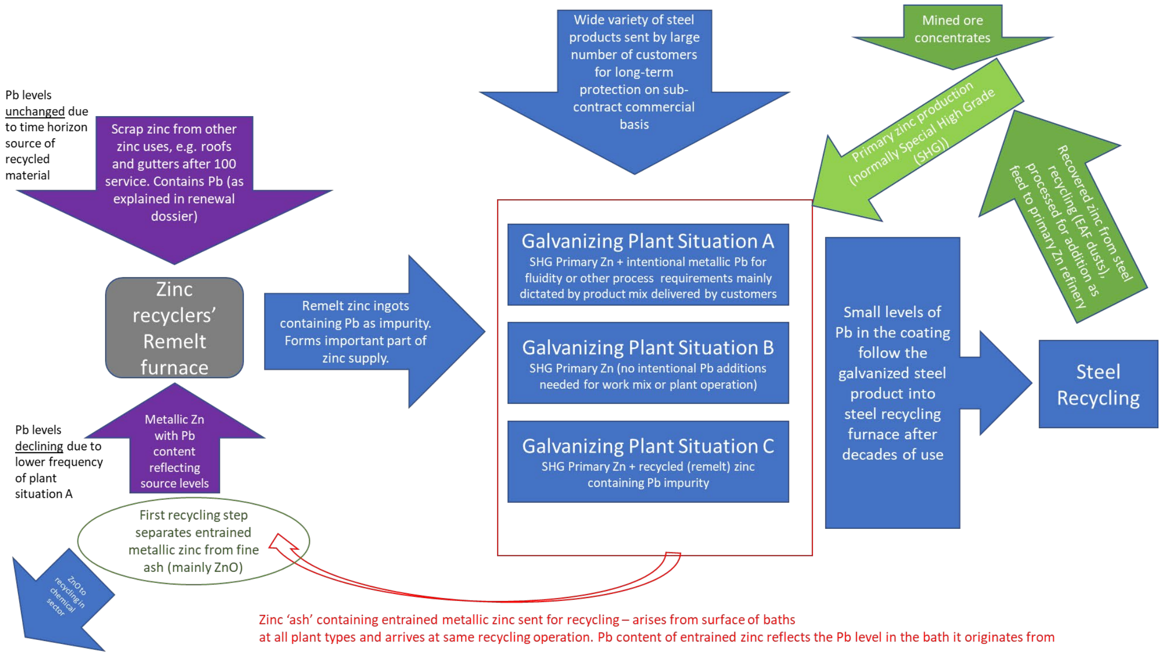
According to the applicant (Umbrella Project 2020a), components are batch galvanised to provide highly durable corrosion protection, resistance to mechanical damage, increased durability allowing lighter steel sections, with another advantage (or rather side effect) being recyclability within existing steel recycling circuits.

The galvanization process results in a zinc coating on iron and steel products by immersion of the material in a bath of liquid zinc. Lead is present as an impurity related to the use of recycled material and remelts of the entrained zinc from the galvaniser's ash for the baths of liquid zinc used in the galvanisation process. During the galvanising reaction, zinc-iron alloys are formed on the surface of galvanised products. Due to the low solubility of lead in the zinc-iron alloys, lead concentrations within the coating on the product are typically half as much as the lead present in the process bath. The lead content of a coating depends on the steel type's reactivity with molten zinc, on the technical features of the plant (related to the age of the plant) and the concrete galvanisation process. During recycling in electric arc furnaces, the zinc in the steel volatilizes quickly compared to the steel core (RED STEEL 2018). The zinc is collected, recycled and returned to zinc production.

Usually, primary zinc does not contain lead impurities (green arrows and Galvanising Plant Situation B in **Figure 6-1** below). The background for lead in galvanised steel is generally that:

- in some case secondary zinc is used which often contains lead, e.g. zinc from roofing includes leaded solders, and contributes to the contamination of the galvanised layer; (Galvanising Plant Situation C in **Figure 6-1**)
- in some cases lead is still contained in the galvanisation baths as a residue from earlier batches, also leading to contamination; (Galvanising Plant Situation C in **Figure 6-1**)
- in other cases, clients ask for lead to be added to the baths to ensure high quality of the coating through lead-initiated drainage of superfluous material. This is typical for applications with small details in their geometry. (Galvanising Plant Situation A in **Figure 6-1**)

Figure 6-1: Flows of Pb-containing materials from different sources and how they are combined in the recycling industry



Abbreviations: SHG = Special High Grade
Source: EGGA (19.08.21) on behalf of the UP

Lead has no beneficial (or adverse) effect on the coated product but influences the galvanization as such: As indicated, it has a positive effect on the drainage of coating material which is especially good in the case of complex geometries where adverse surface finishes can be avoided through a lead-mediated drainage. It can be understood that mainly, the batch galvanised non-EEE components profit from this effect. Thus the UP still claims that at present, some plants intentionally add lead to the zinc bath for improvement of drainage of the coating of the galvanised product '*which is rapidly declining due to technical innovation*' (Umbrella Project 2020a).

Presenting an exhaustive list of applications is not feasible; components include brackets, fixings, fasteners, ancillary items but also large structural steelwork of up to 25m length and '*lighting units that require high levels of durability in outdoor and aggressive environments*'. A total of 7 million tonnes of steel is batch galvanized in Europe, the volume of components in the scope of RoHS and ELV '*is extremely small'*. (Umbrella Project 2020a)

Asked as to the use of batch galvanised components in EEE Categories 8 and 9, the UP (2021f) explains that '*no detailed information is available on the use of batch galva-nized steel in these applications. However, it is highly probable that batch galvanized steel is not used in Category 8 uses (medical devices). It is possible that batch galvanized steel is used for fasteners, brackets and support structures in industrial monitoring equipment which falls in Category 9.*'

6.3.2. Amount of lead used under the exemption for hot dip galvanised steel

For batch galvanised steel, '*the amount of Pb metal used intentionally for applications in the scope of WEEE/ROHS is estimated to be less than 1 tonne p.a.'* (Umbrella Project 2020a). Being asked as to what 'used intentionally for applications in scope of WEEE/RoHS' means, the UP clarified that less than 1 annual ton of lead is intentionally added to the galvanisers melts (Umbrella Project 2021f). In contrast, for lead entering the markets from recycled zinc sources, the UP estimates ~ 0.4 ton/year[26].

6.3.3. Applicant's justification for the requested exemption for lead in hot dip galvanised steel

It is noted that lead in hot dip galvanized steel is in scope of the Umbrella Project's application but not in scope of the Röhm application. This chapter thus only summarises the UP's justification for the requested exemption.

Substitution or elimination of lead

Substitution of lead in zinc originating from recycled zinc is not applicable. The UP (2020a) states that the intentional use of lead is now limited to a narrow set of processes. Research on '*new zinc-based alloys for general galvanising*' is ongoing. Asked to specify these processes, the UP (2021c) states: '*The processes are those operated by galvanizing plants that would process, on a sub-contract basis, EEE products for which the technical features are required (e.g. complex parts requiring fluidity). These plants will not only be processing these EEE products and for trade and open competition reasons the processing of EEE should not be restricted to specific galvanizing plants. Hence, the separate processes are not identifiable as such*.' Additionally, it is explained (Umbrella Project 2021f) that '*batch galvanising plants will serve a wide range of customers that will send a wide range of steel products to be galvanised'*. Compared to components for construction, engineering, agriculture, and renewable energy, EEE only have a '*small proportion of the overall work'*. From the fact that '*there remain a small number of plants for which substitutes or omissions of lead additions are not feasible based on their typical work mix'*, it is understood that certain batch galvanizing plants are specialised in producing galvanizing products with complex geometry. In contrast, '*most plants will have lower demands on fluidity and have therefore been able to switch to alternative approach or substitutes*.' (Umbrella Project 2021f)

According to the UP (2020a), the galvanisation sector is an important user of melts from recycled zinc e.g. from roofing applications with Pb-containing solders and galvanizers' ashes. However, '*customer-driven requirement for lower lead levels in markets outside EEE/ELV and the occasionally higher price of lead than zinc (affecting intentional use)*' are factors reducing the lead in galvanised coating. In the long term,

[26] This is based on the assumptions that '2000 tonnes of steel EEE products galvanized in plants using the highest typical level of Pb in the bath of 0.7% arising from inputs of recycled zinc to the bath; Pb retained in the coating is ~50% of the bath concentration; and Zinc pick-up on the steel is 6% of steel weight (2000 x 0.06)x 0.0035 = 410kg)' Umbrella Project (2021f)

30-50 years due to the lifetime of products going into recycling, lead in recycled zinc will be diluted.

Asked whether the Pb amount in the exemption formulation could be lowered, UP states that 'the European secondary zinc industry may be able to reduce the Pb levels in recycled zinc available to batch galvanising industry by channelling recycled zinc with high Pb levels into sectors where the technical demand for Pb-containing zinc remains.' And further: 'The reductions compared to 2016 levels may as high as 25% although its impact on the exemption threshold is not directly transposed in the same proportions'. (Umbrella Project 2020a; 2021c) As to the reductions of lead introduced into the galvanisation bath by remelts from galvanizers' ashes, the UP explains that 'lead accumulates at the base of the galvanizing bath and takes many years (5-7 years and sometimes longer) to be lowered to de minimums levels after additions have been terminated.' (Umbrella Project 2021f)

To sum up the justification provided, the UP states that 'whilst the primary justification for the exemption is the need to avoid disruption to established recycling loops, there remain a small number of plants that require the intentional additions of lead to the galvanizing bath for technical reasons'. (Umbrella Project 2021f)

Environmental arguments

The UP argues that the use of recycled / secondary zinc is more energy efficient than the use of primary zinc, and that there is no technique available to separate Pb in / from the zinc melt of recycled zinc, rather the applicant expects a dilution of Pb over time. Thus, no benefit was identified for changing the existing practice for galvanisation. (Umbrella Project 2020a)

Socioeconomic impacts

UP does not specifically refer to socio-economic effects of substitution.

However, when asked as to their view on amending the exemption in a way that aims at the maintenance of established recycling loops (from secondary zinc as well as remelts) but excluding intentional use of lead for increased fluidity, the UP strongly disagrees: if plants intentionally adding lead for processing non-EEE components of complex geometry were precluded from the processing of EEE, this would lead to market distortion and/or increased transport distances (Umbrella Project 2021f).

6.3.4. Stakeholder contributions

See chapter 6.2.4

6.3.5. Critical review for hot dip galvanised steel

REACH compliance – Relation to the REACH Regulation

See section 4.1 for details.

Scientific and technical practicability of substitution

Lead is both intentionally and unintentionally present in galvanisation processes where it is introduced through recycled zinc in the latter case. As indicated (chapter 6.3.2), the Umbrella Project estimates ~ 1 annual ton and ~ 0.4 ton / year for intentional and unintentional addition of lead, respectively.

Small amounts of lead in the melt are not disadvantageous from a technical point of view, the exceeding coating material can run off better due to the lubricating effect of Pb. Therefore, there is no interest of the galvanisers in the substitution of lead in the melts nor in separation of leaded and non-intentionally leaded zinc recycling streams. Batch galvanising plants that do not use recycled zinc in their input material, or that do not process components of complex geometry '*would comply with the* [RoHS] *default requirements'*. It is understood that this refers to a content of lead below 0.1% by weight which is the maximum concentration value tolerated by weight in homogeneous materials for restricted substances in Annex II RoHS Directive (Umbrella Project 2020a). It can be concluded that it is not technically useful to substitute the lead in hot dip galvanised steel, additional considerations relate to environmental aspects.

Asked whether the Pb amount in the exemption formulation could be lowered, the argumentation of the UP does not provide a specific answer to this question, rather the explanation can be understood as a suggestion to remain with the current 0.2 % threshold. The available information does not support that lowering of the Pb threshold in Ex. 6(a)-I would be feasible at this time.

Environmental arguments and socioeconomic impacts

Material flows for supply and recycling of zinc in galvanisation are detailed in Figure 6-1.

It is understood that the unintentional introduction of lead is merely a result of lead originating from lead solders in zinc roofing and remelts from galvanisers' ashes, thus, being present in the secondary zinc. Already mentioned by KEMI (2021), there is a conflict of interests whether to save energy through the use of recycled zinc containing lead or whether to reduce the presence of lead in products using virgin material at the same time taking into account high energy consumption during the production of virgin material. The consultant agrees on the existence of the above-mentioned conflict of interest. However, there is the potential that the intentional additions of lead may be reduced, and that concentrations may decrease over time as the less lead is introduced by recycled zinc the further it is diluted. Thus, the consultant can follow the argumentation that the recycling of zinc scrap and its reuse is a positive practice, as it enables a reuse of resources. This opinion hasn't changed since the evaluation of the exemption in 2016 (Gensch et al. 2016).

However, some plants remain with the practice of intentionally adding lead as components of complex geometry are part of their typical work mix. It is understood that the majority of such components is from non-EEE sectors. The consultants acknowledge that amending the exemption in a way that aims at the maintenance of established recycling loops (from secondary zinc as well as remelts) but excluding intentional use of lead for increased fluidity could result in '*market distortion'* which was brought forward by the Umbrella Project (2021f). Not extending the exemption for intentional use of lead in galvanising processes would mean that the EEE clients could only make orders with galvanisers that do not intentionally add lead when manufacturing parts for other than EEE clients. There is no information on the number of such plants. Given that EEE parts are understood to represent a very small share of the galvanised part market, it is assumed that the EEE sector would have little influence over galvanisers. It is unclear if the number of galvanisers willing to commit to no longer adding lead would have future impacts on the EEE sector or not. It is however assumed that galvanisers that deal with components for EEE as a small part of their mix, would not be willing to "sacrifice" clients from other sectors that have a larger market share as this could affect their viability. In addition, the consultant considers *'increased transport distances'* possible *'if these plants were precluded from the processing of EEE*'. (Umbrella Project 2021f)

However, the UP (2021c) states that the secondary zinc industry could already achieve lower lead concentrations today, although exact concentrations are not known. UP adds that '*higher Pb-containing recycled zinc may be channelled to other sectors where the technical demand for Pb-containing zinc remains.*' (Umbrella Project 2021c) This is in line with KEMI's proposal '*to recycle metals containing lead in one loop while metals without lead is recycled in another loop so as not to contaminate all recycled metals*' (KEMI 2021).

If the amounts of lead intentionally added were lower, or if zinc ashes from galvanisation plants intentionally adding lead were treated/recycled separately from the ashes from plants that do not add lead intentionally, it could be assumed that the amount of lead in recycled zinc decreases over time when zinc scrap that no longer contains lead will also be recycled. However, as this is currently not the case, '*dilution is not yet in evidence'* (Umbrella Project 2021c). In the view of the consultant, a separation of leaded and non-leaded material streams should be envisaged for both unintentional and intentional presence of lead in galvanised steel, to determine e.g. whether it is possible for EEE manufacturers to avoid galvanisers that still add Pb purposefully and based on the portfolio of galvanisers intentionally adding lead identifying the share of EEE components amongst their typical work mix of those galvanisers (see recommendations listed in the conclusion for hot dip galvanised steel, chapter 6.3.6).

Scope of the Exemption

The UP was asked whether in analogy to exemption 6(b)-I, an alternative wording for 6(a)-II could be used: "lead as an alloying element in galvanized steel containing up to 0,2 % lead by weight, provided it stems from lead-bearing zinc scrap recycling". The UP strongly disagrees: if plants intentionally adding lead for processing non-EEE components of complex geometry were precluded from the processing of EEE, this would lead to 'market distortion and/or increased transport distances' (Umbrella Project 2021f). From the perspective of an EEE manufacturer who needs a supply of hot dip galvanised steel parts, the availability of galvanisers operating lead-free is limited. In most cases, the parts will be galvanised in baths, that use secondary zinc (from scrap or galvanisers' ashes). In some cases, e.g. due to proximity to the manufacturing plant, galvanisation of EEE components will take place in baths where lead is intentionally added. For those galvanisers intentionally adding lead, EEE components represent a small part of their work mix. Therefore, as long as galvanisers do not have to substitute or reduce lead for steel parts from non-EEE sectors, EEE manufacturers will not have a high economic power to push towards lead reductions. It is concluded with regards to the scope of the exemption for lead in batch galvanised steel, that the intentional addition of lead to the melt should not be treated differently than unintentional presence of lead for the time being.

When asked if **Cat. 8 and Cat. 9 EEE** covered under Ex. 6(a) until July 2021 should be merged into Ex. 6(a)-I in the future, the UP replied that '*all EEE Categories and subcategories covered under Ex. 6(a) would be merged into Ex. 6(a)-I in the future […]'* with the following proposed wording for all EEE categories and subcategories '*Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight and in batch hot dip galvanised steel components containing up to 0,2 % lead by weight'*. This would effectively reduce lead as an alloying element in galvanized steel from 0.35 % to 0.2% for Cat. 8, Cat.9 and Cat. 11. However, it is assumed that based on UP (2021f) hot dip galvanised steel parts do not play any role in Cat. 8 and a minor role in Cat. 9. COCIR, an association with members producing Cat. 8 devices is part of the Umbrella Project, thus of the applicant consortium which apply for the renewal of the exemption. Furthermore, the supplies for Cat. 8 and Cat. 9 devices are expected to be the same supply as for the other EEE Categories. Thus, if the market is ready to supply galvanised steel with a max. of 0.2% of lead, this material should be usable for Cat. 8 and Cat. 9.

Argumentation that a reduction of the threshold would not be feasible for Cat. 8 or Cat. 9 EEE has also not been included in the submissions to the stakeholder consultation nor raised as a technical argument by stakeholders.

6.3.6. Conclusion for hot dip galvanised steel

It is understood that there are two cases for the presence of lead. In some plants, lead is present in the galvanisation baths due to the use of recycled zinc or galvanisers' ashes as it precipitates from secondary zinc added to the process. There are other cases where lead may be added to facilitate the galvanising process of certain parts (for example steel mesh used for construction) which has rather limited relevance for EEE parts. However, the galvanisation of parts for EEE is performed in the same baths. This is because for EEE component manufacturers, it is not a decision criterion whom they commission their orders to, i.e., whether the galvaniser uses lead intentionally or not. In both cases, the presence of lead in some cases cannot be excluded, but lead is understood not to serve a functional purpose in the galvanisation of steel parts for EEE.

From the available information it is concluded that substituting the lead originating from recycled zinc is not intended due to the benefits of using secondary raw material, and that the demarcation between galvanisers using recycled zinc and those galvanisers adding lead intentionally, i.e. to avoid the latter, is not practical. In galvanisation, the EEE segment is too small compared to other sectors, in order to trigger lead reduction or substitution for non-EEE components in galvanisation processes where lead is intentionally added.

In the 2015/16 evaluation, it was concluded that 'that the lead is mostly not intentionally added (or not added for intentions of relevance to the EEE part properties) […]. The intentional addition of lead to a galvanizing bath where it is technically required could not be separated for EEE specific processes or products, which are understood to have only a small share of all galvanised parts' (Gensch et al. 2016). Based on the provided input, the situation has not really changed. Surveying EGGA's members as to their actual contents of lead in the galvanization baths and on the surface of galvanized parts, would have been desirable, as an option of how industry would have been able to justify the exemption comprehensively.

The only way to remove lead from WEEE containing galvanised steel, i.e. remove the risk of lead contamination, would be to commission EEE parts only to those operators that neither use lead intentionally nor use recycled content, and are thus lead free. Based on the available information it is not possible to conclude if such operators exist nor if there are enough operators that do not add lead intentionally, for the exemption to be able to expire. This should be investigated by industry until the next review.

For the next evaluation of the exemption for lead in hot dip galvanization, industry is recommended to:

- provide measurement data as to the content of lead in different types of galvanisation plants;
- clarify to which extent Pb levels could be lowered when lead-containing recycled zinc would be channelled into those loops that have higher needs to take advantage of the Pb in recycled zinc;
- clarify under which circumstances, it would be possible for EEE manufacturers to avoid galvanizers that still add Pb purposefully;
- carry out an analysis of the portfolio of galvanisers intentionally adding lead, i.e. identifying the share of EEE components amongst the typical work mix of those galvanisers;
- clarify if the use of galvanised steel is evenly distributed between the EEE categories or if only certain categories need the exemption; and
- describe in detail the efforts made to reduce the use of lead in galvanisation.

This would additionally contribute to be able to exclude consumer products from the exemption which is in line with REACH restriction entry 63 which specifies among other things that, under certain circumstances, lead and its compounds shall not be placed on the market or used in articles supplied to the general public.

6.3.7. Recommendation for hot dip galvanised steel

It is recommended to split the two applications covered by Exemption 6(a) and 6(a)-I. It is further recommended in order to avoid future co-existence of several sub-items with slightly different scopes to align all categories in terms of the validity period, seeing as stakeholders did not provide information to show that technical differences existed between categories regarding the substitution of lead in steel. For further explanation, see chapter 6.5.

As for hot dip galvanised steel, all EEE Categories should be covered by adding a new exemption item to RoHS Annex III:

	Exemption formulation	Duration
6(a)-II	Lead in batch hot dip galvanised steel components containing up to 0,2 % lead by weight	Expires on 21 July 2026 for all categories

6.4. Final 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.

Applying these criteria to **lead in steel for machining purposes**, it is concluded that possible alternatives are a shift from leaded free-cutting steels to another type of free-cutting steel which is lead-free, 11SMn30-EM + C, at least for some applications which have not been detailed by the applicant. E.g. PennEngineering completed substitution in specialty fastener (PennEngineering 2021a; 2021b).

There remain applications for which substitution is claimed not to be technically practicable or reliable. A one-to-one substitution in the alloy composition of lead through bismuth was excluded due to technical impracticability.

As almost the same conclusion was drawn in the last assessment, a renewal of the exemption should only be granted for a very short duration in order to clarify these remaining applications. A future application for a renewal of the exemption should be application specific.

As to **lead in batch galvanised steel**, the presence of lead is both intentional and non-intentional; it is unclear if avoidance of galvanisers intentionally adding lead is logistically practical. From an environmental point of view, seeing that secondary zinc from zinc scrap and galvanisers' ashes is one of the main sources of lead, and additionally seeing that distinguishing those cases where lead is intentionally present is not practical, the use of secondary material should be preferred.

In both applications of lead in steel, no progress has been presented, neither data has been gathered as to derive a roadmap and present a way forward. As already done in the 2015/2016 assessment of the exemption, this review also recommends differentiating between the two uses of lead in steel. The two uses differ in the direction of substitution or reduction efforts. For lead in steel for machining purposes, narrowing the scope of the exemption to a comprehensive list of applications should be the next step. For lead in hot dip galvanized steel, the possibility to manage material streams and recycling loops is understood to allow a phase out of the exemption.

As long as both uses of lead in steel remain under one exemption, it is also likely that less information per application is presented in future exemption requests.

When asked for a split in two entries, UP makes clear their interest in the numbering of the new exemptions: 'In principle, our response to a similar proposal in 2015/16 remains the same. This may create unnecessary complexity to established supply chain compliance systems' (Umbrella Project 2021f). The consultant can follow that a split of the exemption could result in an administrative burden not related to actual environmental benefit. Nonetheless, the consultant interprets recital 19[27] to mean that the scope of an exemption should be developed in relation to a confied group of applications for which the justification and allowed thresholds for the substance from RoHS Annex II is the same. Moreover, in light of the current RoHS Directive's review and possible consequenses thereof for overall legal structureing and text, the consultant points out that most likely, industry will need to adapt their supply chain compliance systems in the near-future in any case.

For each of these application groups a different strategy is proposed:

- For the case of lead in steel for machining purposes, it would be beneficial to formulate an exemption in relation to (remaining) applications where substitution has not yet been accomplished.
- A future exemption on batch hot dip galvanised steel should consider whether the concentration of lead has decreased, whether reorganisation of material flows of recycled zinc is practical, and whether the exemption threshold limit can be lowered accordingly.

A split of the exemption according to these two uses is strongly recommended.

6.5. Final recommendation

It is recommended to grant the exemption with the formulation specified below.

[27] 'Exemptions from the restriction for certain specific materials or components should be limited in their scope and duration, in order to achieve a gradual phase-out of hazardous substances in EEE, given that the use of those substances in such applications should become avoidable.' RoHS 2 (2011).

Exemption formulation	Duration
6(a): Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight and in galvanized steel containing up to 0,35 % lead by weight	— 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.
6(a)-I: Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight	Expires on 21 July 2024 for all categories
6(a)-II: Lead in batch hot dip galvanised steel components containing up to 0,2 % lead by weight	Expires on 21 July 2026 for all categories

While for most categories exemption 6(a) 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. As explained in Section 5, the applicability of these recommendations to EEE in categories which benefit from the validity of Ex. 6(a) beyond July 2021 is not completely clear from a legal perspective. To avoid future co-existence of several sub-items with slightly different scopes it is recommended to align all categories in terms of the validity period, seeing as stakeholders did not provide information to show that technical differences existed between categories regarding the substitution of lead in steel. 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.

To furthermore ensure that RoHS provides a similar level of environment and health protection as that of the REACH Regulation, and with entry 63 of Annex XVII in mind, it is recommended to add the following phrase for precautionary reasons to the exemption wording: "*The exemption shall not be applicable to articles or accessible parts of an article that 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, except where it can be demonstrated that the rate of lead release from the accessible component /part, 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*". Alternatively, this addition could be added as a footnote to the exemption.

7. Exemptions *6(b) and 6(b)-I*: Ex. 6(b) for "Lead as an alloying element in aluminium containing up to 0,4 % lead by weight"; and Ex. 6(b)-I for "Lead as an alloying element in aluminium containing up to 0,4 % lead by weight, provided it stems from lead-bearing aluminium scrap recycling"

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

Al	Aluminium
Cat.	Category (referring to the EEE Categories outlined in Annex
CLP	Classification, Labelling and Packaging
EEE	Electrical and Electronic Equipment
Pb	Lead
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
UP	Umbrella Project
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment
SVHC	Substance of very high concern

7.1. Background

Two applicants, EU Aluminium and the "RoHS Umbrella Industry Project" (hereafter referred to as "Umbrella Project" or "UP") represented by COCIR, HARTING Stiftung & Co and Pepperl + Fuchs AG, have submitted requests for the renewal of the above-mentioned exemptions. A renewal of exemption 6(b)-I is requested by both applicants; in addition, the Umbrella Project applies for a renewal of exemption 6(b). (EU Aluminium 2019; Umbrella Project 2020c; 2020d)

Exemption 6(b) has been reformulated following its last assessment in 2015/2016 (Gensch et al. 2016), which resulted in a split of 6(b)-I and 6(b)-II differentiating between applications of aluminium alloys where lead is unintentionally present (casting alloys under 6(b)-I) and applications where lead provides necessary properties (wrought alloys under 6(b)-II). Applications that use casting alloys have a higher tolerance for alloying elements than wrought alloys, i.e. the alloys can contain higher concentration of the alloying element (with alloy content up to 20% by weight) (Paraskevas et al. 2013).[28] Exemption 6(b), however is still valid for categories 8 and 9 until July 2021 and will remain valid afterwards for category 8 in vitro diagnostic medical devices (21 July 2023), for category 9 industrial monitoring and control instruments and for category 11 (21 July 2024).

Exemption 6(b) covers the two main application areas of exemption 6(b)-I and exemption 6(b)-II. Therefore, the request for renewal of Ex 6(b) is considered in the course of the assessments of exemption 6(b)-I (this chapter) and exemption 6(b)-II (see chapter 8), but is not reported on its own. This is related among others to the categories for which the applicants apply for the renewal and the recommendation to merge all categories under one exemption as far as possible.

The review therefore focuses on 6(b)-I.

EU Aluminium requests exemption 6(b)-I to be renewed for 5 years for all EEE categories, however, proposing to narrow the scope by lowering the allowance for Pb given in the exemptions to 0.3% lead by weight, and to casting alloys. The UP requests the renewal of the exemption with the current wording for the maximum validity periods foreseen in the RoHS 2 Directive (which means 7 years for Cat. 8 and Cat. 9 EEE and 5 years for all other categories). UP initially submitted the request for renewal for Cat. 1-10 in January 2019. In October 2020 a very similar request was submitted for Cat. 11 as well.

7.2. Technical description of the requested exemption

This exemption covers applications of aluminium alloys where lead is unintentionally present. This is the case for casting alloys[29] where lead is present due to the use of secondary raw material from aluminium scrap. '*Due to the longevity of aluminium products and higher lead limits in the past, different amounts of lead are embedded in the scrap*.' (EU Aluminium 2021a).

In order to produce aluminium cast alloy components, different basic alloys are melted together with recycled aluminium. The properties of the casting alloy can be controlled by adding elements such as copper, silicium or manganese to the melt. There are various casting processes through which the components of interest can be produced. The finished parts are no longer machined to the extent that would require additives

[28] For an overview on the recycling circuits, see Figure 8-1: Recycling circuits in aluminium recycling in section 8.5.2.

[29] The term cast alloy refers to alloys that are melted in a furnace and poured (or casted) into a mould and allowed to cool. In contrast, the term wrought alloy is used when the alloy is worked in the solid form. This can be done by applying various machining processes with the help of specific tools like stamping, bending, rolling, extrusion, etc. These manufacturing processes yield materials with different properties.

for enhancing machinability. Thus, the use of lead (often used as a machinability enhancer) can be avoided in the case of casting alloys.

Relevant applications in which such alloys are used include e.g. frameworks of lamps and lights, heat sinks, electrical and electronic items in housing etc. (EU Aluminium 2019, p.5). The UP provides a non-exhaustive long list of applications: "*Recycled aluminium is used to make castings which have a wide variety of uses in all types of EEE. For example, the production of pinons, gears for chains, various machinery components, lawnmowers, brush cutters, lawn trimmers, scarifies and hedge trimmers, combustion engines, garden and outdoor equipment, petrol chainsaw, power cutters, pistons, flywheel, cylinders, medical devices (e.g. MRI and CT scanners), monitoring and control instruments, frameworks of lamps and lights, heat sinks, electrical and electronic items in housing and industries etc."* (Umbrella Project 2020c, p. 7)

7.2.1. Amount of lead in aluminium from lead-bearing Al scrap recycling used under the exemption

The share of recycled Al from all Al used in EU end-use applications is estimated to have been 26 % in 2000 (EU Aluminium), 37% in 2013 (UP) and is estimated to reach 50% in 2050 (EU Aluminium). This information is understood to concern the general use of Al in the EU and not only the use of EEE articles. As for the amount of Pb entering the market through this exemption, both applicants state that it is not possible to derive the amount of lead associated with the use of recycled aluminium.

7.3. Applicants' justification for the requested exemption

7.3.1. Substitution or elimination of lead in aluminium from lead-bearing Al scrap recycling

The substitution of unintentionally present lead in aluminium originating from Al scrap recycling is explained not to be appropriate. Technological alternatives for removing the lead in the melting and refining step of the Al recycling process have been tested in 2012 without finding a technically feasible way. Both applicants refer to a study on 'Existing technologies for lead removal from Aluminium melts', carried out by MIMI Tech UG and finalized in June 2012. The study shows that only few methods could be found and were assessed, i.e. Phase separation, Electrolysis and Vacuum distillation. These methods are either not approved above lab-scale or not feasible from an environmental / economical perspective. The only alternative is to dilute the metal with primary aluminium. This would result in higher environmental impacts due to the fact that the production of primary aluminium is energy intensive. Both applicants state that a dilution of Pb takes place over time with no "new" Pb being added to the material stream as aluminium produced with primary material enters the waste phase and is recycled. They stress the environmental benefits of using recycled material as compared to virgin resource extraction. (EU Aluminium 2019; Umbrella Project 2020c)

The UP states that a closed loop system exists for Al as "in 2017, collection rates for aluminium were over 95% for new scrap and 70% for old" (Umbrella Project 2020c).

EU Aluminium proposes to lower the lead threshold in the exemption formulation, see the arguments summarised and evaluated in the course of the critical review in chapter 7.5.3:

> *Lead as an alloying element in aluminium casting alloys containing up to 0,3% lead by weight provided recycled lead-bearing aluminium scrap is the only source of the lead.*

7.3.2. Environmental arguments

The applicants argue that health and environmental impacts of recycled aluminium lead to a lower total impact than the use of primary aluminium. This is based on several LCA studies.

7.3.3. Socioeconomic impacts

The UP argue in favour of the exemption explaining that without such an exemption it results in a decrease in recycling of aluminium scrap, which will impact the EU circular economy and limit economic growth and jobs. Whether aluminium scrap can be used or not (in light of lead impurities) also affects the dependency of the EU on primary aluminium for which imports remain very high.

7.3.4. Road map to substitution

No roadmap to substitution was provided given the fact that there are no practical, environmental or other arguments to substitute lead in aluminium alloys where the lead stems from recycled aluminium.

7.4. Stakeholder contributions

In total, seven individual contributions have been submitted during the consultation period from 23 December 2020 to 03 March 2021.

European Aluminium has expressed its views during the consultation. Since European Aluminium is one of the applicants for the renewal of Ex. 6(b)-I, the contribution can be interpreted as an additional clarification of the application: In a foreword, EU Aluminium clarifies the differences between RoHS Ex. 6(b)-I and 6(b)-II based on two categories of aluminium alloys, namely casting and wrought alloys, to justify that both exemptions are treated separately. The exemption that is under review in this chapter (6(b)/6(b)-I) covers the casting alloys. EU Aluminium clarifies that in requesting a potential 5-year transition period to allow adaption of the supply chain to meet the targets of lower lead levels in recycled aluminium, it means that the proposed lower threshold level for lead in recycled aluminium should already be incorporated in the exemption wording that "should immediately follow the present 6(b)-I expiring on 21 July 2021". (EU Aluminium 2021a). As to the actual levels of lead in recycled aluminium currently supplied to the market, EU Aluminium responds that its members '*are able to supply casting alloys according to EN 1676:2020 and EN 1706:2020 with a maximum Pb limit of 0.29% since 2020'*.

Another six contributions were submitted with regards to aspects of relevance to all of the exemptions or to the alloy exemptions evaluated under this study.

- The **Swedish Chemicals Agency** KEMI (2021) addresses in a general comment all alloy exemptions under review (6b, 6b-I, 6b-II, 6c) and also exemption 6(b) and 6(b)-I covering steel products. KEMI claims that the exemptions should be adapted to the corresponding level of the REACH restriction entry 63 (for further information see section 5.2). Furthermore, KEMI states that the exemption formulation should specify both the material or component and the specific applications.

  KEMI acknowledges the conflict of interests with regards to energy savings related to using secondary aluminium on the one side and combining material streams of which one contains hazardous substances on the other side. KEMI proposes: "*One way to get around this in the long run could be to recycle metals containing lead in one loop while metals without lead is recycled in another loop so as not to contaminate all recycled metals. Furthermore, these different metals should be used in different applications in a well-controlled manner*."

- The **Norwegian Environment Agency** (2021) expresses similar arguments to the Swedish Chemicals Agency: Based on Recital (19) in the RoHS Directive (2011/65/EU) that '*exemptions from restrictions for certain specific materials or components should be limited in their scope*', it is put forward that '*the material or component and the specific application need to be defined in the description of an exemption*'. Thus, the exemptions should be '*narrowed down to a scope*'.
- **Test and Measurement Coalition** (2021), see chapter 5.1
- **Fresenius Kabi** (2021), see chapter 5.1
- The contribution of **Huawei** consists of a paper of Andrae (2020) titled 'Does the Restriction of Hazardous Substances (RoHS) Directive Help Reduce Environmental Impacts?' which contains an analyses of environmental implications of RoHS exemptions 4f, 6a, 6b, 6c, 7a, 8b, 15(a), 15 and 34 of Annex III (Andrae 2020). As for lead in recycled aluminium, the work emphasises the negative environmental impacts of diluting secondary aluminium with primary aluminium in order to lower the lead content if the exemption is revoked. This contribution will not further be considered as this aspect has been raised and described in detail by the applicants already.
- **SEMI Europe** (2021b), see chapter 5.1

In addition, the following eleven organisations have expressed their support of the request for renewal of this exemption but did not provide any further detail:

- Trautwein Präzisionsdrehteile GmbH;
- Hacker-Feinmechanik;
- CARL DILLENIUS METALLWAREN GmbH & Co. KG;
- STERO GmbH & Co. KG;
- HEINRICH MUELLER GMBH;
- HUGO KARRENBERG & SOHN GMBH & CO. KG;
- Wilhelm Schauerte GmbH & Co. KG;
- Julius Klinke GmbH & Co. KG;
- Carl Leipold GmbH;
- wafi Walter Fischer GmbH & Co. KG;
- Heinrichs & Co. KG;

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

Due to the unintentional presence of lead, the target of restricting hazardous substances is a question of elimination or reduction rather than substitution. The substitution of lead in the Al recycling stream does not seem to be technically practicable: there exist substitution processes for lead at laboratory scale which have not reached industrial scale since 2012. Moreover, the actual amount of lead in secondary aluminium and thus also on Al cast alloys decreases with time due to the dilution processes. This is detailed in the next section.

7.5.3. Possibilities for reducing lead

EU Aluminium explains that as recycled lead-bearing aluminium scrap is the only source of lead in cast alloys, the lead content is decreasing. Furthermore, the amendments of the EU Standards EN 1676:2020[30] and EN 1706:2020[31] require industry to reduce the Pb content to 0,29% by weight voluntarily, based on a compromise between stakeholders. According to EU Aluminium (2021b), also Member States have been involved in the discussion. The standards are available for purchase since April 2020 and EU Aluminium suggest making use of the standards which are voluntary as long as they are not referred to in legal texts (EU Aluminium 2021b with a reference to www.CEN.eu).

EU Aluminium proposes to lower the exemption's threshold to 0.3% by weight (EU Aluminium 2019; 2021a; 2021b). This reduction of the lead threshold in Ex. 6(b)-I is supported by the Swedish Chemicals Agency (2021). More precisely, EU Aluminium proposes an adapted wording of the exemption as follows:

> *Lead as an alloying element in aluminium casting alloys containing up to 0,3% lead by weight, provided recycled lead-bearing aluminium scrap is the only source of the lead*

EU Aluminium raise the following additional argument: The health classification of lead metal as defined by Regulation (EC) No 1272/2008 (CLP) is based on a concentration level of 0.3% of lead (metal) w/w. '*Considering that for the time being the regulatory procedures addressing lead as a Substance of Very High Concern (SVHC) see that value as a reference, it would make sense to promote alignment in this regard. Doing so would help approach the two positions and, in the event of a potential inclusion of lead metal in the authorisation list under REACH, would help maintaining coherence in the threshold values.*' (EU Aluminium 2021b)

[30] EN 1676:2020 'Aluminium and Aluminium alloys. Alloyed ingots for remelting. Specifications'
[31] EN 1706:2020 'Aluminium and Aluminium alloys - Castings - Chemical composition'

The Umbrella Project states that '*there is no evidence that it would be possible to lower the limit from 0.4% for the time being'* (Umbrella Project 2020c). '*Given that alloy compositions of up to 0.4% lead by weight are currently permissible, there is extremely limited amount of information on the actual lead composition, rather component and equipment manufacturers only know that it is conformant to the RoHS Directive*' (Umbrella Project 2021g). For casting alloys, the UP is not aware of any international standard, but claims a rather high dependency of the EEE industry on the global supply chain. '*Global customer specifications cannot be changed unilaterally by European aluminium alloys suppliers*' (Umbrella Project 2021d). The Swedish Chemicals Agency KEMI has an opposing opinion and emphasizes the leading role of Europe with regards to '*better protection for human health and the environment*': '*The EU legislation should lead the development of new solutions […] we should not take into account the level of lead in aluminium scrap recycled outside the EU*.' The consultant could not follow the argumentation presented by UP, because the statement was not substantiated with figures and data on the content of lead in recycled aluminium. This is further supported by the comments made by KEMI cited above regarding the focus on developments in rather than outside the EU.

The UP contends that a transition period would be needed before lowering the limit of lead in exemption 6(b)-I. This is to allow '*Time for reducing the level of lead to 0.29% + time needed for the global supply chain to exhaust the stock + time for recertification/re-validation*' (Umbrella Project 2021d). After a renewal of the exemption with 0.4% Pb for all categories for five more years, '*the reduction to 0.3% is appropriate*.' (Umbrella Project 2021g) Reacting on the arguments regarding the slowness of global supply chains, EU Aluminium states that '*whilst it is paramount to grant transition time to these systems it is also important to make progress in line with the political wave of the Green Deal and the Zero Pollution Action Plan*' (EU Aluminium 2021b). Since the beginning of RoHS 1 Directive in 2002 the allowed level of lead in aluminium alloys was not lowered[32], neither was it changed in 2015/16. The consultant thus believes that the concentration of lead in recycled Al should have decreased through dilution throughout this period. Thus, the consultant can follow EU Aluminium's statement that '*it is important to make progress*' not only against the background of current political priorities but even more in light of the targets of the RoHS Directive.

The UP points out the risk that if the threshold was lowered, the lower lead concentration could be achieved by diluting the Al scrap with non-leaded Al. In the EU non-leaded Al is understood to stem from secondary sources but it is not clear whether a lowered threshold introduced by this exemption would result in a dilution of the Al scrap with primary aluminium outside the EU. According to the UP, the use of primary aluminium bears various environmental disadvantages (Umbrella Project 2021g). Asked whether it is correct to understand that globally, the lead content in recycled aluminium may not yet be below 0.4%, EU Aluminium answered that '*the maximum*

[32] The wording of exemption 6 was as follows: "Lead as an alloying element in steel containing up to 0,35% lead by weight, aluminium containing up to 0,4% lead by weight and as a copper alloy containing up to 4% lead by weight"; http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0095&from=EN

lead level in ISO 17615:2007[33] *and ISO 3522:2007*[34] *was already 0.35% since 2007. So, even at the global level, we believe that the maximum level of lead can be reduced to 0.3%*' (EU Aluminium 2021c). This contradicts the UP's statement that there are no international standards for casting alloys.

In the view of the consultant, the UP's argumentation is less substantial compared to the arguments put forward by European Aluminium. It is acknowledged that Al scrap should not be diluted with primary non-leaded Al only for the reason of complying with new RoHS restrictions, however, the risk for this to happen is estimated to be rather low. The consultant concludes that globally, Al alloy contents up to 0.3% lead by weight can be achieved given that the two ISO standards have already been adopted in 2007 and that it can be assumed that the lead content in recycled Aluminium has decreased since then through dilution.

7.5.4. Environmental arguments and socioeconomic impacts

Theoretically, the lead content in recycled aluminium could be lowered by diluting the Al scrap with non-leaded primary Al. However, from an environmental perspective, two arguments speak in favour of allowing the use of secondary aluminium with certain lead levels instead of primary aluminium. First, seeing that the alternative of using recycled Al bearing lead in casting alloys is the use of primary Al, it is agreed by the stakeholders that the use of secondary Al has an energy-efficiency related advantage over the use of raw aluminium (Umbrella Project 2020d; EU Aluminium 2019). Second, the EU Circular Economy has the aim to use materials already in the material cycle for as long as possible. Thus, using secondary raw material generally is in line with the closed loop targets of the Circular Economy (European Commission 2020b). As already noted by KEMI (2021), there is a conflict of interests here, whether to save energy through the use of recycled material containing lead or whether to reduce the presence of lead in products using virgin aluminium at the same time taking into account the high energy consumption associated to the production of virgin aluminium.

Throughout the course of the project, EU Aluminium has brought forward the EN and ISO standards related to Al casting alloys. These standards specify the acceptable levels of lead. They are reviewed from time to time, and, if the market allows, the levels of hazardous substances present in the Al casting alloys can be lowered, e.g. Pb levels were lowered in the EN standard revision for Al casting alloys in 2019/2020. Thus, it can be assumed that besides exemption requests for renewal of this specific exemption, there exist additional drivers to track the market's possibilities to reduce the lead content in recycled aluminium.

It is further understood that the use of secondary lead in the production of Al alloys for casting allows a significant reduction in the energy consumed to produce the alloys (i.e. the energy associated with the manufacture of primary Al is significantly

[33] ISO 17615:2007 'Aluminium and aluminium alloys - Alloyed ingots for remelting – Specifications'

[34] ISO 3522:2007 'Aluminium and aluminium alloys - Castings - Chemical composition and mechanical properties'

reduced). In the consultant's view, lead as an impurity is thus to be accepted also seeing as the level of impurities in alloys is controlled and shall decrease with time.

For absolute lead amounts used under this exemption, both applicants specify certain shares of primary versus secondary Al used across all sectors. However, both applicants state that no information can be derived on the share of secondary Al in the EEE sector. While the consultant can follow that the share of secondary raw material specifically used in the EEE sector is difficult to assess as manufacturers of components may not monitor their sales according to sectors, the consultant identifies a lack of substantiation with figures and data on the content of lead in recycled aluminium. This was already mentioned under chapter 7.5.3 in relation to the statement of the UP that '*there is extremely limited amount of information on the actual lead composition'* (Umbrella Project 2021d; 2021g). However, it is acknowledged that without any information on the share of secondary Al used in the EEE sector, numbers on the exact lead content cannot help to derive an absolute lead amount used under this exemption.

7.5.5. Scope of the Exemption

EU Aluminium proposed to specify casting aluminium in the wording of Ex. 6(b)-I. After first refusing to comment (Umbrella Project 2021d), in a later communication the UP finally agreed to the specification (Umbrella Project 2021g).

Applications which consist of or include parts fabricated from casting aluminium alloys based on the input provided from applicants are frameworks of lamps and lights, heat sinks, electrical and electronic items in housing, pinons, gears for chains, various machinery components or garden and outdoor equipment, petrol chainsaw, power cutters, pistons, flywheel, and cylinders (see chapter 7.2).

According to the UP, this list also includes/applies to medical devices (e.g. MRI and CT scanners), and monitoring & control instruments. Stakeholders supplying Cat. 8 & 9 products that participated in the stakeholder consultation such as TMC and Fresenius did not specifically mention the need of a longer validity period. The consultant assumes that this is due to the fact that the material used in casting alloys supplied on the market are the same for all EEE regardless of category and sub-category.

7.5.6. 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 the following conclusions can be drawn:

In the case of exemption 6(b)-I, the substitution of lead in aluminium alloys where lead stems from Al scrap has neither major environmental advantages nor is it technically feasible on a large industrial scale. An approach in which the lead threshold value of the exemption is adapted to the current situation on the market is viewed as preferable, while closing the door to alloys with higher lead contents that remain available on the market but do not serve a functional purpose. In order to achieve the most precise wording, EU Aluminium proposed to specify the applicability of 6(b)-I to 'casting alloys', to which the second applicant, UP, agreed (Umbrella Project 2021g). Technically, this does not change in the material covered by the exemption, rather it provides legal clarity and prevents steps backwards in the future.

On the basis of developments in the EN standardisation process for aluminium alloys and based on the fact that the international standards for aluminium alloys already have lower lead thresholds than the reviewed RoHS exemption, the consultant concludes that the content of lead allowed as an alloying element in aluminium, provided it stems from lead-bearing aluminium scrap, should be lowered to 0.3% lead by weight. Although, according to UP, no exact data for lead content in the international supply chain is known, the consultant believes that the limit value of 0.3% can be complied with internationally, because a lead content of 0.35% has already been specified in the international standards since 2007. Thus, the availability of suitable aluminium alloys is assumed to be given.

EU Aluminium requested to specify the scope of exemption 6(b)-I to casting alloys and to reduce the maximum lead limit to 0.3% not only for Ex. 6(b)-I but also for Ex. 6(b). Data was not made available to suggest that the situation could differ between the categories for which the exemption has an expiration date specified as July 2021 and between categories or sub-categories with a later date.

Overall, the consultant concludes that the exemption could be renewed for 5 years accepting the changes proposed by EU Aluminium and supported by stakeholders. The following wording is suggested for a renewed exemption 6(b)-I:

Lead as an alloying element in aluminium casting alloys containing up to 0,3% lead by weight provided it stems from lead-bearing aluminium scrap recycling

7.6. Recommendation

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

	Exemption formulation	Duration
6(b)-I	*Lead as an alloying element in aluminium containing up to 0,4% lead by weight provided it stems from lead-bearing aluminium scrap recycling*	Expires 12 months after the decision for all categories
6(b)-III	*Lead as an alloying element in aluminium casting alloys containing up to 0,3% lead by weight provided it stems from lead-bearing aluminium scrap recycling*	Expires on 21 July 2026 for all categories

A uniform validity period is recommended for all EEE Categories, thus, it is not recommended to split the validity period of the exemption between Categories 1-7 & 10 and Cat. 8 & 9 for several reasons even though 7 years instead of 5 years exemption duration can be granted for the latter categories. It should be avoided that slightly different exemption formulations coexist in order to avoid confusion (see chapter 5), to ensure market surveillance and to lower the administrative burden of stakeholders and the European Commission with regards to renewed exemption requests for the coexisting exemptions. Especially with regards to the casting alloys targeted by Ex. 6(b)-I, the consultant believes that the material supplied on the market are the same for all EEE regardless of category and sub-category.

The original exemption 6(b) remains unchanged and retains its expiry dates.

To furthermore ensure that RoHS provides a similar level of environment and health protection as that of the REACH Regulation, and with entry 63 of Annex XVII in mind, it is recommended to add the following phrase for precautionary reasons to the exemption wording: "*The exemption shall not be applicable to articles or accessible parts of an article that 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, except where it can be demonstrated that the rate of lead release from the accessible component /part, 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*". Alternatively, this addition could be added as a footnote to the exemption.

8. Exemption 6(b)-II "Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % 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.

Al	Aluminium
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
CRM	Critical Raw Material
EEE	Electrical and Electronic Equipment
Pb	Lead
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
UP	Umbrella Project

8.1. Background

On behalf of the "RoHS Umbrella Industry Project" (hereafter referred to as "Umbrella Project") COCIR, HARTING Stiftung & Co and Pepperl + Fuchs AG have submitted a request for the renewal of exemption 6(b)-II of Annex III of the RoHS Directive with its current wording (Umbrella Project 2019a):

> *„Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight"*

The Umbrella Project (2019a) argues that lead in aluminium alloys improves machinability by acting as a lubricant. Through the presence of lead, better chip fracturing and surface finish as well as higher cutting speeds and a longer tool life are achieved. In a later communication (Umbrella Project 2021l), the Umbrella Project points out that the renewal request is mainly based on the 3rd criterion of Art. 5(1)(a) namely that the total negative environmental, health and consumer safety impacts caused by the substitution of lead with bismuth are likely to outweigh the total environmental, health and consumer safety benefits thereof. The Umbrella Project (2019a) requests the applicability of the exemption for the categories 1 to 10.

Aluminium (Al) alloys can be differentiated into two principal classifications:

- **Wrought alloys:** Al alloys primarily used for wrought products; they have an alloy content up to 10% and therefore strict and very low compositional tolerance limits for the alloying elements. Wrought alloys are designated with a four-digit number according to the alloy designation system. Wrought alloys intentionally containing lead for machining purposes.
- **Cast alloys:** Al alloys primarily used for the production of castings; cast alloys have much higher compositional tolerance limits for alloying elements; the alloy concentration is of up to 20%. For cast alloys, a different designation system with five digits is used. Cast alloys unintentionally contain lead, due to the use of Al scrap for the manufacture of such alloys.

Exemption 6(b) has been split after the last evaluation to properly address the presence of lead being intended or not (Gensch et al. 2016).

8.2. Technical description of the requested exemption

The Umbrella Project (2019a) states that leaded aluminium is still required for some so called "niche" applications but on the other hand that an exhaustive list of applications cannot be provided due to the diverse nature of the end products which utilise components with leaded aluminium. In the answer on the clarification questions, the Umbrella Project (2021l) specifies the following applications where leaded aluminium is still required:

- Cast and machined aluminium gear boxes from handheld tools made of the Al alloy EN AC-46000-D-F;
- Charge holders for MEMS sensor applications made of EN AW 2007 that are cut of from a rod and must run at accelerated temperature;
- Stand-offs and spacers that are used to electrically connect parts in medical equipment.

The Umbrella Project (2019a) explains the required use with technical characteristics that relate in part to manufacturing and in part to the manufactured components:

- Micro-machining;
- Electrical conductivity;
- Galvanic corrosion prevention;
- Corrosion resistance against e.g. chemicals;
- Mechanical relaxation;
- Tribological behaviour;
  - Superior machinability due to factors such as chip fracturing and surface finish;
  - Enhanced cutting tool lifetime;
  - Better wear resistance of components made of leaded aluminium as it reduces friction and wear of surfaces that slide against others (such as connectors);
- Ability to form lightweight, intricate shape parts.

The Umbrella Project (2019a) does not provide performance indicators for these characteristics / functionalities.

8.2.1. Amount of lead used under the exemption

The applicant does not specify the volume of lead to be placed on the EU market through the exemption (Umbrella Project 2019a). Rather the applicant provides estimates that are based on general considerations on the European Al production and the share thereof for industrial sectors. The estimations provided by the Umbrella Project[35] are hard to follow and suggest that an estimated annual amount of lead of about 90 tonnes is not recycled. The Umbrella Project states generally that only a very low amount of leaded aluminium is still required for some niche applications. No more detailed information is provided.

8.3. Applicants' justification for the requested exemption

The Umbrella Project claims that no suitable alternative exists for all applications and argues that "*until all applications are able to trial lead free alloys then the reliability is not ensured.*" (Umbrella Project 2019a).

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

The Umbrella Project mentions cadmium, tin, bismuth and beryllium as possible substitutes (Umbrella Project 2019a):

- **Cadmium** is not further detailed because it is itself RoHS restricted.
- **Tin** is mainly argued as providing less favourable mechanical properties to the material (causing cracking in machined parts when exposed to stress and high temperature; causing surface darkening on annealing and increasing the susceptibility to corrosion).
- **Bismuth** is the main substitute; the Umbrella Project states that "based on the feedback of a few companies, about 2/3 of aluminium parts have already been transferred from leaded to unleaded aluminium. In these cases, bismuth is used instead." However, the Umbrella Project further argues that bismuth has limited availability due to its being defined as a critical raw material. The Umbrella Project claims that Bismuth has a more negative overall health and environmental impact (see further details in section 8.3.2).

  On the machinability level, the Umbrella Project states that the manufacturability of bismuth alloys for some alloy types is similar to lead containing alloys: "*However to fully understand the quality of a machined surface after machining it is essential to know for each alloy type the microstructure which has not been fully investigated for all alloys and uses*."
- **Beryllium** is also not further detailed because the Umbrella Project concludes that it has similar toxicity to lead and limited availability.

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[35] "In Europe about 7,7 million tonnes of Aluminium were produced in 2018. Assuming that about 4,5 million tonnes are in industrial sectors, out of this (based on statistical assumptions) about 450000 tonnes (10 %) is not recycled. However, not all of these applications would contain lead up to 0,4 %, assuming that 5 % of the unrecycled material includes lead up to 0,4 % results in 22500 tonnes of aluminium containing lead. Consequentially, this would result in 90 tonnes of lead which is not recycled. In the overall scheme this will have minimal impact as it results in 0,3 % of the EU total aluminium production."

The Umbrella Project provides a list of some lead-free aluminium wrought alloys designated with a four-digit number according to the alloy designation system. The Umbrella Project depicts the composition ranges of bismuth and tin, arguing that these alloys rely on bismuth and / or tin. There is no further assessment of technical performance presented. Rather general statements are given such as (Umbrella Project 2019a):

- "*In some alloys tin is used as a substitute to lead often in combination with bismuth. However, in turning and machining tests long and continuous stripes were observed which cause very poor machinability.*"
- "*The lack of availability of bismuth and lead-free aluminium alloys would support the assessment that the technical performance of tin alloys is not as closely matched to the traditional lead containing aluminium alloys.*"
- "*Some alloys have been substituted by lead free compositions like e.g. AW-6026 to AW-6026LF as lead free alternative with high bismuth content. However, this is not possible for all applications currently.*"

Another substitution option is indicated as aluminium foam compositions (without the inclusion of lead), however without giving further information. UP explains that aluminium foam compositions are currently only available as sheets and that testing is needed for complex structures (Umbrella Project 2019a).

As for the reliability of substitutes, the Umbrella Project claims that some products need to be requalified such as e.g. medical devices where the Medical Devices Regulation requires a re-approval by a Notified Body. The roadmap for substitution is also specified for medical devices, indicating a total time of 5 years.

8.3.2. Environmental and health arguments *(also LCA aspects)*

The UP claims that there are negative environmental and health impacts of bismuth and refers to an LCA that compares the life cycle stages mining, purification, and refining of different metals (Umbrella Project 2019a). According to the Umbrella Project (2019a), the total negative environmental, health and consumer safety impacts caused by substitution with bismuth are likely to outweigh the total environmental, health and consumer safety benefits thereof (Umbrella Project 2019a).

Furthermore, the UP claims that the use of bismuth containing alloys can negatively affect recycling of aluminium and might increase the waste to be landfilled, however without providing further information.

8.3.3. Socioeconomic impacts

The UP expects an increase in direct production costs because lead-free alloys may require more energy for machining, cause greater tool wear and create more scrap. Further the UP claims that bismuth is around 7 to 17 times more expensive than lead and states that "*if the demand for bismuth increases and the demand for lead decreases, the price of bismuth may become even higher*." The UP also claims that for medical devices this could impact on EU patients' health, but without giving further information (Umbrella Project 2019a).

8.4. Stakeholder contributions

Twelve individual contributions have been submitted during the consultation period from 23 December 2020 to 03 March 2021. The arguments of the individual contributions are summarized in the following.

- The **Swedish Chemicals Agency** KEMI (2021) addresses in a general comment all alloy exemptions including exemption 6(b)-II. KEMI claims that the exemptions should be adapted to the corresponding level of the REACH restriction entry 63 (for further information see section 4.1). Furthermore, KEMI states that the exemption formulation should specify both the material or component and the specific applications.
- The **Norwegian Environment Agency** (2021) expresses similar arguments as KEMI: Referring to Recital (19) in the RoHS Directive (2011/65/EU) ('exemptions from restrictions for certain specific materials or component should be limited in their scope'), the Norwegian material Agency claims that 'the material or component and the specific application need to be defined in the description of an exemption'.
- The **Federation of the Swiss Watch Industry FH** (2021a) supports the request from the Umbrella project regarding all alloy exemptions. They explain in a general way that lead-free alloys are harder to work and their electrical conductivity is also worse. Besides, the Federation of the Swiss Watch Industry FH claims that leaded alloys in external watch components have already been substituted and that for internal components of the watch movement, substitution is more challenging. They furthermore refer to the derogation made in REACH entry 63 for internal components of watch timepieces inaccessible to consumers.
- **European Aluminium** (2021a), the association of European Aluminium manufacturer states that an extension of exemption 6(b)-II is not necessary because there is no technical need for lead-containing aluminium alloys as lead-free wrought aluminium alloys with high machinability have been developed with properties compatible with lead-containing alloys in use for any kind of application. European Aluminium provides a compilation of leaded and lead-free aluminium alloys.[36] The alloys contain a wide variety of metallic elements, e.g. iron, silicon, copper, magnesium, manganese and zinc as well as bismuth and lead. The overview on the alloy compositions shows that leaded aluminium alloys also contain bismuth in quantities between 0.2 and 1.5 %. Thus, bismuth cannot be considered as the drop-in or one-by-one substitute. Tin is also used as replacement, alone or in combination with bismuth in tens of alloys. It is explained that tin cannot be used on higher temperature applications, but it is an excellent chip-forming element.

  European Aluminium (2021a) estimates that a replacement of a leaded Al alloy by a lead-free alloy would take from 6 months to some years, depending on the quantity of components.

[36] According to International Registration Records and the Addenda at https://www.aluminum.org/standards
- Teal Sheets (Wrought Aluminum International Alloy Designations & Chemical Composition Limits) and
- Addendum to Teal Sheets.

According to European Aluminium (2021a), the lead-free Al alloys are globally available on the market.

- **EURAL® GNUTTI S.p.A.** (2021b), one aluminium manufacturer, expresses similar arguments as European Aluminium. EURAL® GNUTTI S.p.A. (2021b) provides data on the volume of lead used by the Eural Gnutti in 2018; accordingly alloys with lead content in the quantity of almost 40.000 tons have been manufactured that results in a use of lead in a quantity of about 205 tons in 2018; "*that means that in our factory we must have in our warehouse a minimum quantity of 20-30 tons of pure Lead, we cannot have any less in order to guarantee the regular flow of production. Such number is comparable with many Extruders and Rollers in Europe*". Both, European Aluminium and Eural Gnutti heavily refer to workers protection against pure lead metal as it causes health problems for the workers.
- **Mondragón Componentes S. Coop.** (2021a) applies for the renewal of the exemption for category 1 (large household appliances) referring to "*Aluminium gas valves for gas control and regulation in gas household appliances, including hobs, free standing cookers, industrial appliances, home comfort appliances and barbecues*" as specific application. Mondragón claims to have difficulties in obtaining lead-free material for industrial trials. This is explained to delay the adaptation process for which Mondragón estimates to need around 5 years, global approvals included. The alloys already tested have not given expected results in terms of machinability. Mondragón explains that as gas valves are guaranteeing safety in appliances, the dimensional aspects of the components must be carefully taken care of.
- The contribution of **Huawei** (Andrae 2020) consists of a paper of Andrae as a analyses of environmental implications of RoHS exemptions 4f, 6a, 6b, 6c, 7a, 8b, 15(a), 15 and 34 of Annex III.[37] As for leaded aluminium alloys, the work refers to the initial exemption wording 6(b) that does not differentiate between aluminium alloys that is manufactured using scrap and the exemption 6(b)-II that refers to alloys being manufactured with primary aluminium due to their low tolerance limits for the alloying elements. The assumptions made in the paper are not applicable to the RoHS exemption 6(b)-II.

Furthermore, there were three contributions referring to a renewal of the exemption for specific categories:

- **Test and Measurement Coalition** (2021), see section 5.1.
- **SEMI Europe** (2021b), see section 5.1.
- **Fresenius Kabi** (2021), see section 5.1.

Aside from the contributions specified above, the following 14 organisations have expressed their support of the request for renewal of this exemption but did not provide any further detail: Trautwein Präzisionsdrehteile GmbH; Hacker-Feinmechanik; CARL DILLENIUS METALLWAREN GmbH & Co. KG; STERO GmbH & Co. KG; HEINRICH MUELLER GMBH; HUGO KARRENBERG & SOHN GMBH & CO. KG; Wilhelm Schauerte GmbH & Co. KG; Julius Klinke GmbH & Co. KG; Carl Leipold GmbH; wafi

[37] Anders S.G. Andrae Does the Restriction of Hazardous Substances (RoHS) Directive Help Reduce Environmental Impacts? In: International Journal of Green Technology, 2020, 6, 24-37.

Walter Fischer GmbH & Co. KG; Heinrichs & Co. KG; Maier GmbH & Co. KG Präzisionstechnik; Fischer Automaten-Drehteile GmbH & Co. KG; Grieshaber GmbH & Co. KG

8.5. Critical review

8.5.1. REACH compliance – Relation to the REACH Regulation

See section 4.1 for details.

8.5.2. Scientific and technical practicability of substitution

From the information provided by the aluminium manufacturers, the consultant concludes that lead-free aluminium alloys are available providing comparable machining properties: "*All kind of machining processes are perfectly suitable for lead-free alloys, in particular turning, drilling, milling*" (European Aluminium 2021a). Experiences exist and are made available by the alloy manufacturer on adaptions of machining parameters and tools to achieve high productivity in all kinds of machining operations (EURAL® GNUTTI S.p.A. 2021a). Also for the properties of the final component, the alumnium manufacturers state that lead free wrought aluminium alloys have passed all field tests when it is needed to have a good response in anodizing, low roughness on the surface, high mechanical properties, good welding attitudes, resistance in contact with fluids, including brake fluids, at high temperatures (for Lead and Tin Free alloys). From the information provided by European Aluminium (2021a; 2021b), it becomes obvious that within the AlMgSi alloys (6xxx series) and AlCu alloys (2xxx series) already a number of alloys with a lead content <0.1% is available since quite some time: According to the Aluminum Teal Sheet, where the year of registration of each alloy is indicated, the first alloys in the 2xxx and 6xxx series have been registered between 1993 and 1999 (four alloys registered), from 2000 to 2006 seventeen new alloys were registered and from 2016 to 2020 four additional alloys were registered. As for specific components where the various substitutes have been applied successfully, the alumnium manufacturer lists "*pistons and cylinders for brake systems, pistons and covers for brake disks (calipers), transmission valves, all kind of valves for pneumatic and oleo-hydraulic systems, threaded parts, high precision machined parts, connectors, bolts, nuts.*"

The consultant understands from this information summarized above that there are lead-free alternatives on the market that are reliable according to aluminium producers.

For the EEE manufacturers, the Umbrella Project (2019a) argued in the beginning that the machining properties of leaded aluminium alloyys are favourable, however, without providing further details and claimed that an exhaustive list of applications could not be provided due to the diverse nature. Parallely, the Umbrella Project (2019a) describes that only niche applictions still need leaded aluminium alloys. After a set of first clarification questions, the Umbrella Project (2021l) describes three niche applications. During the stakeholder consultation another specific application was submitted by Mondragón Componentes S. Coop. (2021a).

When asked to specify the applications for leaded aluminium alloys in watches, the Federation of the Swiss Watch Industry FH (2021b) revoked the request for renewal of exemption 6(b)-II. The Federation of the Swiss Watch Industry FH (2021b) states that "*after studying the possibilities of substitution of the lead aluminium alloys in our industry, it appears that they can be substitued by other alloys, wether based on aluminium or not. Thus, we want to withdraw our request for an extension of the exemption 6(b)-II. However, we maintain the requests for exemptions 6(a)/6(a)-I and 6(c), because we need them*."

The four remaining specific applications of leaded aluminium alloys in EEE that were applied in the course of this evalution are disccused in the following.

Cast and machined aluminium gear boxes from handheld tools made of the Al alloy EN AC-46000-D-F

According to the alloy designation[38] the alloy is a cast alloy which is not in scope of the exemption here at hand.

During the last evaluation (Gensch et al. 2016), it was proposed to split the exemption for lead in aluminium alloys in order to differentiate between cast aluminium alloys where lead is unintentionally present and between applications where lead provides necessary properties (wrought alloys).

- Cast alloys are primarily used for the production of castings and have much higher tolerance limits for alloying elements. They unintentionally contain lead, due to the use of Al scrap for the manufacture of such alloys.
- Wrought alloys or Al alloys intentionally containing lead for machining purposes: Wrought alloys have strict and very low tolerance limits for the alloying elements.

The Umbrella Project (2021k) claims that the exemption 6(b)-II does not make a reference to the source of the aluminium and only relates to the reason for lead addition into aluminium. Though it might be that also an aluminium cast undergoes a machining process, basically the two alloy types can clearly be distinguished by their designation. However, for further clarification, in the assessment for Ex. 6(b)-I included in this report (see section 7) it is proposed to refine the wording of the exemption by adding the term "for casting alloys". It is further planned to propose a decrease in the lead threshold of this exemption, meaning that the use of recycled aluminium would not necessarily suffice for achieving properties where a specific function is needed.

The Umbrella Project (2021k) further claims that also for the production of wrought alloys, scrap can also be used as input. The consultant understands from the input in the last evaluation that for wrought alloys, the lead might not always be "newly" added but present at a sufficient concentration in Al used for production that might also stem from scrap. Taking into account the strict chemical composition of wrought

[38] The EN designation system for cast alloy composition is made up of the following:
- EN for European standard,
- Letter A for aluminium
- Letter C for casting
- Alloy composition is specified either by a) numericals (5 digits) or b) by chemical symbols, followed by a letter for the casting process and possibly by a letter and/or digit(s) for temper designation;

https://www.european-aluminium.eu/media/1533/aam-materials-3-designation-system.pdf alloys, it is understood that if scrap is used as input it has to be strictly sorted wrought alloy scrap. The following figure illustrates these material flows.

Figure 8-1: Recycling circuits in aluminium recycling

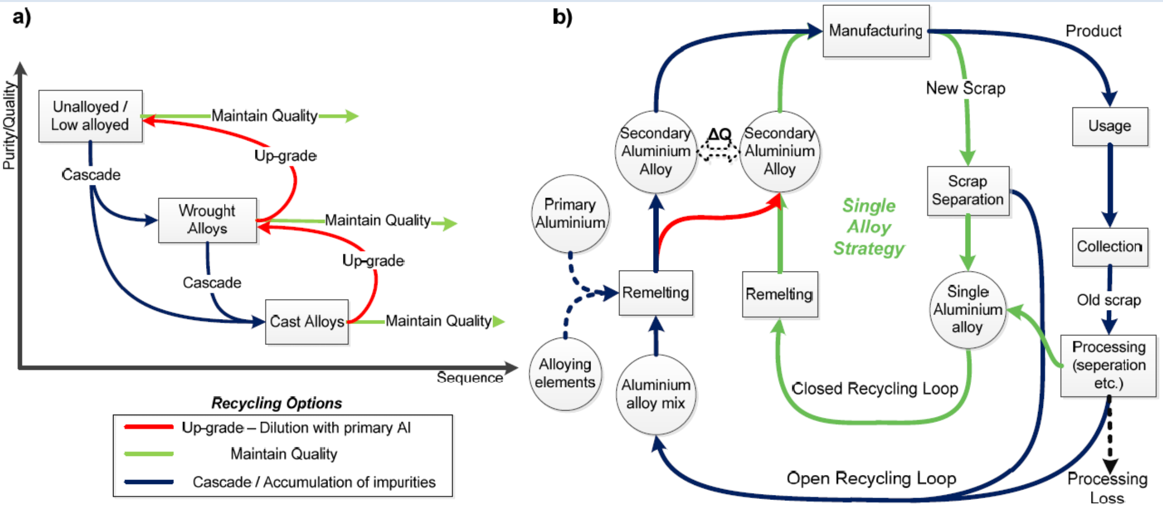


Figure 1: a) Al Cascade recycling chain and b) Recycling options and corresponding pathways.

Source: (Paraskevas et al. 2013)

Therefore, the consultant concludes here that a refined wording of 6(b)-I respectively the new item 6(b)-III that adds the term "in aluminium casting alloys" might prevent such misunderstanding in the future. Besides, the application of this cast alloy does not have to be further considered here.

Charge holders for MEMS sensor applications made of EN AW 2007 that are cut off from a rod and have to run at accelerated temperature

The wrought alloy EN-AW 2007 has according to the International Registration Records and the Addenda[39] a chemical composition with a lead content in the range of 0.8 to 1.5 %. Thus, the use of this alloy is not allowed under RoHS. Confronted with this, the Umbrella Project (2021h) argues that this particular charge holder is a fixture used for processing purpose in manufacturing processes and is not part of an electrical tool. As it is supplied to the end user as a standalone mechanical article it is not in scope of the RoHS Directive. The Umbrella Project (2021h) states that this application does not require the exemption here at hand. This application will also not further be considered. Whether this application is in scope of the RoHS Directive or not has not been investigated.

[39] International Registration Records and the Addenda at https://www.aluminum.org/standards:
- Teal Sheets (Wrought Aluminum International Alloy Designations & Chemical Composition Limits) and
- Addendum to Teal Sheets.

Stand-offs and spacers that are used to electrically connect parts in medical equipment

According to the Umbrella Project (2021h), a number of different alloy specifications are used for the above mentioned application, however the specific alloys could not be identified. The Umbrella Project (2021h) specifies that the lead-free aluminium alloy 6061 has been in the focus of investigation into alternatives, "*however it has demonstrated insufficient deformation behaviour to allow the complex geometrical shapes to be achieved.*" The Umbrella Project (2021h) further specifies thermal conductivity and performance of the heat sinks as being important parameters. However, performance indicators and ranges have not been indicated by the Umbrella Project. The Umbrella Project (2021h) states that "*once a suitable alternative is identified recertification will be required to be undertaken by the MDR, which is estimated to take 1-2 years to complete*."

As the identity of the leaded aluminium alloy is not revealed by the Umbrella Project, the availability of suitable alternatives cannot be concluded here. Based on an additionnal internet research[40], the consultant understands that stand-offs and spacers are offered in varying materials, e.g. stainless steel, brass, ceramics, nylon and also aluminium, where also for example stand-offs of lead-free aluminium EN AW 6060 is offered. The consultant can therefore not follow that stand-offs and spacers are a specific application where lead cannot be reliably substituted.

Gas valves for category 1 (large household appliances)

The application for "gas valves for gas control and regulation in gas household appliances, including hobs, free standing cookers, industrial appliances, home comfort appliances and barbecues" was specified in the contribution of Mondragón Componentes S. Coop. (2021a) and further elaborated in Mondragón Componentes S. Coop. (2021c). According to Mondragón Componentes S. Coop. (2021a), the gas valves have formerly been produced with leaded brass. The consultant understands the switch to leaded aluminium therefore as an overall lead reduction as the lead content in brass is higher (up to 4 % according to RoHS exemption 6(c)) then in leaded aluminium under the exmeption here at hand. Such an overall lead reduction approach was also mentioned by other stakeholders[41] where the exchange of leaded brass by leaded aluminium was performed to reduce the overall amount of lead used in a specific sector.

Mondragón Componentes S. Coop. (2021a) explains that they are in migration process from brass to aluminium components, and at the same time trying to adapt to a lead free aluminium alloy. Mondragón explains to obtain good process results, however certifications and customer approvals would take at least 5 years. According to Mondragón Componentes S. Coop. (2021c), the performance of the gas valves for household appliances depends on the achievment of surfaces that generate an airtight sealing in the assembly to prevent gas leakages without the need of an excessive

40 For example: https://www.ettinger.de/en/products/fastening-technology/standoffs/, https://uk.rs-online.com/web/generalDisplay.html?id=ideas-and-advice/spacers-standoffs-guide, https://www.mouser.com/Electromechanical/Hardware/Standoffs-Spacers/_/N-aictf

41 E.g. during the online meeting hold for RoHS exemption 6(c) on 9 June 2021.

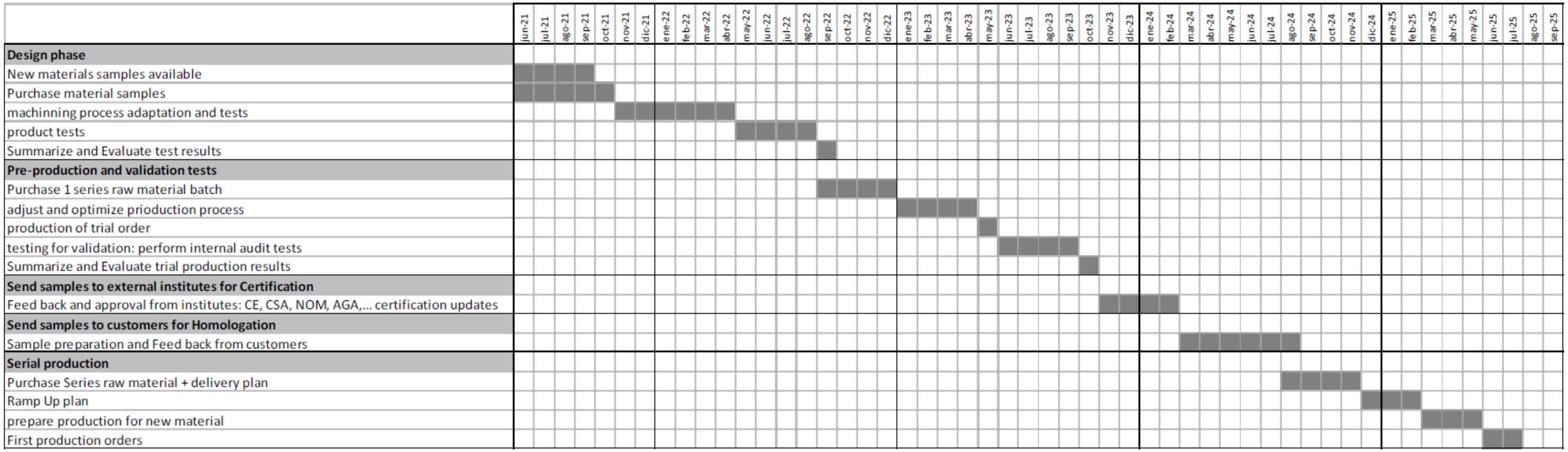
contact pressure between them, so that the valve can be opened and closed with a hand torque. The gas-tight seal must endure in time without getting damaged.

This requires a very strict machining tolerance and surface quality. Mondragón has tested different lead-free Al alloys, e.g. 6026, 2033, 2041 and 2077. Results for test pieces are explained to be "satisfactory and promising" however, series production has not yet been achieved. As the alloy 2077 that showed good hot workability and machinability is only registered since 2020, the consultant can follow that validation tests are still ongoing.

The statement on the substitution efforts presented by Mondragon has been verified by Miele & Cie. KG (2021), another manufacturer of gas household appliances.

To achieve the substituion, Mondragón Componentes S. Coop. (2021c) provides a roadmap that is shown in the follwing figure.

Figure 8-2: Roadmap for substitution in gas valves detailing the different steps that still need to be fulfilled



Source: (Mondragón Componentes S. Coop. 2021c)

To summarise, the roadmap presented above suggests that time is needed to complete the substitution process. It was agreed with Mondragón Componentes S. Coop. (2021b) on an expiry date of 31 December 2024.

Initial conclusion

The consultant concludes that the applications provided by the Umbrella Project are not sufficiently detailed so that it can not be followed why substitutes are not comparable in performance in the specific applications. The consultant reminds the clear statement made in the recommendation of the last evaluation where a short review period was recommended to allow industry a longer transition period as well as providing time to apply for new exemptions should substitutes not be comparable in performance for specific applications (Gensch et al. 2016).

The application specifed by Mondragón is supported with detailed evidence. The initial approach of the manufacturer was to shift to leaded aluminium alloys instead of leaded brass, leading to a reduction in the total amount of lead used. Lead-free Al alloys have been identified that could potentially eliminate the use of lead in this application, however require some additional time to complete the substitution process. Should Ex. 6(b)-II be revoked, the manufacturer could revert back to leaded brass to allow the further marketing of the application until substitution with lead-free aluminium alloys is completed. With the pending renewal of Ex. 6(c) recommended in this report (see section 9) in mind, as an overall lead reduction is achieved in this application by susbtituting leaded brass with leaded alumnium alloys the consultant recommends to allow this use for a limitted period, to allow the completion of the substitution with lead-free alloys.

The following point should be noted regarding the availability of lead-free alloys: Mondragón Componentes S. Coop. (2021c) mentions "*very long delivery dates, for example for alloy 2077*" and further states that for "*Ø10.5mm aluminium coil*" there is no lead-free alternative on the market. This is in contrast to the statement made by aluminium manufacturers e.g. EURAL® GNUTTI S.p.A. (2021b) that "*the aluminium industry is immediately able to supply any quantity needed of Lead-free alloys*". The available evidence does not allow concluding whether there is a supply risk that would affect the availability of substitute alloys and thus also the ability of the EEE manufacturers to transition to such alternatives where they are applicable.

8.5.3. Environmental arguments and socioeconomic impacts

In response to first clarification questions, the Umbrella Project (2021l) points out that "the renewal request for exemption 6bII, submitted by the Umbrella Project is mainly based on the 3rd criterion listed in RoHS article 5.1.a): the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof. In the renewal dossier we highlight the higher environmental impact of bismuth compared to lead."

The Umbrella Project (2019a) supports this claim refering to the EU COM decision to define bismuth as a critical raw material (CRM) and refering to an LCA (Nuss und Eckelman 2014) that compares the life cycle stages mining, purification, and refining of different metals by means of the LCA impact categories such as human toxicity, fresh water eutrophication, cumulative energy demand, terrestrial acidification and global warming potential. However, higher values in the above-mentioned LCA impact categories for bismuth compared to lead that hold for a few life-cycle stages would not justify a renewal of the exemption in the consultant's view.

European Aluminium (2021a) and EURAL® GNUTTI S.p.A. (2021b) provide an overview on the chemical composition of the leaded and lead-free alloys that shows that bismuth is also present in the leaded aluminium alloys. Both state that bismuth is not the substitute element in the lead-free alloys. The Umbrella Project (2021l) continues argueing that "*lead and tin free machinable alloys tend to have higher bismuth specification ranges, up to 1.5% than alloys than most leaded alloys*."

The consultant can not follow this argumentation, also seeing that bismuth has no classificication for any enviromental or human health hazard[42] in contrast to lead. Identification of a resource as a CRM reflects its economic importance and possible risks to its supply, but does not necessarily imply that its sourcing results in negative impacts on the environment or health. Though the European Commission has classified bismuth as a CRM, considering whether such risks are of higher relevance than those related to the continued use of lead is not related to the three primary RoHS criteria and is thus beyond the mandate of the consultant.

The consultant concludes that the 3rd criterion is not fulfilled and cannot follow the argumentation of the Umbrella Project (2021l) that a renewal of the exemption is justified on the background of the higher environmental impact of bismuth compared to lead described in an LCA study on metal extraction.

8.5.4. Scope of the Exemption

The consultant concludes that the exemption in its current formulation should be revoked because there are reliable lead-free aluminium alloys on the market. The consultant reminds here that the last evaluation report already clearly expressed that this exemption is to expire and recommended renewing the exemption only for a short period, to allow EEE manufacturers a sufficient transition period for applying lead-free alloys available on the market. It was further clearly stated in the last evaluation that further exemptions for specific applications shall only be justified where there is sufficient evidence that lead cannot be reliably substituted.

However, it is understood from the numerous organisations, especially German SMEs,[43] that expressed their support of the request for renewal of this exemption but did not provide any further detail that for some applications produced by SMEs in Europe substitution with lead-free aluminium alloys might still not be completed. Taking the situation of the SMEs into account, the consultant recommends the longest transition period that is possible. According to Article 5(6) of the RoHS Directive, this is a period of 18 months calculated from the date when the EU takes a decision. Until the date of the decision, the current exemption remains also valid.

[42] ECHA CL Inventory for bismuth at: https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/15811;
Bismuth has not harmonized hazard classification and by most notfiers is also not classified; a minority of notifiers classify bismuth being may cause long lasting efefects to aqiatic life (Aquatic Chronic 4, H413) and being a Flammable Solid 2 (H228).

[43] See the names at section 8.4.

For the application of gas valves applied in category 1 equipment (large household appliances, the case is different and a short termed exemption could be granted to support the completion of the shift to lead-free alloys, also avoid the risk of a temporary shift back to copper alloys that use higher amounts of lead, should 18 months not be sufficient for the transition. This means that the scope of the exemption could be narrowed down to this specific application.

8.5.5. 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.

It can be followed that substitutes are available on the market for which reliability is claimed by aluminium alloy producers. It has also been demonstrated that most of these alloys were already available on the market in 2016 when the last review of this exemption was finalised. This availability is understood to have allowed substitution in most applications, leaving only some niche applications where the process may still be ongoing. The consultant concludes that the current scope of the exemption is no longer justified and should be revoked, providing an extended transition period to support the smooth phase-out of lead-free alloys where this is still ongoing.

As for niche applications, where additional time may be needed, the evidence provided in the course of this assessment refers only one application where the consultant agrees that the phase in of lead-free alloys needs additional time. This is the case for gas valves for gas control and regulation in gas household appliances, including hobs, free standing cookers, industrial appliances, home comfort appliances and barbecues. These components could also be manufactured by leaded brass. Thus, the switch to leaded aluminium alloys until substitution with lead free ones can be implemented is considered to provide an overall lead reduction and thus to be the "lesser evil". The shift to lead-free aluminium alloys is claimed to need additional time for testing until July 2025; at the end of 2024, the first steps to achieve serial production are to be completed.

The applicant raised concerns related to the 3rd criterion, according to which the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof in light of the presence of bismuth. However, the consultant cannot follow this argumentation as the information on the compositions provided by European Aluminium (2021a) shows that both lead and lead-free Al alloys contain a similar content of bismuth.

8.6. Recommendation

It is recommended to renew the exemption with a narrowed scope, as specified in the following table. It is further recommended, that for all other applications, the exemption shall expire at the latest possible date (18 months, after the date of the decision).

	Exemption formulation	Duration
6(b)-II	Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight.	Expires 18 months after the decision for all categories
6(b)-IV	Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight in gas valves applied in category 1 EEE (large household appliances)	Expires on 31 December 2024

As explained in Section 5, the applicability of these recommendations to EEE in categories, which benefit from the validity of Ex. 6(b) beyond July 2021 is not completely clear from a legal perspective. Industry did not provide specific evidence to show that the suitability of lead-free Al alloys used for machining purposes differs between EEE in Cat. 8 in-vitro, Cat. 9 industrial and Cat. 11 and between other EEE. Seeing as it has been shown that Al alloy suppliers have developed alternatives with performance comparable to most uses of leaded-alloys, it is conceivable that manufacturers of such EEE should also be able to phase-in such alternatives where this has not already been performed. Given that these categories have expiration dates in the short term (July 2023 or 2024), it is also assumed that where this is not the case, they have already started to prepare applications for renewal where the exemption is still needed. Such applications would need to be submitted at least 18 months ahead of expiration according to Article 5(5), i.e., by January 2022 or 2023 at the latest. It is thus assumed that should the above recommendation not be feasible for such categories that stakeholders will be able to submit a request for the renewal of Ex. 6(b) for machining purposes in such cases relatively quickly, providing detailed evidence as to why available substitutes are not applicable for specific EEE.

8.7. Overview on the recommendations for Exemption 6(b)

The following table provides an overview on exemption 6(b) on lead as an alloying element in aluminium and the associated new items and expiry dates that are recommended.

Table 8-1: Overview on the recommendations for Exemption 6(b) with new sub-items

Ex. No.	Exemption wording	Expiry date & scope
6(b)	*Lead as an alloying element in aluminium containing up to 0,4 % lead by weight*	— 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
6(b)-I	*Lead as an alloying element in aluminium containing up to 0,4% lead by weight provided it stems from lead-bearing aluminium scrap recycling*	Expires 12 months after the decision for all categories
6(b)-II	*Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight.*	Expires 18 months after the decision for all categories
6(b)-III	*Lead as an alloying element in aluminium casting alloys containing up to 0,3% lead by weight provided it stems from lead-bearing aluminium scrap recycling*	Expires on 21 July 2026 for all categories
6(b)-IV	*Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight in gas valves applied in category 1 EEE (large household appliances)*	Expires on 31 December 2024

9. Exemption 6(c) “Copper alloy containing up to 4 % lead 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.

C36000 / CuZn39Pb3	Leaded copper alloy, CuZn39Pb3 with a lead content between 2.5 - 3.5%
CuZn21Si3P	Lead-free silicon-containing copper-zinc alloy
CuZn37Mn3Al2PbSi	Copper alloy with 0.2 to 0.8% Pb
CuZn42	Lead-free copper alloy with a higher zinc content
ECHA	European Chemicals Agency
EEE	Electrical and Electronic Equipment
KEMI	Kemikalieninspektionen, Swedish Chemicals Agency
MMC	Mitsubishi Materials Corporation
Pb	Lead
UP	Umbrella Project
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment
TMC	Test and Measurement Coalition
tpa	tons per annuum = tons per year

9.1. Background

Two applicants, Bourns Inc. and the “RoHS Umbrella Industry Project” (in the following “Umbrella Project (2020f)”), represented by Rosenberger Hochfrequenz-technik and PHOENIX CONTACT, request the renewal of exemption 6(c) for:

“Copper alloy containing up to 4 % lead by weight”

Lead is embedded as tiny nodules in the matrix of copper alloys. It thereby improves the machinability by acting as an internal lubricant and chip breaker and by preventing cracks of the material. Lead also improves the technical performance of parts e.g. increases corrosion resistance and influences stress relaxation behaviour or mechanical deformation.

According to the Umbrella Project (2020f), the exemption covers the following copper alloys:

- Leaded brass: copper-zinc-lead alloys are the most used leaded copper alloys; among them the alloy CuZn39Pb3 as a standard alloy of copper and zinc containing 3.3% lead is most commonly used.

Other leaded copper alloys are used in smaller amounts than brass:

- Leaded bronze: copper-tin-lead alloys;
- Leaded nickel silver: copper-nickel-zinc-lead alloys;
- Leaded copper beryllium: copper-beryllium-lead alloys.

The Umbrella Project (2019a) claims that electrical or thermal conductors are the majority of applications of leaded copper alloys in EEE, e.g. all kinds of connections for the transfer of data, signal or power. Furthermore, leaded copper alloys are widely used for specifically designed mechanical parts with small scale features like e.g. cable glands, housing parts, filigree formed accessory parts, etc.

Bourns Inc. (Bourns Inc. 2020a) is a manufacturer of small passive electronic components for which the following components of leaded copper alloys are needed: bushings, shafts, terminals, terminal strip and rivets. Bourns Inc. explains that leaded copper alloys can be precisely processed in fast screw machines.

The Umbrella Project applies for the renewal of the above-mentioned exemption for electrical and electronic equipment (EEE) of category 1 to 10 with the maximum validity periods. The Umbrella Project additionally applied for category 11 on 9 October 2020, which was also included in this evaluation. Bourns Inc. applies for EEE of category 1-11 "depending on EEE manufacturer using electronic components as part of their assembly" as well with the maximum validity period.

There is a corresponding exemption in the end-of-life vehicles (ELV) Directive 2000/53/EC (listed in Annex II as exemption 3) with the same wording "Copper alloy containing up to 4% lead by weight". This exemption has recently been reviewed[44] as its mandatory review date is in 2021 however, the report has so far not been published (September 2021). A harmonisation of the exemptions should be considered once the assessment report is published.

9.2. Technical description of the requested exemption

The Umbrella Project (2020f) generally claims that copper alloys are neither cheap nor light materials and assumes that they will only be used when needed. The Umbrella Project argues that the machinability of the leaded copper alloys is important to

[44] See information at https://elv.biois.eu

produce a specific component/part and makes substitution impracticable as components/parts made of leaded copper alloys have essential properties e.g. conductivity, relaxation, corrosion, lubricity, for which substitutes have not shown comparable performance.

According to the Umbrella Project (2020f), electrical or thermal conductors are the majority of applications of leaded copper alloys in EEE, e.g. all kinds of connections for the transfer of data, signal or power. Furthermore, leaded copper alloys are widely used for specifically designed mechanical parts with small scale features like e.g. cable glands, housing parts, filigree formed accessory parts, etc. The Umbrella Project does not provide further specifications for the components made of leaded brass besides examples where substitution has shown special problems, e.g. crimp connections, knurls, gas nozzles and retaining heads.

Bourns Inc. manufactures electronic components such as precision potentiometers, encoders, panel controls, rotary sensors, and trimming potentiometers for which they need leaded copper-zinc alloys (or the "free cutting brass C36000", CuZn39Pb3) for the following parts:

- Encoders: (shafts, terminals, terminal strip);
- Panel Controls: (brass shafts, strips, rivets);
- Precision Potentiometers: (wiper terminal, terminal, shafts, bushings);
- Rotary Sensors: (bushings);
- Slide Potentiometers (rivets); and
- Trimming Potentiometers (shafts).

Bourns Inc. explains that the brass can be precisely processed in fast automatic screw machines.

9.2.1. Amount of lead used under the exemption

Both applicants are not able to give an estimation on the amount of lead placed on the EU market through leaded copper alloys:

- The Umbrella Project states that nearly no "new" lead from primary sources will enter the EU market as the alloys (especially brass) are made from recycled material. The Umbrella Project confirms the numbers reported in the last evaluation in 2015/2016 on "*ca. 2500 tpa [tons per year] lead based on a use amount of leaded alloys in EEE of 100,000 tpa with 2.5% lead threshold is assumed.*" But it adds that due to slightly smaller production volumes also the amounts have slightly decreased.
- Bourns explains that their electronic components are sold by distribution so that they do not know the number of components including the leaded copper alloy C36000 (CuZn39Pb3[45]) brass entering the EU.

However, Bourns Inc. specifies the use of lead by providing a list of the different models of the electrical components that Bourns manufactures, with unit weight in

[45] The material designation of this alloys is: CuZn39Pb3 with the number CW614N; the alloys contain 2.5-3.5% lead.

grams and the share of lead of the total unit weight based on the C36000 composition. The finished units contain between 0,0003 and 0,33 gr lead.

9.3. Applicants' justification for the requested exemption

The Umbrella Project (2020f) has reviewed European standards defining the composition of copper alloys and identified four commercially available lead-free copper-zinc alloys (brass), which have different mechanical properties compared to leaded brass:

- CuZn21Si3P, is defined with a lead content ≤ 0.1% w/w; this silicon brass, also called Ecobrass, has a lower electrical and thermal conductivity than leaded brass.
- Three Copper-Zinc alloys with a lead content ≤ 0.1% w/w and a higher zinc content: CuZn40, CuZn42 and CuZn38As. These alloys do not contain a chip breaker such as lead or silicon.

The Umbrella Project concludes that no new lead-free copper alloy became available in the last five years since the last evaluation of the exemption in 2015/2016. The Umbrella Project (2021e) further pointed out that other lead-free copper alloys are under development and have been tested by partnering companies/associations, but that these alloys mostly only exist on lab scale and research is ongoing.

Bourns Inc. argues that no substitutes have been identified that showed the same machinability in automatic screw machines; the machinability is not further specified e.g. by speed or tool life.

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

The Umbrella Project (2020f) specifies the less favourable properties of the lead-free brass alloys as follows:

- The **high zinc content** in the alloys **CuZn37, CuZn40 and CuZn42** cause several changes to the mechanical behaviour e.g.:
  - The higher hardness together with long chip formation causes a higher wear or a break of tools: Special tools with chip breaker partly help to overcome the problems, however, for the occurrence of chatter marks, burrs or edges no solutions were found.
  - A lower cold forming ability makes the material unsuitable for crimping as cracks from the conductor until the edge of the connection and at the outside surface were reported from several manufacturers.
- The **silicon brass (Ecobrass) CuZn21Si3P** has a lower electrical and thermal conductivity and can therefore not be used for electrical or thermal conductors. In mechanical parts/components, the machinability of CuZn21Si3P is indicated at 70 – 75% of the leaded copper alloy CuZn39Pb3/C36000. For drilling of small bores, no practicable solution has yet been found. A five-step drilling strategy as proposed by the Ecobrass manufacturer allows a maximum number of 25,000 bores by one drill whereas the Umbrella Project specifies the requirement to be at 1.000.000 bores before a drill change. Therefore, Ecobrass was not found to be practicable. Since the last evaluations of this exemption in 2015/2016, possible

adaptations in the machining processes were used by companies for in-house research and development but no working solution was reported to the Umbrella Project (Umbrella Project 2021e).

For Bourns, the use of Ecobrass is not possible for the reason that the distributor of Ecobrass only provides bars with the smallest diameter of 0.250 inches. However, Bourns require a much smaller diameter size of 0.075. Using 0.250 bars would result in 91% waste if machined down to 0.075.

Other substitutes mentioned by the applicants but not further explored are the following:

- The alloy CuZn38As is applied in some drinking water applications as Arsenic hinders de-zincification; this requirement is not relevant in EEE; regardless of the high toxicity of arsenic, this alloy is not used in EEE.
- Lead-free alloys with high copper content, e.g. C18625 with 99.4 % w/w copper are much softer than brass which results in a lower strength and shows long chip formation.
- Stainless steel has a lower machinability of 40-50 % compared to leaded brass.
- Bourns Inc. mentions different material such as aluminium, zinc die cast and nickel silver but state that all three alternatives have a higher raw material cost and a slower machining rate which reduces the overall capacity the company can manufacture and shortens tool life.

The Umbrella Project dedicates one chapter of the application to "Examples for Successful Substitution" where feedback from a survey among the 50+ partnering associations of the Umbrella Project is cited.

- The **electrical and electronic manufacturers' associations** reported no examples of successful substitutions. One citation states that this topic should be better addressed directly to the members of metal industry associations and component manufacturers within the Umbrella project.
- From **mechanical engineering associations**, statements indicate that one company was able to mostly substitute leaded copper alloys, another partly and still another company applies low leaded copper alloys for some applications. When asked for clarification, the Umbrella Project specifies the following components/ parts where substitution could be achieved: for mechanical parts, bearings, housings, couplings and spindles and by another company cast or forged and machined counterweights used in air conditioning and refrigeration compressors when space allows the use of lead-free material.

9.3.2. Environmental and health arguments (also LCA aspects)

The Umbrella Project claims that for leaded copper alloys a closed loop exists and that semi-finished goods of leaded brass are nearly entirely produced from recycled material. The Umbrella Project claims that a sudden restriction of leaded brass would cause an adverse effect as the required material could not be made by direct recycling anymore.

Bourns Inc. refers to information e.g. to a life cycle assessment (LCA) on metals covering the life cycle stages mining, purification and refining (Nuss und Eckelman 2014) and to the comments of the European Copper Institute on the socio-economic analysis on classification and labelling of lead in copper alloys, which is however not relevant in an exemption evaluation under RoHS.

9.3.3. Socioeconomic impacts

Both applicants mention direct costs related to substitution but without further substantiating their statements:

- The Umbrella Project claims that investments in new machines would be difficult for small and medium sized enterprises; changes in the production process might require additional manual work that further increases direct costs ("especially problematic for companies in regions with high salaries").
- Besides, the Umbrella Project also raises the aspect of the direct recycling of chips that are a pre-consumer waste of the machining processes. According to the Umbrella Project, mixing of silicon brass and leaded brass chips would impede a direct recycling; they argue that a parallel use of both alloys is not practicable.
- Bourns Inc. mentions as direct costs a higher raw material price, higher prices if machining is slower and/or tool life shortened.

9.4. Stakeholder contributions

Twelve individual contributions have been submitted during the consultation period from 23 December 2020 to 03 March 2021. The arguments of the individual contributions are summarized in the following.

- **Mitsubishi Materials Corporation** (2021b), a material manufacturer, provides information on the lead-free silicon-based brass, Ecobrass. Mitsubishi Materials Corporation describes Ecobrass as
  - having equivalent machinability and productivity to C36000;
  - providing equivalent surface quality and dimensional precision to components made of C36000 even though it depends on machining conditions; and
  - providing a better surface roughness than C36000.

  Mitsubishi Materials Corporation provides information on the test machining of 15 small components weighing from 0.4 to 10 g that included different machining methods, e.g. turning, drilling, threading, knurling, and grooving and concludes that the tools incurred only minor damage.

  As for the disposal of chips, no specific problem occurred.

  Ecobrass is so far applied in various drinking water-related and automobile components, e.g. Small Car Air-Conditioner Components.

  Furthermore, Mitsubishi Materials Corporation announced the development of another silicon-based brass called "GloBrass" that has a higher electrical conductivity then Ecobrass and thus would be applicable for electrical/electronic parts.

  In a separate Annex, Mitsubishi Materials Corporation (2021a) provides technical information on continuous micro-drilling of Ecobrass and the availability of

Ecobrass material, where Mitsubishi Materials Corporation proposes to supply "more slender" bars upon request.

The input of Mitsubishi Material Corporation is further discussed in section 8.5.1.

- The **Swedish Chemicals Agency** KEMI (2021) addresses in a general comment all alloy exemptions including exemption 6(c). KEMI claims that the exemptions should be adapted to the corresponding level of the REACH restriction entry 63 (for further information see section 4.1). Furthermore, KEMI states that the exemption formulation should specify both the material or component and the specific applications.
- The Norwegian Environment Agency (2021) expresses similar arguments as KEMI. Referring to Recital (19) in the RoHS Directive (2011/65/EU) ('exemptions from restrictions for certain specific materials or component should be limited in their scope'), the Norwegian material Agency claims that 'the material or component and the specific application need to be defined in the description of an exemption'.
- The **Federation of the Swiss Watch Industry FH** (2021a) supports the request from the Umbrella project regarding all alloy exemptions. They explain in a general way that leadfree alloys are harder to work and their electrical conductivity is also worse. Besides, the Federation of the Swiss Watch Industry FH claims that leaded alloys in external watch components have already been substituted and that for internal components of the watch movement, substitution is more challenging. They furthermore refer to the derogation made in REACH entry 63 for internal components of watch timepieces inaccessible to consumers.
- **FRANCÉCLAT**, the French Watch, Clock, Jewellery, Silverware, Tableware Committee, contributed specifically to exemption 6(c) referring to the complex structure of a great number of small and extremely small parts with tolerances in the micro-range: "major difficulties were encountered during machining of the driving and regulating parts, e.g. the dimensions, tolerances and surface quality requirements are not met. The absence of equivalent quality for these parts has a negative impact on the primary functions of a watch, namely the precise time measuring function and the service life. Moreover, potential alternative materials currently don't meet other manufacturing criteria such as the productivity, the tool life, the energy consumption and therefore generate additional production costs in an already severe context of competition with countries where labour costs are low."
- **FMTI - Austrian Association of Metaltechnology Industries** supports the renewal request for 6(c) and refers to the recent re-evaluation of the European Chemicals Agency ECHA of the derogation for keys and locks, including padlocks in entry 63 of REACH Annex XVII (ECHA 2020). Keys, locks and padlocks are derogated from the lead restriction in articles because the decreased sliding behaviour of potential alternatives, that results in inferior surface quality. Lead provides properties such as improving sliding/ gliding property of keys in lock cylinders and padlocks when these locks are not lubricated; less brittle material, which is of importance for keys not breaking, and also for improving resistance against certain burglary attacks on cylinders.
- The **EVVA Sicherheitstechnologie GmbH**, a manufacturer of building hardware (e.g., locks, locking cylinders, keys, door handles, padlocks), expresses similar arguments as the Austrian Association of Metal technology Industries.

- **Rudolf Riester GmbH** explains that "Ecobrass is not machinable and does not have the electrical conductivity we require; the material should be machinable by CNC-lathe and milling machines and should be correspond with lead-containing in electric conductivity; if we have alternative material, we could switch to it within 5 to 10 years. Because in the medical industry, we have to revise the risk assessment documentation for every part. And there are thousands of parts that need to be changed to a new material".
- The contribution of **Huawei** (Andrae 2020) consists of a paper of Andrae as a analyses of environmental implications of RoHS exemptions 4f, 6a, 6b, 6c, 7a, 8b, 15(a), 15 and 34 of Annex III.[46] As for leaded copper alloys, the work compares four proxies of environmental impact (e.g. abundance in earth's crust and in the Oceans) only to the point of the alloy composition. Aspects such as e.g. different machining properties of the alloys are not considered. Thus, the work is not of relevance for the current assessment.

Furthermore, there were three contributions referring to a renewal of the exemption for specific categories:

- **Test and Measurement Coalition** (2021), see chapter 5.1.
- **SEMI Europe** (2021b), see chapter 5.1.
- **Fresenius Kabi** (2021), see chapter 5.1.

Aside from the contributions specified above, the following 12 organisations have expressed their support of the request for renewal of this exemption but did not provide any further detail: Trautwein Präzisionsdrehteile GmbH; Hacker-Feinmechanik; CARL DILLENIUS METALLWAREN GmbH & Co. KG; STERO GmbH & Co. KG; HEINRICH MUELLER GMBH; HUGO KARRENBERG & SOHN GMBH & CO. KG; Wilhelm Schauerte GmbH & Co. KG; Julius Klinke GmbH & Co. KG; Carl Leipold GmbH; wafi Walter Fischer GmbH & Co. KG; Heinrichs & Co. KG; Paul Weber GmbH & Co.KG

After the consultation was closed, GEM Terminal IND. CO., LTD (2021b) submitted a request to the EU COM to revoke exemption 6(c) of Annex III RoHS. GEM Terminal IND. CO., LTD (2021c) describes to have developed a custom model alloy "GEM19-589" that is a C2800 low-lead copper material produced by VIETNAM GEM ELECTRONIC AND METAL CO.,LTD.; GEM Terminal specifies the composition as follows: "Composition: Cu: 58~63.5%, Pb: less than 0.08%, Fe: less than 0.07%, Zn: Allowance, no Bismuth-containing" and has more favourable machining properties. Two different components, copper tubes/rods and hollow copper tubes/rods, manufactured in high-speed turning machines with specialized/customized cutting tool for terminals, electrical plug brackets and high-precision special-shaped contour strips materials.

46 Anders S.G. Andrae Does the Restriction of Hazardous Substances (RoHS) Directive Help Reduce Environmental Impacts? In: International Journal of Green Technology, 2020, 6, 24-37.

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

As in the last evaluation of this exemption, Mitsubishi Materials Corporation (2021b; 2021a; 2021c) submitted a contribution to the consultation pointing out the lead-free copper alloy Ecobrass as a substitute material for many components where electrical conductivity is not critical although it is not possible for Ecobrass to replace all leaded copper alloy. Besides, Mitsubishi Materials Corporation presented a newly developed silicon brass called "Globrass" that has a higher electrical conductivity compared to Ecobrass. The Umbrella Project (2021i) stated that its members so far have no experience with Globrass but will test it.

In the course of the evaluation, an online meeting was held on 9 June 2021 to clarify areas where conflicting views exist with regards to the machinability of Ecobrass. At the online meeting also the information from GEM Terminal IND. CO., LTD (2021a) on the successful substitution in elements for electrical contact was presented to the Umbrella Project and the Umbrella Project was given the opportunity to comment on this case of successful substitution.

It has to be noted that the Umbrella Project (2021c) basically agreed on a classification of components according to the main function that usually is either of electrical or mechanical nature. Whereas for components with electrical function, no successful substitution was reported by the Umbrella Project (2021c), for mechanical components, the Umbrella Project (2021b) reported some cases of successful substitution. The two groups of application are discussed separately in the following.

Components with electrical function

Thanks to the advance of the company GEM Terminal IND. CO., LTD (2021b), one example of successful substitution for electric elements was made public: GEM Terminal IND. CO., LTD (2021c) has developed a customized model of the high zinc alloy CuZn40 (C2800) to manufacture copper rods and hollow copper rods for e.g. plugs and terminals.

The Umbrella Project (2021b) referred to limitations of this example, e.g. the components have a simple geometry and do not need any bore, cut, knurl, cold forming steps and relaxation, and that the components are for transfer of power only. However, the Umbrella Project (2021k) generally agreed that "*for parts with more simple manufacturing or component characteristics it will be earlier possible to substitute leaded copper alloys*." The Umbrella Project (2021b) further argued that the achievements presented by GEM Terminal IND. CO., LTD (2021b; 2021c; 2021a) are basically in line with their findings: "*For electrical and electronic applications, e.g. all kinds of connections for the transfer of data, signal or power, the discussed brass types without chip breaker (e.g. CuZn42) seems at the moment to be the most promising material (e.g. CuZn42)*"

The consultant therefore concludes that in the next assessment of the exemption, industry will be able to provide a classification for those components where a substitution is possible or will be possible in a defined period of time.

For more complex components / parts, it is understood that the high zinc brass types without chip breaker (e.g. CuZn42) are technically impractical because insufficient stress relaxation and crimp ability of the material are often safety relevant (Umbrella Project 2020f). The Umbrella Project also describes that due to the lower machinability the material cannot be processed with standard tools. These applications where substitution is stated to be more challenging (Umbrella Project 2021k) are understood to be the following:

- components / parts with more complex manufacturing characteristics (e.g. with boring, cutting, knurling, cold forming, etc.) or
- (more) complex component characteristics (e.g. transfer of data or signal, relaxation requirements, etc.)

To conclude for the next review, industry is expected to elaborate a classification of applications for which an earlier substitution is possible and of applications where additional substitution will still need more time so that the scope of the exemption can be narrowed down in the next evaluation.

Mechanical components

For mechanical components, the Umbrella Project (2021e) states that cases of successful substitution have been reported by their members. The alternatives used were mainly Ecobrass but some members did not reveal the identity of the alloy type (Ecobrass or CuZn37/CuZn40/CuZn42) due to confidentiality. Based on their internal survey, the Umbrella Project (2021e) estimates that 4% of leaded brass can be substituted by Ecobrass in the field of mechanical engineering companies and provides the following examples: bearings, housings, couplings and spindles. All are from the mechanical engineering sector. One partnering company named cast or forged and machined counterweights used in air conditioning and refrigeration compressors when space allows the use of lead-free material. For these cases, adaptions in the production process like feed rate and speed have been mentioned without providing further specific information. The Umbrella Project (2020f) claims an increase of costs and refers to a calculation by Schultheiss et al. (2018). There, an increase in manufacturing cost by 77% was claculated for substitution with the low lead silicon brass CuZn21Si3P in a Swedish SME producing thermostatic radiator valves, radiator manifolds, fittings, and control values for heating of buildings. The Umbrella Project (2021e) states that answers received from the partnering associations support this finding but do not allow a quantification as information required therfore (e.g. production amounts or market share of the companies) are confidential. The Umbrella Project concludes this cost increase as being far beyond everything acceptable for series production. The consultant understands herefrom that substitution might be technically reliable on more cases then initially concluded by the Umbrelly Project but that socio-economic implications are at least in some cases the real reason why substitution is not completed.

Responding to the information provided by Mitsubishi Material Corporation, the Umbrella Project (2021k) argues that components manufacturers have to perform additional reliability testing which cannot be overseen by the material manufacturer; e.g. "*is the component reliabel under lab and field conditions and can the required shape be formed under series production conditions*". The Umbrella Project was asked to provide examples to substantiate this claim. According to the Umbrella Project (2021k), the publication of research on alternatives are usually confidential business information where also the fact that certain materials are tested can provide insights to competitors. Some examples have been compiled by the Umbrella Project (Umbrella Project 2021k) and four companies have sent confidential information directly to the consultant. According to this information, Ecobrass has been tested but also additional materials such as bronze alloys as well as specific coatings on steel parts. Information on substituion tests made available by the Umbrella Project (2021k) which are not confidential comprised the following components: solenoid valves, hydraulic pumps/motors, nut inserts that slide on a threaded spindle and nozzle housings.

The consultant concludes that a specification of the applications where the substitution with Ecobrass is basically possible still remains open. This should be tackeled in a future assessment to clarify whether differentiation between e.g. simple geometry versus complex shapes, low geometric tolerances etc. could help to narrow down the scope. It should be clarified by industry in future evaluations where substitution is technically practicable and where socio-economic considerations are the actual obstacle for performing further reliablity testing.

Initial conclusion

The reporting of the RoHS Umbrella Industry Project is partially hampered by the fact that companies did not report on their research and development efforts due to market competition but rather claimed the information to be confidential business information. At one stage in the evaluation process, some companies directly reported on their component testing and the failure of alternative alloys. Such input is essential to the assessment to substantiate claims alongside aggregated information provided by the Umbrella Project. However, the input remains exemplary and the consultant could not gain a conclusive overview.

The consultant understands that there is no "one-fits all" substitute for all EEE applications. In principle, lead-free alloys are available, but their applicability is limited to specific cases and does not allow a demarcation of applications that could be excluded from the exemption. Furthermore, the substitutes that are so far available cannot be used as simple" drop-in" but need further adaptations in the alloy composition and/or in the machining processes to allow their successful implementation.

The application of the Umbrella Project overall presents the failures of potential substitutes and does not provide any insights as to the general substitution efforts nor provide data on the overall lead reduction. The UP explains that this is very much due to confidential business information where single companies do not want to reveal any elements regarding their substitution strategy. As for electrical elements, it can be followed that Ecobrass is not a suitable all-round alternative due to its low conductivity.

It has to be noted that the Umbrella Project (2021c) basically agrees with the need for an approach based on the classification of components according to the main function of lead, which is usually either of electrical or mechanical nature. Whereas for mechanical components, the Umbrella Project (2021b) reported some cases of successful substitution, for components with electrical function no successful substitution examples have been reported by the Umbrella Project (2021c) or its individual members.

It should be noted here, that the newly developed silicon brass “Globrass” by Mitsubishi Materials Corporation (2021b) might allow new substitution options and test results are expected for the next review.

9.5.3. Environmental arguments and socioeconomic impacts

In the context of environmental impacts, the closed loop for copper recycling was brought forward by the applicants because a mixture of lead- and silicon-containing scraps cannot allegedly be remelted but has to undergo an energy intensive recycling via smelter.

It is understood that this is relevant for component manufacturers that sell back the scrap to the material supplier directly: Through the machining processes, a substantial proportion of the ingoing material is transformed into industrial scrap in the form of chips which are cleaned from oil and lubricants by the component manufacturers to allow its recycling and reuse. Thus, the prevention of a potential contamination of leaded brass would need a separate cleaning and storing chip cycle where both alloy types are applied. This is understood to be feasible in theory, however in practice it implies investment and would hinder a partial or sequential use of e.g. Ecobrass within one SME.

As already mentioned above, the Umbrella Project (2021e) claims an overall and unacceptable cost increase when substituting leaded brass CuZn39Pb3 by CuZn21Si3P. However, it is understood that the information only applies to the level of specific components and not to the final EEE. The impact of such a cost increase on the final EEE cost has not been demonstrated. Detailed information on higher costs is exemplary and does not allow a conclusion as to the severity of such impacts.

9.5.4. Scope of the Exemption

The scope of the current exemption is wide and consequently the contributions of the Swedish Chemicals Agency KEMI and the Norwegian Environment Agency claim a specification of the exemption for materials and components of EEE and for specific applications. This could basically be achieved by a split of the exemption into several items for specific applications where it has been verified that feasible alternatives are currently not available or reliable. The consultant generally agrees with the need to narrow the scope of the exemption, however, concludes that it is not possible on the basis of the evidence made available during this assessment.

Though industry agrees to a differentiation between two big application groups (components with electrical function and mechanical components), this does not allow narrowing down the exemption's scope in a way that would exclude applications from the exemption where substitutes are available. A future possibility might be to base a grouping on geometry or properties of the final component (for components with electrical function this could be e.g. transfer of power versus transfer of data). Thus, the consultant concludes that industry should provide a proposal for an approach to narrow down the scope in the next review.

Finally, the consultant urges other material manufacturer to take a more active role, e.g. the European Copper Institute or the Copper Development Association Inc. (CDA) in communicating further steps and visions for copper alloy development.

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.

The consultant understands from the different information provided that there are substitutes available that could at least be used for some applications. However, the use of alternatives (e.g. Ecobrass) requires adaptations in the machining process. Consequently, substitution with Ecobrass is currently understood to have restrictions limiting its applicability to only certain applications.

As for components with electrical function, it is further understood that lead-free copper alloys (high zinc alloys) are applicable for components with a simple geometry and transferring power. This application group should be confirmed or revised by industry for the next review.

It is noted that though the applicants and stakeholders provide some details as to their efforts towards substitution, in most cases information remains exemplary and does not allow an overview as to the substitution efforts and problems, e.g. economic considerations that might prevent further reliability testing.

The consultant concludes that the current general scope is not justified, however demarcating applications where substitutes are available was not possible on the basis of the data made available during the assessment. Industry is urged to generate input that would allow narrowing the scope of the exemption to a comprehensive list of applications.

It is also noted that an alignment of the exemption with results of the evaluation under ELV should be considered.

9.6. Recommendation

It is recommended to renew the exemption with the current formulation.

As for the duration, the exemption currently has a different validity for the various RoHS Annex I EEE categories. While for most categories, it is set to expire on 22 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. To avoid future co-existence of several sub-items with slightly different scopes it is recommended to align all categories in terms of the validity period, seeing as stakeholders did not provide information to show that technical differences existed between categories regarding the substitution of lead in copper alloys.

	Exemption formulation	Duration
6(c)	"Copper alloy containing up to 4 % lead by weight"	Expires on 21 July 2026 for all categories

To furthermore ensure that RoHS provides a similar level of environment and health protection as that of the REACH Regulation, and with entry 63 of Annex XVII in mind, it is recommended to add the following phrase for precautionary reasons to the exemption wording: "*The exemption shall not be applicable to articles or accessible parts of an article that 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, except where it can be demonstrated that the rate of lead release from the accessible component /part, 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*". Alternatively, this addition could be added as a footnote to the exemption.

10. Exemption 7(a) "for lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)"

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

BGA	Ball Grid Array
Bourns	Bourns, Inc.
DA5	Die Attach 5, a consortium established to develop a Pb-free die-attach solution consisting of STMicroelectronics, NXP Semiconductors, Infineon Technologies, Bosch (Division Automotive Electronics), and Nexperia
DCB	Direct copper bonding
EEE	Electrical and Electronic Equipment
ESD	Electro-Static Discharge
HID	High Intensity Discharge
HMP	High melting point
HMPS	High melting point solders
IC	Integrated circuit
LED	Light emitting diode
LHMPS	High melting point solders with a lead content of at least 85 %
Pb	Lead
PCB	Printed Circuit Board
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
SMD	Surface Mount Device
TFCB	Thick film copper bonding
TLPS	Transient liquid phase sintering
THT	Through hole technology
UP	Umbrella Project: A large number of company/business organizations/business associations that are participants in the RoHS Umbrella Industry Project

10.1. Background

10.1.1. Overview of the Submitted Exemption Requests

Three applications (Bourns Inc. 2020c; Umbrella Project 2020e; 2020g) were submitted for the renewal of Ex. 7(a) for:

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

Both applicants (Bourns Inc. and the Umbrella Project) request the renewal of the exemption for categories 1-11 with its current wording for the maximum duration allowed by Article 5 of the Directive.

Bourns Inc. (hereinafter referred to as Bourns) requests the exemption explaining that lead enables soldering at higher temperatures, while maintaining the reliability of the connection. Lead-containing high melting point solders with a lead content of at least 85 % (LHMPS) are used in electronic components to maintain the integrity of the joints between the die and lead-frame at the board level assembly. Bourns argues that substitutes are currently not available, explaining that alternative solders must have properties to protect the solder from melting, thereby creating a failure situation. (Bourns Inc. 2020c)

STMicroelectronics srl and Infineon Technologies AG apply for the exemptions renewal on behalf of a large number of company/business organizations/business associations that are participants in the RoHS Umbrella Industry Project (Umbrella Project, hereinafter referred to as UP). Their first request was submitted for categories 1-10 of Annex I of the RoHS Directive and the second for category 11. The UP specifies a wide range of applications where LHMPS are still needed, claiming that though research into possible substitutes has been underway for many years, suitable substitutes are yet to be identified. In essence, alternative technologies with similar ductility and strength to that of lead (Pb) alloys and that can survive a standard reflow process (or several) on printed circuit board with either leaded or unleaded solder are as yet unavailable. (Umbrella Project 2020e; 2020g)

In the later rounds of clarification questionnaires, Bourns participated in the UP Group's discussions regarding the extension of this exemption and in preparation of responses to some clarification questions. Bourns agrees with the points addressed in the UP submission with the addition of the individual Bourns-relevant inputs.

10.1.2. History of the Exemption

Exemption 7(a) for "*Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)*" was initially listed in Directive 2002/95/EC (RoHS 1) [47], when it was published in 2003. 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 available for the full range of relevant applications. However, it was also concluded that the exemption wording created a loophole, as its formulation did not restrict the application of the exemption only to areas where substitutes were not available. Evidence for this was provided already in the first assessment, where stakeholder information showed that in some cases, LHMPS are applied also in cases where solders with a lower lead content can be used.

An effort was made in the past (Gensch et al. 2016) to develop an exemption wording that would apply only to areas where the use of LHMPS could not be avoided, however this attempt did not culminate in a formulation that was adopted into Annex III of the Directive (see details in (Gensch et al. 2016)).

It is noted that Delegated Directive (EU) 2018/742 of 1 March 2018, which presents the final decision regarding the prior evaluation of this exemption, constitutes the legal renewal of Ex. 7(a) with its initial wordi

ng. At that time, the document was based, among other things, on the following rationale: "*no reliable alternatives are available on the market or are likely to be available on the market in the near future, a renewal of the exemption with a validity period until 21 July 2021 is justified, while nonessential splitting of the wording and a shorter period could generate unnecessary administrative burden for the industry*."

10.2. Technical description of the requested exemption

10.2.1. Specific Properties of lead in LHMPS

Bourns and UP present the required properties of lead in HMPS which can be demonstrated by the following performance: high melting point (>260°C), thermal conductivity, ductility, electrical conductivity, electrical resistivity, corrosion resistance, resistance to thermal oxidation. Lead is still the only known element which gives all these properties (Umbrella Project 2020g; 2020e). Other factors include the manufacturability, reliability factors in a harsh environment and cost effectiveness. For lead-containing solders, the historical data of over 50 years of usage provides proven reliability (Bourns Inc. 2020c).

A more detailed description of specific properties of lead can be found in the last evaluation report (Gensch et al. 2016).

[47] 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, RoHS 1, European Union (13 February 2003)

10.2.2. Uses of LHMPS

Bourns Inc. (2020c) specifies that LHMPS can be applied in various equipment and refers to the medical equipment, aerospace, automotive and military sectors as their customers. Semiconductor products use high-lead solder as a die attach material and/or as internal electrical interconnections within components including diodes, transistors, clip bonding of discrete devices and for surface mount and insertion components. Bourns refers to specific applications many of which are components that inherently protect EEE from irregularities in power supply such as Electro-Static Discharge (ESD), electricity surges, voltage level irregularities and overcurrent situations. Among the equipment and components that need to be protected from such impacts, Bourns mentions appliances in general, light emitting diode (LED) lighting and batteries in both vehicles and EEE such as mobile phones and medical equipment. In relation to fuses for protecting battery packs, it is mentioned that these are typically used in a harsh, extreme heat environment, where the solders must thus have properties to protect the solder from melting thereby creating a failure situation. It is not clear if these environmental operation conditions apply to all applications mentioned by Bourns.

UP (2020e; 2020g) also described that high-melting point solders (85% by weight or more lead) are used in a wide range of electronic components as well as to manufacture equipment. This exemption is required in many types of electrical and electronic equipment applications (in all RoHS categories). UP provided a non-exhaustive list of application areas of LHMPS as below (Umbrella Project 2020e; 2020g):

- combining elements integral to an electrical or electronic component such as:
  - a functional element (e.g. die, lamp socket) with a functional element, or,
  - a functional element with wire/terminal/heat sink/substrate, etc.
- mounting electronic components onto sub-assembled modules or sub-circuit boards;
- sealing materials between a ceramic package or plug and a metal case,
- connecting magnet wire coil to flexible conductor in high power transducers (both low and high frequency) used for professional sound application.

LHMPS are said to have excellent wettability, reliability due to ductility and no re-melting during PCB reflow process. Components containing high lead solder are reflowed up to 260°C without melting the inner component solder which will soften at about 300°C. Semiconductor-type devices require these high temperature solders to maintain the integrity of the joint between the die and lead-frame at board level assembly (Bourns Inc. 2020c; Bosch, STMicroelectronics, Infineon, NXP, Nexperia 2021b; Umbrella Project 2020e; 2020g)

Intended use and examples for related products in which HMP lead (Pb) solders utilized are shown in Appendix A.2.1.

In a later communication (The RoHS Umbrella Project 2021a) a table was provided to show the properties provided through the use of Pb that are of relevance to the various applications in the scope of the exemption. The table is reproduced in the appendix A.2.2. It is noted that few thresholds were provided in that table, which was intended to be used to understand the performance range in which LHMPS applications would be considered.

LHMPS used as combining elements integral to an electrical or electronic component

Plenty of microelectronic components are given as examples[48] by applicants, which need LHMPS. The Umbrella Project (2020e; 2020g) provides figures to illustrate that LHMPS are used to combine elements integral to an electrical or electronic component. The figures below (Figure **10-1** and Figure **10-2**) are selected and reproduced from the UP application to demonstrate different usage of LHMPS. Generally, LHMPS is used for connection between two functional elements (e.g. semiconductor chips) or a functional element and carriers (i.e. printed circuit boards, lead frames, wire, terminals, substrates or other final assemblies). It can be seen that the LHMP solders are used either in internal connections inside the components or in integral connections where the LHMPS is inside the component but also visible from the outside. The difference between „internal" and "integral" was raised in the last evaluation report (Gensch et al. 2016), it was discussed that "integral" covers all joints which are connections that are partly within the space envelope of a single component (i.e., non-visible in part from the outside) but also partly external to that space, i.e. visible in part from the outside.

[48] Umbrella Project (2020e), (2020g): Resistors, capacitors, chip coil, resistor networks, capacitor networks, leaded inductors, power semiconductors, discrete semiconductors, microcomputers, ICs, LSIs, chip EMI, chip beads, chip inductors, chip transformers, power transformers, lamps, resistance temperature devices (RTD), electromechanical relays for automotive (just as reference) and industrial use, etc

Bourns Inc. (2020c): Components include Transient Voltage Suppressor Diodes, Fast Response Rectifier Diodes, High Voltage Rectifier Diodes, Schottky Barrier Rectifier Diodes, Power TVS Diodes, Telecom CPTC Resettable Fuses, Thick Film Molded DIP/SIP, Thin Film Molded SIP, Thin Film Wide Body Gull Wing Resistor Network, Thick Film Surface Mounted Body Wide Resistor Network, Thyristor Surge Protector (SMA and SMB packages), Telecom Ceramic PTC Resettable Fuse, Fast Acting Precision SMD fuse, Single Blow Fuse for Overcurrent Protection, High Inrush SMD Fuse, Telecom Protectors, High Surge, Time Lag & Low Power SMD fuse. These electronic components are typically used on circuit boards and other internal electronics of the various categories used by our customers.

Figure 10-1: Examples of LHMPS used as combining elements integral to an electrical or electronic component

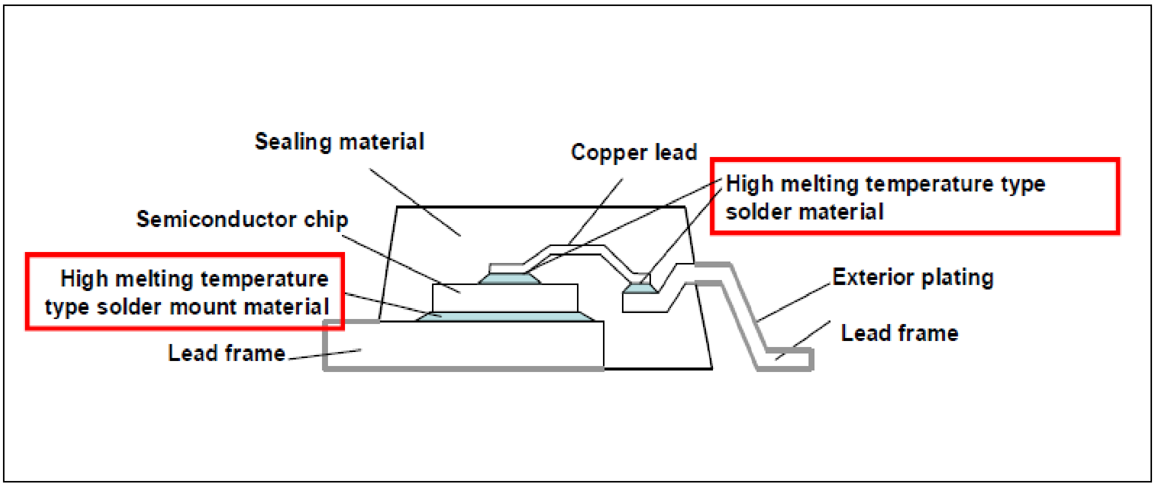


Figure 3: Schematic cross sectional view of internal connection of semiconductor

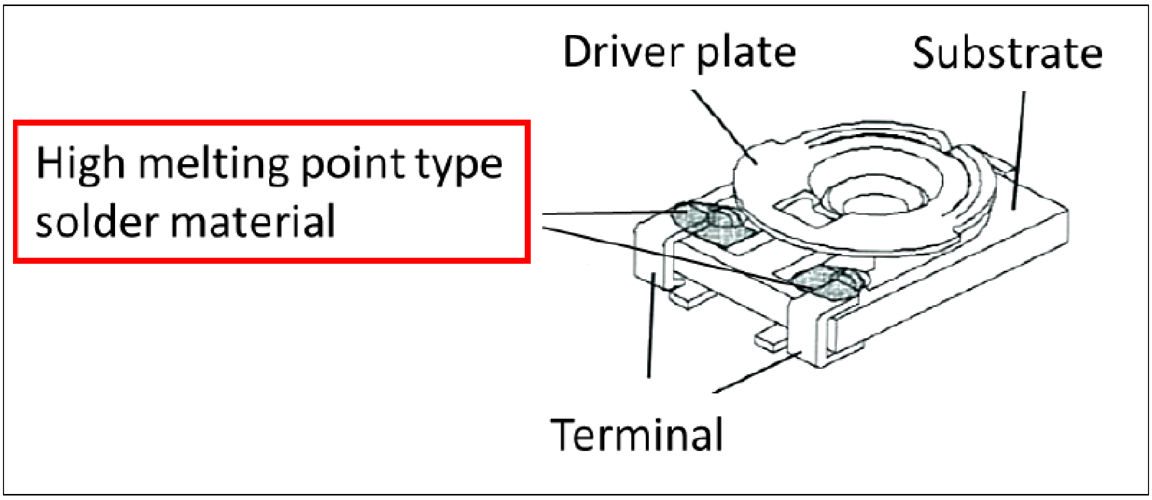


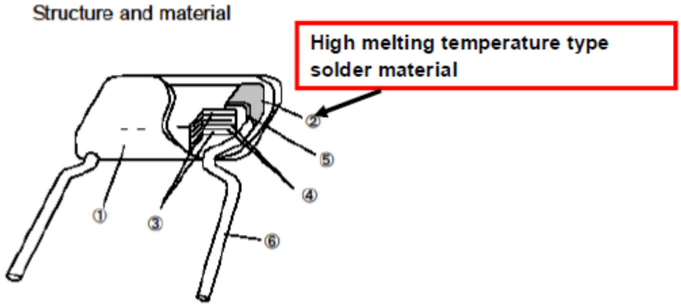
Figure 1: Schematic view of potentiometer with HMP lead (Pb) solder visible from the outside

Source: (The RoHS Umbrella Project 2021d; Umbrella Project 2020e; 2020g)

Figure 10-2: Examples of LHMPS used as combining elements integral to an electrical or electronic component

Structure and material

1. Structure



2. Material and Description

No.	Material	Description
①	Enclosure	Epoxy resin
②	Inner solder	Sn-Pb type solder *1
③	Dielectric	Ceramic
④	Inner electrode	Ni or Pd or Ag/Pd
⑤	Outer electrode	1)Ag/Pd or 2) Ag or Ag/Pd or Cu + Ni plating + Sn plating
⑥	Lead wire	Solder(Sn-2.5Cu) coated copper wire or Solder(Sn-2.5Cu) coated CP wire

*1 Lead in high melting temperature type solders (Pb;85% or more) are exempted from the requirements of RoHS.

***Figure 4**: Schematic view of capacitor with lead wire*

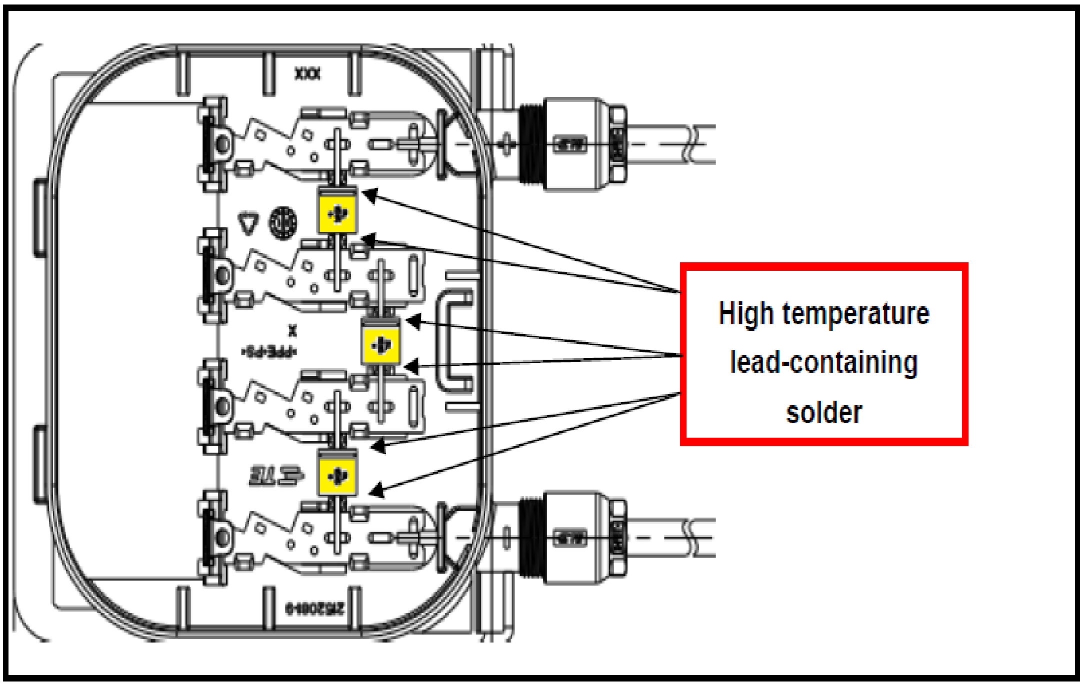


***Figure 8:** Bypass diodes (3) used in photovoltaic array connection module*

Source: (The RoHS Umbrella Project 2021d; Umbrella Project 2020e; 2020g)

Another example raised by Umbrella Project (2020e) is ribbon cable connections to capacitors in medical devices (category 8). It is described that a medical device manufacturer connects capacitors to ribbon cables using a HMP solder which are then reflow soldered to a printed circuit board (PCB) using lead-free solder. The higher melting point of the HMP solder is essential to prevent the bonds to the capacitors failing during reflow of the PCB, which is typically at 240 - 260°C. The medical device manufacturer is evaluating alternative lead-free solders, but has not found any reliable alternative to date. If standard lead-free solders are used to connect to capacitors, these melt and de-bond when the cables are soldered to the PCB.

Further detailed description of the technical background can be found in the last evaluation report by Gensch et al. (2016) and contributions of applicants.

LHMPS used as mounting electronic components onto sub-assembled modules or sub-circuit boards

This application group refers to components that are externally mounted onto e.g. PCB or lead frames by using LHMPS solders. Solder joints are visible from the outside. Examples of related products are hybrid IC, modules, optical modules, etc (Umbrella Project 2020e; 2020g).

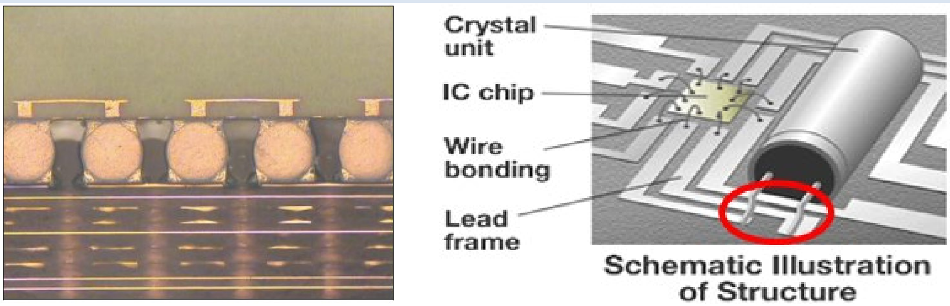
Figure **10-3** shows examples for how LHMPS are used to mount electronic components onto sub-assembled modules or sub-circuit boards. With respect to second level solder joints, two concrete cases can be identified:

I) solder balls for the attachment of ceramic ball-grid-array (BGA)

II) when attaching high temperature plastic overmouldings (> 220 °C)

Regarding item I), a graphic (Figure **10-3**, left) can be found in the evaluation report of 2009 (Gensch et al. 2009). With respect to item II), one use case provided is plastic molded timing devices (like i.e. crystals, oscillators), where the cylinder crystal is soldered onto a lead frame using LHMPS (The RoHS Umbrella Project 2021d). The RoHS Umbrella Project (2021e) clarifies that LHMPS is used to solder components onto printed circuit boards or lead frames, which afterwards are overmoulded with high temperature plastics.

Figure 10-3: BGA component with HMP balls (left) and cylinder crystal soldered onto a lead frame using HMP (right)



Source: left (Gensch et al. 2009); right (The RoHS Umbrella Project 2021d)

Further detailed description of the technical background can be found in the last evaluation report by Gensch et al. (2016).

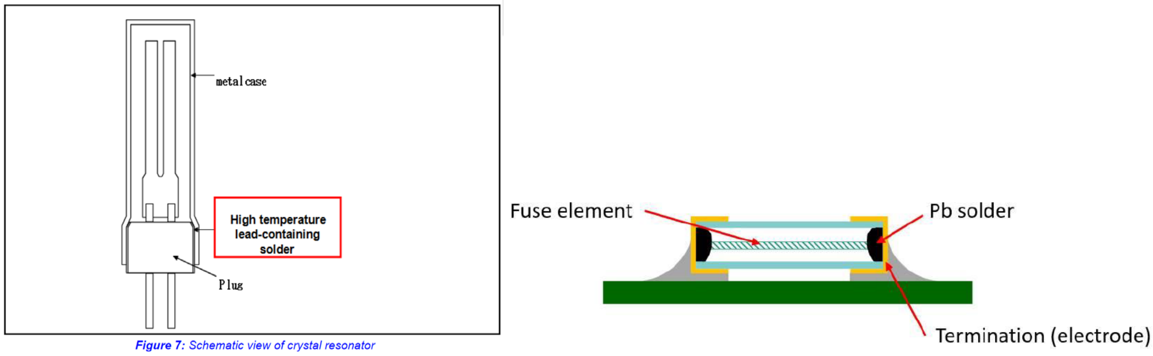
LHMPS used as sealing materials

Examples of related products are SAW (Surface Acoustic Wave) filter, crystal resonators, crystal oscillators, crystal filters, etc (Umbrella Project 2020e; 2020g).

LHMPS is used for sealings between a ceramic package or plug and a metal case. In a later communication, Bourns Inc. (2021d) added that LHMPS is also used for sealing between component terminations and internal sub-parts.

Figure **10-4** illustrates examples of these two cases, in which Pb (>85%) is used as a hermetic sealing material. The left figure shows the use of LHMPS for sealings between a ceramic package or plug and a metal case in a crystal resonator. The right figure demonstrates that LHMPS is used as a hermetic sealing material between component terminations (electrode) and an internal sub-part (fuse element) in a SMD fuse.

Figure 10-4: LHMPS used in a crystal resonator (left) and a SMD fuse (right) as sealing material

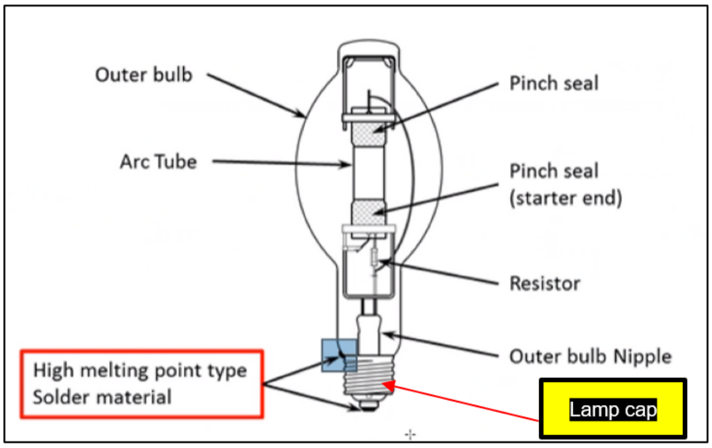


Source: left (Umbrella Project 2020e); right (Bourns Inc. 2021e)

LHMPS used in lamps

Oven lamps are commonly used in various household ovens. (Umbrella Project 2020g; 2020e) explains that the temperature of the lamp can reach >250°C during the baking process and it may reach 300°C during the oven cleaning cycle, the so-called pyrolysis. The electrical contact between lamp and lamp socket is provided by mechanical contact of the solder in the lamp base with a spring in the lamp socket. Any oxidation between these parts will cause an increased electrical resistance that may result in electrical arcs which poses a safety risk. In the later communication, The RoHS Umbrella Project (2021d) explains that LHMPS materials in lamps are mainly used for soldering a solid electrical connection between electrical (lamp) components (and not in or inside lamp components). The solder point connection in many cases is visible from the outside, e.g. when used to connect the lamp cap to the internal wires (Figure **10-5**).

Figure 10-5: Example of an HID lamp with LHMPS material to connect the lamp cap to the internal electrical wiring of the lamp



Source: (The RoHS Umbrella Project 2021d)

LHMPS used in audio transducers

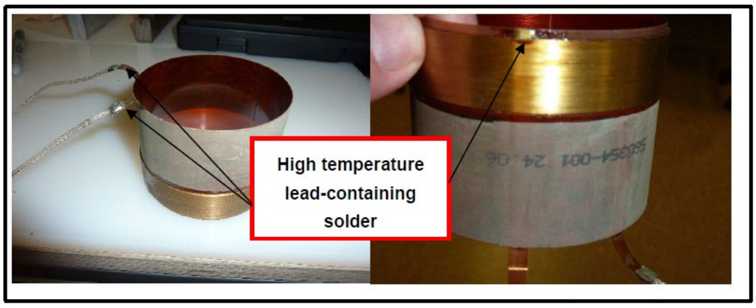
Audio transducers, e.g. voice coils, are used to measure flow and density properties in industrial measurements in combination with a permanent magnet. The application includes chemical plants, refineries, food and beverage, pharmaceutical industries, etc. Industrial equipment that uses voice coils and magnet wire include magnetic flow meters, Coriolis flow meters, density meters, and many others. Additionally, solenoid valves and other types of valves also use voice coils and LHMPS. In these examples, process temperatures can extend into areas where LHMPS is required. Additionally, many applications use steam and/or heated liquid cleaning which also requires use of LHMPS. Termination of magnet wire is required of many other types of components (The RoHS Umbrella Project 2021d).

The RoHS Umbrella Project (2021d) explains that LHMPS is needed where the peak operating temperature exceeds the melt point of lead-free solders. Because these solder joints are on the moving voice coil, they have very high acceleration forces on them when they are being driven at levels high enough to reach the peak operating temperatures. Any softened or molten solder will be thrown from the electrical connection in those cases. The solder joint will then either open electrically or it can also start arcing due to the very high voltage potential. Both conditions cause field failures, the arcing can also lead to things such as arc tracking and combustion issues.

An example of a voice coil is shown Figure **10-6**.

Figure 10-6: Example of a voice coil

Das verknüpfte Bild kann nicht angezeigt werden. Möglicherweise wurde die Datei verschoben, umbenannt oder gelöscht. Stellen Sie sicher, dass die Verknüpfung auf die korrekte Datei und den korrekten Speicherort zeigt.



Source: (The RoHS Umbrella Project 2021d; Umbrella Project 2020e; 2020g)

Further detailed description of the technical background can be found in the last evaluation report by Gensch et al. (2016) and contribution by applicants.

10.2.3. Amount of lead used under exemption 7(a)

The content of lead for HMPS applications is 85% or more by weight of the homogeneous material based on (Umbrella Project 2020e; 2020g) and 88%-95.5% (Bourns Inc. 2020c).

In relation to the amounts of lead placed on the market in LHMPS used in EEE, the 2015/2016 report (Gensch et al. 2016) specifies around 11,000 t corresponding to around 9,400 t of lead globally for 2000. For 2009 it refers to a JBCE statement, estimating LHMPS put on the EU market with 3,600 t/year corresponding to at least 3,100 t of lead. This figure is understood to have not included the LHMP solders contained in products imported into the EU market. In 2015/16 Freescale/NXP et al. estimated the amount of LHMPS put on the EU market with around 2,700 t, which corresponds to at least 2,300 t of lead. This figure was also understood to not include the lead from LHMPS used in products imported into the EU.

In the current review, Bourns estimated the worldwide amount of lead from LHMPS based on its own products at around 0.838 tonne (Bourns Inc. 2021c). Bourns Inc. (2021c) adds generated information that the metric tons average, based on parts shipped to the European market (including the UK), for the last three years is 0.15 metric tons of Pb from high temp solder.

The Umbrella Project estimated the amount to range between a few kg and 31 tonnes per year (Umbrella Project 2020e). However, this is understood to be based on answers of individual member companies of this working group that participated in a survey, i.e., representing amounts for single companies and not an aggregation representative for all members let alone for the complete market.

Based on data provided by stakeholders, the contractor attempted to estimate the amount of Pb in HMP solders using the following information/assumptions:

- "the amount of Pb in HMP solders for EEE is estimated to be less than 0.2% of the total Pb placed on the market per year"[49].
- "According to the International and Lead Zinc Study Group, in 2015, around 10,000 tons of lead were used in the EU for 'miscellaneous' uses which includes leaded alloys and solders, presumably including those going into the electronics sector. This amount represents approx. 1% of the total EU usage of lead per year"[50].
- the amount of Pb per year in HMP solders in the EU: 10,000 tonnes / 1% *0.2%=20,000 tonnes

The applicants and contributors were asked to comment on the above estimations. UP commented that they do not have a reliable estimate on the total LHMPS in EEE in Europe. However, UP states that these estimations with 20,000 tonnes are excessive based on a new UP estimation, which is described below (The RoHS Umbrella Project 2021c; 2021d):

- an estimation of the total scrap WEEE collected in EU accounts for 15 Million t/a Urban based on Urban Mine platform 2020
- PCB are estimated to be 1 % of the total waste scrap, this accounts for 150,000 t PCB/a.
- according to Swiss Federal Office for the Environment (FOE) - Substance flows in Swiss e-waste, 11.000 ppm (= 1,1 %) of Pb in PCB are mainly used related to the soldering of packages onto the PCB. The FOE study was based on E-scrap before RoHS entered into force. UP estimates that the average amount of lead in PCBs has reduced by around 90 % by introducing lead-free soldering of PCBs following the RoHS lead ban.
- Hence, the estimated amount of Pb soldered to PCBs in the EU would be:150,000 t PCB/y*1,1%*(1-90%) ≈150 tonnes Pb/year.

When asked whether the estimation of 150 tonnes/annum covers LHMPS used for all applications, e.g. sealing materials, UP explains that all devices soldered to a PCB are counted for in the estimated 150 tonnes/annum. This estimation includes sealing applications. A typical value for sealing of a ceramic housing encapsulating a die structure is 2 mg per component (The RoHS Umbrella Project 2021d).

The consultant notes that this estimation is based on the amount of WEEE collected. In 2018, the collection rate of WEEE was 47 % in the European Union[51]. In this sense, this estimation may still represent only part of the WEEE placed on the market.

Table 10-1 summarizes the trajectory of lead used in HMP in the scope of exemption 7(a) since the last evaluation.

[49] Umbrella Project (2020e), Page 11
[50] Umbrella Project (2020e), Page 28
[51] See: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Waste_statistics_-_electrical_and_electronic_equipment#Electronic_equipment_.28EEE.29_put_on_the_market_and_WEEE_collected_by_country

Table 10-1: summarized the trajectory of lead used in HMP in the scope of exemption 7(a) since the first evaluation

In the scope of exemption 7(a)	Lead brought on the global market in LHMPS	Lead brought on the EU market in LHMPS
2000 (Gensch et al. 2016)	9,400 tonnes	unknown
2008/2009 (Gensch et al. 2016)	unknown	3,100 tonnes (This figure did not include the LHMP solders contained in products imported into the EU market.)
2016 (Gensch et al. 2016)	unknown	2,300 tonnes (this figure did not include the lead from LHMPS in products imported into the EU.)
Current assessment: 2020 own estimation	unknown	20,000 tonnes
Current assessment: 2020 estimated (The RoHS Umbrella Project 2021c; 2021d))	unknown	150 tonnes

The figures differ depending on the applied calculation base and product spectrum as well as assumptions taken into account. The estimation made often have a degree of uncertainty and do not allow concluding as to the total amount of lead. However, one issue is clear, i.e. the amount of lead used under this exemption is NOT negligible.

10.3. Applicants' justification for the requested exemption

Bourns (2020c) explains that Bourns is still researching and testing alternative solders or processes to eliminate LHMPS in applications in some cases. Additional detail is not provided as such information is regarded as proprietary; however, this effort is explained to relate to a specific product line and Bourns states that it may not provide a solution for other product lines.

The Umbrella Project (2020e) explains that substitution is currently not possible, mentioning the various properties required from substitutes. Alternative technologies are not yet available that have the combination of ductility and strength of Pb while retaining reliability during one or several reflow processes (melting of solder) which would otherwise weaken the bond.

10.3.1. Availability of alternatives

Lead-free Solders

Bourns Inc. (2020c) refers to a few potential substitutes in its application including gold, zinc, bismuth or tin/ antimony-based solders. Potential substitutes are explained to have reliability issues including voiding/cracking/disruption after stress, growth of brittle intermetallics at high temperature and disruption during temperature cycling. For gold-based solders low ductility and a low melting point is explained to be a disadvantage in comparison to LHMPS. For the other mentioned candidates there is limited experience with alternatives regarding their reliability.

The Umbrella Project (Umbrella Project 2020e; 2020g) refers to two additional sources of information related to alternatives for die-attach applications: Vishay and the DA5 consortia. Vishay is said to have evaluated lead-free materials for internal die-attach, including solder pastes and solder wires based on the BiAg, AuSn and SnAgCu systems as well as silver sinter pastes, sinter epoxy and silver epoxy from several suppliers. None of the evaluated materials have proved capable of replacing HMP lead (Pb) solder in terms of manufacturability, quality and reliability. Detail given in the Umbrella Project applications provides a summary of experience with some alloys (reproduced in Appendix A.2.3). Bosch, STMicroelectronics, Infineon, NXP, Nexperia (2021b) provides similar information as the last evaluation. Advantages and disadvantages of alternative solders are shown in Appendix A.2.3 to justify that alternative Pb-free HMP materials currently available on the market do not meet or exceed the required functionality and reliability for the various uses.

Conductive Adhesives

Advantages and disadvantages of conductive adhesives are shown in Appendix A.2.3. More detailed information is presented in the section on "Efforts of the Die Attach 5 (DA5)" in the Umbrella Project applications (2020e; 2020g). However, it is very similar information to that in the application submitted to the 2015/2016 assessment.

As of mid-2019, the DA5 consortia are not aware of any solution (glue or other materials) that can replace HMP lead (Pb) solder, for the time being. HMP solders and adhesives belong to completely different material classes and perform very differently. Some adhesives constituents are classified as CMR[52] (Umbrella Project 2020g; 2020e).

For conductive adhesives, these are said to have the same or better mechanical, thermal, and electrical properties compared to solder, and can be used in die bond equipment for dispensing, chip placement, and curing of the material (Drop-In Solution) (Bosch, STMicroelectronics, Infineon, NXP, Nexperia 2021b). As it is also specified that, depending on package type and die size, these can pass automotive environment stress test conditions (AEC-Q100, AEC-Q101) (Bosch, STMicroelectronics, Infineon, NXP, Nexperia 2021b). The consultant assumes that at least in some cases, conductive adhesives provide sufficient reliability. In this respect, limitations are specified to possible applications with the following aspects that also have quantified

[52] Assumed to refer to "carcinogen, mutagen or reprotoxic", hazardous properties of a substance

thresholds (additional aspects can be viewed in (Bosch, STMicroelectronics, Infineon, NXP, Nexperia 2021b)):

- the maximum die size (~50 mm²), which is strongly dependant on package design, bill of materials and inclusion of a backside metal,
- Use is currently only possible when the die thickness is >120 µm (though the Umbrella Project (2020e) mentions that adhesives are the typical solution for very thin lead-frames (~200µm) due to unacceptable lead-frame bending after a high temperature soldering process),
- The moisture sensitivity level, which is greater than MSL3/260°C, is a limitation for high power devices. However, from past information application in low and medium power devices is understood to be possible,
- Information provided during the last assessment (Gensch et al. 2016) further clarifies that adhesives cannot be used for products with a high junction temperature (>175°C), as organic components of the glue tend to degrade at such temperatures,
- Umbrella Project (2020e; Umbrella Project) also indicates that adhesives can be a solution for packages which don't need to be exposed to the higher soldering temperature (~400°C soldering temperature versus ~150°C glue curing temperature). E.g. Ball Grid Array (BGA) packages with organic substrates use adhesives for die-attach. Furthermore, adhesives are explained to have a bigger process window as compared to solder and can be used also for non-metalized chip backsides.

TLPS sintering

New information (Bosch, STMicroelectronics, Infineon, NXP, Nexperia 2021b) on transient liquid phase sintering (TLPS) suggests that these could be used for smaller dies but have potential incompatibility for dies above 50 mm^2 due to high modulus and delamination risk. Potential reliability issues related to the formation of cracks are related to Kirkendall voids that form during IMC (consultant addition - intermetallic compounds) growth at 175°C during HTSL (consultant addition - high temperature storage life). A risk of oxidation of copper is also mentioned if the oxygen concentration exceeds 300 ppm during sintering under nitrogen. In summary, though these materials are considered to have potential for use in SiP (system-in-package) and clip packages, the maturity of the technology is still low and requires additional research to establish reliability, which appears to be dependent on the package / lead-frame material. Potential use for thin die (thickness <100µm) is also not yet clear.

DCB (direct copper bonding)

The last evaluation report in 2016 (Gensch et al. 2016) concluded that DCB (direct copper bonding) technology, sometimes also named "direct bonded copper (DBC)" can eliminate the use of lead in LHMPS at least in specific cases, but these are restricted to ceramic substrates, and surface mount technology (SMT) components require LHMPS in the internal interconnects. Gold-silicon DCB is applicable for die size less than 3 mm. The AuSi eutectic die attach on a bare copper lead frame may have a risk of brittleness. Littelfuse Inc. corporation (2021) confirms in this current evaluation phase that this knowledge is still valid. A full switch for lead free soldering for all products is still not possible. As for asking for specifying application areas with a combination of corresponding technical parameters where the usage of DCB is possible and reliable, no further information is provided. The UP was asked to provide more information on application areas with a combination of corresponding technical parameters where the usage of DCB would be possible and reliable but did not provide further information.

Thick film copper bonding (TFCB)

The RoHS 2 assessment of exemption 7(a) in 2016 (Gensch et al. 2016) described thick film copper bonding (TFCB) in the context of die attach. This information was submitted by TT Microelectronics/AB Mikroelektronik GmbH (AB) at the time. TFCB could partially replace LHMPS and thus eliminate the use of lead. The relevant description is reproduced below from the 2016 assessment report: "*According to AB, thick film substrates are sintered structures so there is more flexibility in comparison to the laminated DCB substrates. This flexibility reduces stresses in the die attach materials as well as the large area soldering joint needed to contact to the heatsink or baseplates. In general, the thick film substrates can be directly substituted for a DCB for instance, when higher current applications demand thicker copper conductors electrically and thermally. AB has successfully tested TFCB on AlN (aluminium nitride ceramic) and Al2O3 (aluminium oxide ceramic) substrates. Organic substrates such as FR4 have not been tested as of yet, but the processing requires high temperatures of more than 800 °C. AB are a supplier to the automotive industry, and they have a sister company working in the aerospace industry, where TFCB has proven to be more effective concerning lifetime between zero and 350 °C.*"

The Umbrella project was asked to comment on TFCB technology. UP Exemption # 7a WG Participants understand that the thick film copper bonding (TFCB) technology mentioned is limited to a narrow subset of substrate and not suitable to all electronic components. The higher mechanical stress acting on dies is caused by the mismatch between the coefficients of thermal expansion of silicon and copper, which does not change when using TFCB instead of copper lead frame (The RoHS Umbrella Project 2021b). UP are not aware of any specific EEE product groups where this technology can be used as an alternative to LHMP.

10.3.2. Environmental and health arguments (also LCA aspects)

Bourns Inc. (2020c) refers to the carcinogen properties of Pb and Pb soldering being considered an activity with a risk of exposure. However, hazardous properties are also mentioned for silver, copper and tin as comparison. Regarding the possible preparation for reuse or recycling of waste, Bourns Inc. (2020c) states that as a component manufacturer it is not aware of the treatment of e-waste. In the US, the EPA classifies electronic waste as universal waste and requires specific handling.

The Umbrella Project (2020e) does not raise environmental arguments, explaining that as long as a suitable substitute is not identified, assessment data cannot be provided. Nonetheless it is mentioned that a proposed alternative contains dibutyltin dilaurate (CAS# 77-58-7) which is a REACH SVHC, while other materials under current evaluation are also under assessment for possible hazardous properties like silver and antimony. Concerning the reuse or recycling issue, Umbrella Project (2020e) explains that no closed loop system exists specifically for HMP lead (Pb) solders as most component and equipment suppliers do not take back their own products at the end of life. HMP lead (Pb) solders are incorporated into the larger EEE and should be recycled according to the requirements of the WEEE Directive and EU waste legislation. Umbrella Project (2020e) concludes based on a few references (see detail in section 5 of application document) that recovery and recycling of lead is well established for the larger flow of WEEE where these solders are used.

10.3.3. Socioeconomic impacts

Bourns Inc. (2020c) states that alternatives for LHMPS with high gold content are typically high priced. For example, if a gold material was a potential substitute, it may drive the cost of the finished components up where it is difficult to be competitive. Equipment and/or process changes could be necessary in case that substitutes become available, currently however such substitutes do not exist.

The Umbrella Project (2020e) does not raise socio-economic arguments, explaining that as long as a suitable substitute is not available, assessment data cannot be provided. It is however explained that a very large proportion of the electrical equipment currently used in the EU could not be sold in the EU, should the exemption not be renewed, which would have adverse impacts on the EU’s economy.

10.3.4. Roadmap for Substitution or Elimination of Lead

Bourns Inc. (2021e) explains that it continue to view potential substitute claims but, so far, they cannot compare to the properties and reliability of the LHMPS. Bourns continues to follow up on these potential substitutes with the intention of finding alternatives that can meet or beat the current LHMPS but also continue to be cost effective. Bourns does not yet have a definitive timetable since current potential alternatives do not seem to exist at this point in time.

The RoHS Umbrella Project (2021d) describes that material suppliers are working on alternatives for LHMPS to address the requirements of industry. High temperature adhesives and Transient Phase Liquid Sinter materials are showing particular hope for the future, but there is nothing now that meets all the technical requirements that LHMPS meets. Umbrella Project (2020e) states that various efforts are undertaken by the EEE industry to find substitutes for LHMPS, which currently have not concluded. The applicant explains the typical time scale from identification of a suitable substitute material to commercial use in electrical equipment as follows: Research and development of candidate materials lasts 4 years on average. If successful, an additional 6 years is considered necessary for the next phases up to mass production.

Information on efforts related to die attach is provided on the basis of the Die Attach 5 consortia which has been working with suppliers for several years to identify and evaluate alternatives to LHMPS. DA5 (2020) have evaluated a variety of new materials available from global suppliers of solders, high thermal conductive adhesives, silver (Ag) sintering and transient liquid phase sintering (TLPS) materials. DA5 recognize (Bosch, STMicroelectronics, Infineon, NXP, Nexperia 2021a) that substantial development efforts have been running for more than 11 years. 145 materials from more than 13 suppliers were evaluated. Close to 50 of those materials were selected for extensive testing by DA5 member companies. Although some promising results were identified in specific applications, none of the materials proved suitable as a general Pb-replacement solution. While the DA5 consortium has not yet found a reliable lead-free package technology for power semiconductor components, the research is promising for long-term solutions (Bosch, STMicroelectronics, Infineon, NXP, Nexperia 2021a).

10.4. Stakeholder contributions

The exemption was subject of a stakeholder consultation, where contributions were submitted by Huawei, SEMI Europe, Test Measurement Coalition, Fresenius Kabi, Norwegian Environment Agency, Hitachi, Lucky Forests Corporation Ltd. Seven individual contributions have been submitted during the consultation period from 30 March 2021 to 08 June 2021. The individual contributions are summarized in Table 10-2 below.

IXYS Semiconductor GmbH who submitted a request for the renewal of Ex. 7(a) in 2014 which was included in the last assessment did not participate in the consultation. Due to their past involvement and indications that they were looking into substitutes, IXYS was asked if they had substituted LHMPS in their applications or still needed the exemption. The company responded that it became part of Littelfuse Inc. corporation in 2017 and still need the exemption.

Table 10-2: An Overview of other contributors and main statements in relation to Ex. 7(a)

Contributors for exemption renewal	Relevant EEE categories	Relevant components/applications	Remarks
SEMI Europe (2021) (support renewal)	Not indicated	• AMPLIFIER, SENSOR, CCD MICROMETER • TOWER, COMPUTER • CONVERTER, PNP OUTPUT • CRYSTAL 24MHZ SMD / CRYSTAL OSC 1.8432MHZ SMD • DIODE,3A / DIODE,P6KE15CA. • FUSEHOLDER + FUSE 2A SMD • I/O UNIT, SEQ CONTR • IC REG POS VOLT 1A 5V D2PAK	support applications made on the behalf of the Umbrella Project Participants
Test & Measurement Coalition (support renewal) (Test & Measurement Coalition 2021)	Cat. 9: industrial monitoring and control equipment	Not indicated	maintaining the exemption's references unchanged, i.e. application will be submitted 18 months before the expiry date of 21 July 2024;

Contributors for exemption renewal	Relevant EEE categories	Relevant components/applications	Remarks
(ABB Power Grids Switzerland Ltd., Semiconductors 2021a) (support renewal)	Cat. 8 and 9	High Power Semiconductors are used and installed in rush environments. These modules are not defined as EEE, as they are specified for high-power applications exempted per definition in Article 3(1). We need the exemption 7(a) to prove the conformity with the directive for our end customers in the Railway-, Energy Distribution-, and with new designs in the Medical Industry.	• The unique properties such as the high melting point and thermal conductivity of the high-lead alloys are necessary for the level of reliability required. • so far, no lead-free solution has been identified
Lucky Forests Corporation Ltd. (support renewal) (Lucky Forests Corporation Ltd 2021a)	Cat. 1-11, depending on the EEE in which the electronic component is used in an assembly	TVS and Zener Diode (power rating: 1.5 Watt-15000 Watt): Solder and Electrical and electronic components containing lead in a glass	No suppliers can be found to deliver lead-free solutions.
Fresenius Kabi (2021)	Agrees with the scope statements in the Bourns and first Umbrella Project application		
Huawei (Andrae 2020)	Provides indicative calculation of environmental impacts of Sn-95Pb compared to lead-free alternative solders.		
Norwegian Environment Agency (2021)	• Article 5(1)(a) in the RoHS Directive (2011/65/EC) stipulates that exemptions can be included in Annexes III and IV for materials and components of EEE for specific applications. Our interpretation is that both the material or component and the specific applications need to be defined in the description of an exemption. • With the current wording of exemption 7(a), it is almost impossible to perform enforcement activities, since it is unclear when it is justified to take advantage of this exemption.		
Littelfuse Inc. corporation (Littelfuse Inc. corporation 2021)	• After inquiring: IXYS Semiconductor GmbH being since 2017 part of the Littelfuse Inc. corporation, does still need the exemption 7(a).		
The Swedish Chemicals Agency, KEMI (2021)	• KEMI states that the current wording of exemption 7(a) makes it almost impossible to perform enforcement activities, since it is unclear when it is justified to take advantage of the exemption.		

Contributors for exemption renewal	Relevant EEE categories	Relevant components/applications	Remarks
	• To improve the situation KEMI proposes that manufacturers be required to justify the use of such exemptions in the technical documentation of the application (component/EEE). For this purpose, KEMI further proposes to investigate whether it is possible, to add requirements for such a justification in standards or in module A in Annex II in 768/2008/EC[53].		

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 core of the applications submitted for renewal of Ex. 7(a) and of the stakeholder contributions submitted to the consultation focus on the difficulties of substitution. In general, it is claimed that available substitute candidates have various limitations and do not provide the combination of technical properties and high reliability that LHMPS do. In relation to some of the candidate alternatives, it can be understood that use may be possible for certain applications, some of which are understood to be in the range of the current exemption:

- For conductive adhesives that can be used in die bond equipment for dispensing, chip placement, and curing of the material it is specified that, depending on package type and die size, these can pass automotive environment stress test conditions (AEC-Q100, AEC-Q101) (DA5 2021a). From the consultants experience, automotive applications often have quite high reliability specification and so though additional research may be needed, the consultant would assume that at least in some cases, the reliability of conductive adhesives would suffice also for EEE applications, though certain limitations were mentioned,
- For TLPS sintering it was mentioned that these could be used for smaller dies but have potential incompatibility for dies above 50 mm^2 and the maturity of the technology is still low and requires additional research to establish reliability (Bosch, STMicroelectronics, Infineon, NXP, Nexperia 2021b),
- The last evaluation report in 2016 (Gensch et al. 2016) already concluded that DCB technology, can eliminate the use of lead in LHMPS at least in specific cases, which are restricted to ceramic substrates,
- It was understood in the past that TFCB could partially replace LHMPS and that the company AB had successfully tested TFCB on ceramic substrates.

However, it is claimed that this is not the case for most of the application range, i.e. that substitutes are not available for applications for which the renewal of the exemption is requested. The consultant understands this to mean that in some specific

[53] Decision No 768/2008/EC on a common framework for the marketing of products, available under: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32008D0768&from=DE

cases it was possible to apply substitutes for certain applications. This is also assumed to be represented in the communicated decrease over time in the amount of lead placed on the market through this exemption. Stakeholders were asked to provide positive experiences of substitution of LHMPS. Bourns Inc. (2021e) and The RoHS Umbrella Project (2021d) stated that at the current state there are no examples of direct substitution. This seems to contradict other statements made by some of the stakeholders.

Only little information is provided as to research into substitutes and further planned actions, concerning only a few application areas like die attach and research on lead-free solders by Vishay. Nonetheless, Annex V of RoHS specifies the minimum information requirements for exemption applications, specifying that these should detail among others "*g) the proposed actions to develop, request the development and/or to apply possible alternatives including a timetable for such actions by the applicant*". For most application areas, such information has only been provided in very general terms and does not clarify to what degree industry is actually engaged in the search for substitutes.

The applicants claim that LHMP solders are used for a wide variety of applications. The Umbrella Project (2020e) states that no new lead-free HMP solder alloys have been discovered since the last exemption 7a renewal request was submitted in January 2015. They argue that this is hardly surprising as extensive research was carried out when RoHS was adopted in 2002 and all possible combinations and permutations of chemical elements available in the periodic table have been evaluated. Industry continues to research novel substitute technologies. However, only little new information is provided by applicants as compared to the last evaluation.

Three potential lead-free solders (Bi System, BiAgX and Au-Sn) have a melting temperature above 260°C, which could be comparable to LHMPS. The consultant therefore asked for the concrete physical properties of certain lead-free solders compared to the performance of lead-based HMPS. No values on physical properties were provided, although the disadvantages are generally described by applicants (reproduced in Appendix A.2.3). The consultant assumes that not all properties referred to are relevant to all applications of LHMPS. In this sense, there may be areas where a certain alternative could be relevant for a narrow set of applications that only require a few of the properties provided by lead and that are thus also provided by a candidate alternative. When asked for examples of concrete applications, in which BiAgX could successfully replace LHMPS, The RoHS Umbrella Project (2021c) states that they do not have concrete application examples and explains that the material is not suitable for mass production due to low yield. Trials were stopped due to low performances. In any case this material cannot replace LHMPS, it can be used in case the product would have lower requirements, as it can happen with glues and conductive solid adhesives. The consultant contacted Indium Corporation as suppliers of one potential substitute, BiAgX, hoping to get a better understanding of physical characteristics and in which components and in which concrete applications BiAgX can be applied without any loss of reliability. Though the company responded to a first inquiry, it did not provide additional detail and did not respond to further requests.

As for any new knowledge or findings concerning the applicability of DCB technology as a substitute, The RoHS Umbrella Project (2021b) states that they have no evidence of new findings concerning the usage of DCBs in combination with Gold Silicon solder (IXYS technology). DCB technology has limitations (such as significantly lower thermal conductivity than Copper-based alloys) which make it unsuitable for replacing copper alloy-based lead frames in SMD devices.

Lead used in oven lamps

Constrained by the operating temperature, currently available lamp technologies (Incandescent, CFL, LED lamps) are unable to apply any reliable or safe alternatives for light sources using HMP lead (Pb) solders (Umbrella Project 2020e; 2020g). Umbrella Project (2020e; 2020g) claims that various combinations of solder and spring materials have been proven in use for a long time in existing oven technologies. No reliable solution has been found. Commonly available Pb free solders ($Sn_xAg_yCu_z$) usually exhibit melting points up to 230°C, and thus will melt under maximum temperature regimes in ovens. After cooling down to ambient temperature, the again hardened solder will have established a permanent mechanical fixation of the lamp base with the spring in the lamp socket. The limited time and resources available for the review of this exemption did not allow further discussions with the applicants to find out whether melting point of lead is the only essential property considered in this specific application, since other alternatives e.g. BiAgX solder has a melting temperature (s. Appendix A.2.3) above 320°C. In addition, The RoHS Umbrella Project (2021d) confirmed that the lamp types in which the current application of LHPMS is needed can be considered as conventional lamp technologies. These include incandescent and halogen lamps and high intensity discharge lamps (ceramic metal halide lamps, quartz metal halide lamps and high-pressure sodium lamps). The consultants are aware that such technologies are older and are being replaced where possible by light emitting diodes (LED) and organic LED (OLED) where possible or by future innovations. UP (2021d) states that current LED and OLED technologies are not able to withstand the heat occurring in this specific application and therefore cannot be applied to eliminate the use of lead.

Lead in high power audio transducers

The RoHS Umbrella Project (2021d) explains plausibly why LHMPS is still needed in high or low frequency audio transducers. Regarding the definitions of "low frequency" and "high frequency" transducers, The RoHS Umbrella Project (2021b) explains that there are not fixed rules. Generally, "low frequency" transducers are up to around 2kHz, while "High frequency" transducers are usable in the 1kHz to 20kHz range. It is noted that these are general frequency ranges and should not be used as a fixed definition. The RoHS Umbrella Project (2021d) further explains that the low frequency transducer versus the high frequency transducer does not directly affect the peak operating temperatures. It can have an effect on the heating mechanism, but the peak operating temperatures remain around the same. The reason for the separation is that the options for designing the need for LHMPS out of the high frequency transducer is more limited than in the low frequency transducer. For example, one of the best ways to remove the need for LHMPS in an audio transducer design is to move the location of the solder joint far enough away from the coil of wire that drives the transducer so the heat generated in that coil cannot overheat the solder. In a high frequency transducer this is not easy to accomplish. The high frequency transducer is very sensitive to mass changes in the voice coil and the dimensions are very small. There physically is not enough distance available on the entire coil structure to move the solder joint far enough away to make a difference in temperature. Moving the solder joint off the coil means that the very fine gauge magnet wire will have to extend through the area of the moving structure in the transducer that operates as the compliance in the mechanism. That "Suspension" area is basically the flexible hinge point that allows for the diaphragm of the transducer to move axially. This magnet wire often must be aluminum for mass reasons and as such it is even more susceptible to fatigue failure modes from the flexing. In current typical designs Bosch solders either a beryllium copper or phosphor bronze strip of wire to the coil wire on the coil form and then this more flexible material is what passes through the suspension area.

Bosch has developed a way of producing low frequency transducer coils that moves the solder joint far enough away from the coil windings to make the use of lead-free solder possible. Bosch is in the process to industrialize these new coils in one of its factories. There are a small number of cases where the new coil is not capable of matching the performance of the current coil made using LHMPS and in those cases Bosch is committing to phasing these products out of production over the coming 5 years. This is a somewhat lengthy process because Bosch must engineer new systems to replace those current systems in the market place (The RoHS Umbrella Project 2021d). In addition, Bosch also states that they have also made progress in removing the need for LHMPS in high frequency transducers and are committing to making these changes in all products where it is possible and to phasing out any products where the changes are not possible.

The RoHS Umbrella Project (2021b) considers that some legacy products will NOT be able to be converted. The reason for this is that making those changes would too dramatically change the products performance and specifications making it no longer viable as a product and/or incompatible with existing products and installations. Bosch is asking for transducers related LHMPS exemption to be renewed for a period of 5 years to allow for this industrialization, re-engineering, and phasing out process to be completed (The RoHS Umbrella Project 2021d; 2021b).

10.5.3. Environmental arguments and socioeconomic impacts

Generally, no environmental and socioeconomic impacts are raised by the Umbrella project, since no suitable substitutes exist at present. Bourns mentions the hazardous properties for silver, copper and tin as comparison. Regarding the reuse or recycling at the end-of-life, both applicants argue that HMP lead (Pb) solders are incorporated into the larger EEE and components manufacturers do not take back their products. In the later communication, The RoHS Umbrella Project (2021c) argues that they do not believe that LHMPS used in Europe ends up untreated in Europe since 1) EEE from Europe are sold everywhere and 2) EEE are separately collected and treated according to the WEEE recycling scheme. The consultant does not agree with these statements. According to Eurostat data[54], in 2018 for most of the Member States collection rates of

54 EUROSTAT Website: Total collection rate for waste electrical and electronic equipment (EEE), 2018 (env_waselee), https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Waste_statistics_-_electrical_and_electronic_equipment#Electronic_equipment_.28EEE.29_put_on_the_market_and_WEEE_collected_by_country , last viewed 24.9.21

WEEE were still below 60% and even below 40% for around a third of the MS. This suggest that still a significant amount of waste is not disposed of properly. Regarding the second point, the consultant is aware that in some cases the illegal export of toxic electronic waste to developing countries still takes place[55], whereas developing countries often do not have recycling technologies and schemes comparable to those of the EU or US.

Andrae (2020) provides a contribution with indicative LCA calculations. Results show that revoking exemption 7(a) would likely cause considerably higher environmental impacts, around 872 times higher. The scope of the investigation is limited to the production of materials, i.e. production of single individual metal. The environmental impacts are then calculated based on the different composition of solders investigated. Other life stages, such as processing of solders (use of other process chemicals like flux) as well as use and end-of-life are not considered.

The focus of RoHS is to avoid hazardous substances in the use and waste phase and as such in the consultants view these life cycle stages would need to be considered to allow a comprehensive conclusion.

10.5.4. Increasing certainty for manufacturers and market surveillance

In the discussions on the scope of the exemption (see Section 10.5.5) the consultant stated that part of the motivation to specify the exemption has to do with the difficulties encountered with its enforcement and the possibility of misuse that the current exemption wording enables. UP responded to this that "*Considering the exemption has been around for 10 years, as correctly stated in this questionnaire, UP Exemption # 7a WG Participants are not aware of any case where enforcement has been difficult or impossible due to wording or where the exemption has been misused. If misuse or enforcement difficulties have been encountered by control authorities, a better solution to splitting the wording could be to work with industry to develop a guidance on enforcement*" (The RoHS Umbrella Project 2021c).

During the stakeholder meeting, a few cases of uncertainty were presented to shown as evidence for the difficulties of enforcement and possible misuse.

An inquiry made in March to the European Commission by the Danish Ministry of Environment and Food - Environmental Protection Agency (DEPA) as to compliance with Ex. 7a stated the following:

- […] a company […] that their products contain lead above the threshold concentrations […] would like to know […] whether their product is exempted from the RoHS-limitations on lead in accordance with annex III exemption 7a. The last-mentioned company has sought clarification on this, both from their supplier and a consultant company. However, the two disagree on the scope of exemption 7a. The supplier argues that we are within the scope, as the factory producing the product uses high melting temperatures for reasons of production efficiency. The

[55] https://www.theguardian.com/environment/2019/feb/07/uk-worst-offender-in-europe-for-electronic-waste-exports-report, last viewed 20.09.21

consultant company argues that we are not within the scope, as it is not necessary for the correct functioning of the lamp that the solders are of the type that can withstand high temperatures. […]

- This has led us to the following question […] When would this exemption be inapplicable, where high melting temperature type solders are used or are we correct in assuming that the applicability of exemption 7a depends solely on whether or not the type of solders being used contain 85% lead by weight or more – independent of the reason for using such solder?" (specified in a communication sent to the European Commission March 24, 2021.)

This information makes clear that neither market surveillance nor various actors of the supply chain are in agreement as to the scope of the exemption and what types of uses are considered to be in or outside of the exemption scope. The following evidence also suggests potential misuse of the exemption:

- A stakeholder sent the EC the following inquiry: "[…] Now we meet a problem about the use of RoHS exemption 7a. This exemption is something about the use of lead in high melting solder. As we know the lead content exceed 85 % in high melting solder should be exempted taken literally. But we think not all the high melting solder lead exceed 85 % can be exempted. We also found some recall case in RAPEX[56] the solder contain lead exceed 85 % […] Otherwise it would be a free pass to use high melting solder everywhere and always, even on circuit boards and cables, as long as the lead content is high enough."
- The stakeholder attached a RAPEX notification – the content is anonymized to demonstrate the case of a musical toy surveyed in 2019 in two Member states: "The solders contain lead (measured value up to 93.5 % by weight) in concentrations above limit values. Lead poses a risk to the environment. The product does not comply with the requirements of the Commission Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2 Directive)".

It is not clear from the notification if the product claimed use of Ex. 7(a) or not, nor the component in which it was used. However, this shows again that there is not clarity as to when the use of LHMPS is justified.

KEMI (2021) and the Norwegian Environment Agency (2021) also referred to the difficulty that the current exemption formulation leads to in market surveillance in their contributions, further affirming that enforcement may be hindered.

Though in the consultants' view, evidence exists as to enforcement difficulties and possible misuse, stakeholders were still asked to explain how they decide which applications are in the scope of the exemption and which are not.

How to interpret the exemption and what applications benefit from it, as opposed to those that do not, is understood by the consultant to be both a problem for market surveillance as well as for EEE manufacturers when purchasing certain components from the supply chain. Whereas OEMs seek assurance that the use of the exemption is

[56] RAPEX is the EU rapid alert system for dangerous non-food products

correct in supplied components, suppliers may be requested to justify the use of the exemption in such cases.

DA5 provides a confidential document and states that in DA5 Material Requirement Specification there is a clear specification what requirements are valid for LHMPS (The RoHS Umbrella Project 2021d). No other stakeholders provided examples of guidance or instructions which are used to support the understanding of which applications would be considered in scope of the exemption and which would not (e.g., other alternatives available). The RoHS Umbrella Project (2021d) states that UP Exemption #7a WG Participants would be at the disposal of Oeko and the Commission to provide their expertise in developing such guidance.

KEMI (2021) has made a similar proposal, that manufacturers be required to justify the use of such exemptions in the technical documentation of the application. KEMI refers in this context to the Conformity Assessment Procedures specified under module A in Annex II of Decision 768/2008/EC on the common framework for the marketing of products.

In the consultant’s view, such a requirement would not suffice on its own but would need to be supported with some kind of guidance or standardisation that would specify in more detail cases where the use of LHMPS is considered necessary in lack of suitable substitutes. This would create a common understanding both for manufacturers and enforcement as to the actual scope of application of the exemption. Developing such a standard or guidance, however, requires sufficient time to clarify the state of technical progress and to come to a mutual agreement of involved stakeholders. From prior knowledge of the consultant, developing a standard as well as assurance and certification systems to accompany it can easily require 4-5 years. Though this direction could be of interest if further specification of the exemption is seen as unfeasible, time would be required until it results in a solution for enforcement. The consultant has made an attempt to split the exemption into separate items for its various application areas (see Section 10.5.5) and would recommend following this approach. However, should it prove to be unfeasible, developing such guidance or even a standard to clarify the full spectrum of applications where there are no alternatives for LHMPS could be a way to allow more certainty for the various stakeholders.

10.5.5. Scope of the Exemption

Potential strategies for specification considered

Exemption 7(a) is requested for all categories (1 – 11). As described in the previous evaluation reports, the consultant considers the scope of the exemption 7(a) wording to be very wide as it is not limited to a specific application but rather describes a material that can be used for various applications. This is not consistent with the intention of the RoHS Directive embodied among others in recital 19[57]. The exemption should only be available for specific applications and technologies where it is deemed

[57] Directive 2011/65/EU, Recital 19: Exemptions from the restriction for certain specific materials or components should be limited in their scope and duration, in order to achieve a gradual phase-out of hazardous substances in EEE, given that the use of those substances in such applications should become avoidable.

justified based on Art. 5(1)(a). Usually this means for applications where no lead-free alternatives are available. The current exemption wording has been available for over 10 years. Industry has communicated that where substitutes were suitable, they have been applied, however has not given indication as to application areas that could be excluded from the exemption. The scope of the exemption should be targeted and focused on application fields and technologies where it is necessary. This would ensure a higher certainty among companies and market surveillance as to when the exemption is used properly and when it is misused, despite the existence of alternatives.

The broad formulation results in the exemption assessments being focused on how to reformulate the wording in relation to areas where LHMPS is applied instead of in relation to the actual progress of substitution efforts which remains vague. In this sense, a splitting of the wording would also allow a higher focus on specific applications in future assessments as each separate item would be assessed separately.

The consultant has considered a few strategies for specifying the exemption formulation:

- Strategy 1: the application approach
- Strategy 2: the functional purpose of lead (properties, performance) approach
- Strategy 3: Category approach

Various considerations lead the consultant to pursue the exemption specification based on the first strategy. Considerations regarding the other strategies are summarized in Appendix A.2.4.

Specifying the scope and rewording of Exemption 7(a)

With respect to the concrete wording proposed, the consultant has had exchanges with applicants through three clarification rounds via questionnaires and one workshop. The following section provides a summary of the main aspects discussed and their relation to application groups considered to be in scope of Ex. 7(a) and how they have been termed as a means of including such applications in a more specific wording.

Based on information provided by the applicants in this review and in previous exemption assessments, the consultant formulated an initial wording proposal which was sent to stakeholders for commenting. This allowed a first fine tuning of the proposal which together with stakeholder responses was discussed in a technical workshop with a view to establish a better understanding of the applications in scope of the exemption and how they could be formulated into a concise wording. Based on the discussions, a further proposal was prepared by the consultant and sent to commenting. A few last considerations were made and consulted on with UP and Bourns before arriving at the wording recommended for the future exemption in Section 10.6.

Disclaimer: It is noted that Bourns, UP, and the Test and Measurement Coalition (TMC) have explicitly stated that they do not agree with the exemption splitting. SEMI EUROPE (2021a) also supports this view. They advocate the renewal of exemption

7(a) with its current wording. The reasons are summarised in the separate section (s. 10.6.2). Insofar, in the section below, when the agreement of stakeholders is referred to, it means that stakeholders agreed (or did not) that the wording principally covered the applications it was intended to. Where stakeholders provided an alternative proposal, this is only to be understood as a wording that describes certain applications. This is not to be confused with stakeholders being in agreement with the general formulation or the need to split the exemption or prosing a split of the exemption.

In the following, the application areas identified as the application groups that should be covered by the exemption either prior to the first proposal or in the discussion process are listed. These are considered application areas of "Lead in high melting temperature type solders (i.e., lead-based alloys containing 85 % by weight or more lead) used". For each application area, the summary explains the main points of discussion, how these were concluded upon and how this was taken up in the final proposal made.

Internal interconnections in electrical and electronic components

The initial proposal referred to 4 sub-items under the general term "internal interconnections". This included a sub-item for internal connections of die attach and one for other than die attach as well as a sub-item for lamps that was later excluded (see discussion under last section) and a sub-item for other applications that was assumed to catch everything else (see discussion under next section). The first two items were initially specified as follows:

- a-I) for die attach in power semiconductors with steady state or transient/impulse currents of 1 A or greater and/or blocking voltages beyond 200 V, or die edge sizes larger than 0.5 mm x 0.5 mm
- a-II) in components with steady state currents of more than 1 A and/or blocking voltages beyond 200 V other than die attach

Stakeholders (Lucky Forests Corporation Ltd 2021b; The RoHS Umbrella Project 2021c; Bourns Inc. 2021d; ABB Power Grids Switzerland Ltd., Semiconductors 2021b) commented on three parameters (i.e., transient/impulse/steady state currents, voltage and die edge size) specified in the two sub-items and the threshold levels that they refer to. The consultant suggested various changes to these parameters and also asked stakeholders to comment whether applications raised in the 2015-2016 assessment by Freescale/NXP were covered by one of the two sub-items. It was also questioned whether only one parameter or all three would need to be fulfilled for an article to be in scope and how this affected the semantic relation of the three parameters.

In a later communication on the first item, the The RoHS Umbrella Project (2021d) explained that the phrase "die attach" usually has a narrow meaning of die bottom side to the lead frame/substrate attach but also attaching components on the top and bottom sides of the die is possible. They proposed a revised formulation for this item: "*for attaching die, or other components along with a die in semiconductor device with steady state or transient/impulse currents of 0.1 A or greater and/or blocking voltages beyond 10 V, or die edge sizes larger than 0.5 mm x 0.5 mm*." UP explained the removal of the reference to power semiconductors with the lacking definition of this term as well as since "*Not all uses of LHMPS are in power devices*".

As for the second item, stakeholders provided examples of articles that would still not be covered in light of the thresholds set. Further correspondence looked into these examples and whether they would be covered by the first or second item. The RoHS Umbrella Project (2021e) referred to most of the examples, explaining that they would not be covered without a change of the die attach size threshold. A threshold of 0.3 mm x 0.3 mm was proposed. Applications included:

- Zener diodes which have die sizes smaller than 0.5 mm x 0.5 mm, use LHMPS in die attach and are not intended to block voltages but only to regulate it,
- Some transient voltage suppressors also use LHMPS in die attach. These may use currents below 0.1 A and have die sizes smaller than 0.5 mm x 0.5mm,
- Integrated Circuits, such as voltage regulators and references and current monitors use LHMPS in die attach and do not block voltages,
- Self-protected MOSFETs use LHMPS in die attach and are not covered by the Oeko proposed wording;
- SMD and axial diodes with die attaches of a size < 0.5 mm x 0.5mm

UP also confirmed in this last correspondence that the word device that they initially used in the formulation could be replaced with the term "*assembly*" to prevent false interpretations of device to mean EEE.

This means that many of the examples initially assumed to be covered under item II would be covered by item I should the thresholds be changed. UP did not provide a clear answer as to whether this meant that item II was redundant. Though there may be internal connections that do not include die attach this is uncertain. To cover such items, the formulation of item c was adjusted, and it is proposed to limit item a to the die attach applications.

The following wording is thus proposed:

> *"a. for internal interconnections for attaching die, or other components along with a die in semiconductor assembly with steady state or transient/impulse currents of 0.1 A or greater or blocking voltages beyond 10 V, or die edge sizes larger than 0.3 mm x 0.3 mm*

Aside from the examples mentioned above, stakeholders also mentioned three additional examples.

Products with life-time expectation above 2000 h of product use and products where operating conditions exceed 60°C were two of these examples. Though it can be followed that products with higher reliability requirements may need LHMPS in certain cases, additional detail was not provided as to the exact applications, nor to clarify why these thresholds would be considered to require a high reliability. A life-time expectation for 2000 h can be very long if the product is used only a few minutes a day or very short if it is in constant operation (ca. 80 days). It is also not clear if a temperature of 60 °C and above refers to the general operating conditions as in the case of ovens or to internal conditions in which case this threshold would not necessarily mean that the internal heat would lead to a melt of the solder. In the consultant's view, including such vague descriptions into an exemption formulation would again create uncertainty and allow misuse. UP was asked for further detail in this respect but did not provide further elaboration.

A further example, which is not die attach referred to crystals parts that use LHMPS internally to solder the crystal element to the package. In reference to the illustration in Figure **10-4** (left figures), UP was asked if the use of LHMPS in this case was as for hermetic sealing, covered by one of the other items. The RoHS Umbrella Project (2021e) clarified that some crystal parts are using LHMPS in three different areas that need to be covered by the exemption:

- as a hermetic sealing material
- as a connecting material for the crystal chip to the plug, which is a 1st level solder joint
- as connection material between lead frame and plug which is a 2nd level solder joint

This example shows the complexity of this exemption. It seems that even for industry there is no consensus or standardized definition, as to how to assign the usage of lead to a certain application type. Though the initial proposal has items for hermetic materials as well as for first and second level connections, it is not clear that these would cover these applications and UP did not provide further detail to support a further adjustment of the wording. The reference to these three applications does not allow concluding whether they would be considered to be internal and to fall under this item or to fall under a different one. The consultant assumes this not to be the only case that a single component may have multiple uses of different nature of LHMPS, but also assumes that an EEE making use of LHMPS in different ways could still do so, as long as the different uses are covered by various items of the revised exemption. In the consultant's opinion, this is comparable to the case of a specific component or EEE benefiting from of a number of RoHS exemption (e.g., from both the LHMPS exemption and from the exemption for lead in copper). Though the split of Ex. 7(a) in to different items may add to the complexity of compliance, addressing such applications under a single and general formulation does not only contradict the principle of exemptions being specific to an article and a material but also does not support a clear understanding of the different application types and their technical justifications for using RoHS substances such as lead in LHMPS.

Integral connections of die attach in electrical and electronic components

In the first proposal a sub-item was included under the item for internal interconnects for "*other integral interconnections in electrical and electronic components excluding those in the scope of exemption 24*". In the consultant's view this item is vague and would basically allow the use of LHMPS in any "integral interconnection". Seeing that an integral joint was considered one in which the connection is partly within the space envelope of a single component (i.e., non-visible in part from the outside--> hence internal) but also partly external to that space, (i.e. visible in part from the outside --> hence external). (i.e., external – see section 10.2.2), it was also suggested to exclude this item from the one for internal interconnects. Stakeholders were asked to provide information as to applications that would fall under this item.

Some of the examples specified by stakeholders demonstrate this aspect:

- Bourns (2021e) states that many of their models included applications using **internal** connections that would be included under this entry but not limited to. Several examples were provided: ceramic PTC fuses, SMD fuses, diodes including many TVS and Rectifier models, Resistor Networks.
- UP (2021d) also states that some such applications would be **internal** connections in numerous passive electrical components such as fuses, relays, sensors, transformers, crystals, oscillators, resistors, capacitors, etc. which are designed for SMD assembly.

In the consultant's view, the only way to understand these statements in relation to this item is to assume that some of these components would have more than one application of LHMPS, with at least one application of LHMPS being internal and another being integral (i.e., internal and external). This was later confirmed by UP who stated that "*For what concerns LHMPS in fuses, in general, UP Exemption #7a WG Participants would like to clarify that LHMPS can be used as interconnection or sealing materials. Both uses need to be covered by the exemption*" (The RoHS Umbrella Project 2021e).

The consultant suggested creating a separate item for "integral connections" to cover the other components which currently are not included under item a) with the following wording: "*for integral connections of die attach in electrical and electronic components, if the thermal conductivity of the cured/sintered die-attach material is >35W/(m*K) AND the electrical conductivity of the cured/sintered die-attach material shall be >4.7MS/m AND solidus melting temperature has to be above 260°C. This item excludes those in the scope of exemption 24.*"

UP was asked to comment on this proposal and stated that they "do not agree with this new Oeko wording proposal since this changed wording would only cover die-attach, and thus would exclude other applications like the connection of a crystal chip to the plug for crystals and oscillators and many more […]. A huge number of passive electrical components not limited to fuses, relays, sensors, transformers, crystals, oscillators, resistors, capacitors, would not be covered."

Though the consultant agrees that the proposed wording is limited to die attach, other integral joints are understood to be covered by the next item for "integral connections for components other than die to be mounted to sub-assemblies".

The RoHS Umbrella Project (2021e) clearly states that it does not agree with the current proposal wording, explaining that "*uses needing to be covered are both internal and integral. As integral is intended to be any connection made as a part of the component manufacture*". Though the consultant agrees that in principle an "integral" component is also "internal", and for that matter also external, the idea behind this categorization is to allow a clear distinction between different applications. In other words – an item would either be internal, external or integral, the latter meaning that it is both internal and external.

In the consultant's view, this clear cut would mean that items for integral connections could not be a sub-item of an item for internal connections. To ensure clarity, the formulation now clearly states what is meant by integral.

UP did not respond to the parameters and thresholds suggested in the formulation and it remains unclear if they would be sufficient for integral connections to die attach or not. One option would be to adopt the item as proposed, with a short-termed exemption for the original formulation aimed at allowing the identification of applications currently not covered. In that case, the following wording could be used:

> *"b) for integral (meaning internal and external) connections of die attach in electrical and electronic components, if the thermal conductivity of the cured/sintered die-attach material is >35W/(m*K) AND the electrical conductivity of the cured/sintered die-attach material shall be >4.7MS/m AND solidus melting temperature has to be above 260°C.*

A second option would be to simplify the wording by removing the thresholds as follows:

> *"b) for integral (meaning internal and external) connections of die attach in electrical and electronic components.*

A third option for specification would be to combine this item with the item for "Integral connections for components other than die" under one simplified item. This option is discussed under the next item.

Given that "integral" can also be interpreted differently, it would also be possible to refer connections (or joints) that are both internal and external to the component being connected.

Given that Ex. 24 is not related to die attach, the exclusion of such items, if proposed to be related to Ex. 7(a), ensures no overlapping.

Integral connections for components other than die to be mounted to sub-assemblies (first level solder joints)

The proposal initially included an item for covering LHMPS when used "*for mounting electronic components onto subassemblies (first level solder joint), i.e. modules or sub-circuit boards*". Hitachi asked to add substrates as a further example of a sub-assembly in this wording. Following the discussions on internal items, it was also decided to add "internal" first level applications under this exemption, to ensure that such applications would not be excluded from the exemption altogether. Die attach applications are excluded here as they are understood to be covered under items a and b. Hermetic sealings are also excluded as these would be covered under item e. Should industry come forward with additional types of hermetic sealings, a sub-item should be added there.

The following wording is proposed:

> *"c) In first level solder joints (internal or integral connections - meaning internal and external) for manufacturing components so that subsequent mounting*

of electronic components onto subassemblies (i.e., modules or sub-circuit boards or substrates or point to point soldering) with a secondary solder does not reflow the first level solder. This item excludes die attach applications and hermetic sealings."

Here too, to avoid the introduction of a new term, the word integral could be omitted, referring to joints that are either internal or both internal and external.

As explained above, due to the uncertainties raised by stakeholders in relation to the item for "Integral connections of die attach", it could also be considered to simplify and merge these items a, b and c together. Though in the consultant's view, this is not the preferred course of action, in this case, the following wording could be used:

In first level solder joints (integral connections - meaning internal and external) for manufacturing components so that subsequent mounting of electronic components onto subassemblies (i.e., modules or sub-circuit boards or substrates or point to point soldering) with a secondary solder does not reflow the first level solder.

Second level solder joints for the attachment of components to printed circuit board or lead frames

In the initial proposal two items were included that referred to different types of second level solder joints: solder balls used for attaching ceramic ball-grid-array and solders used to attach components to PCBs overmoulded with plastic. Stakeholders made a number of comments on the carriers to which the components were being connected to and clarified that in both cases PCBs and lead frames were meant. Due to the similarity in the item wordings and with the purpose of simplifying the wording, the two items were included as sub-items under a single item for second level solder joints. In the case of plastic overmouldings, it was also clarified that the overmoulding did not refer to the component being connected but rather to the "*printed circuit boards or lead frames, which afterwards are overmoulded with high temperature plastics*" (The RoHS Umbrella Project 2021e).

The following wording is finally proposed after being confirmed by stakeholders:

"d) In second level solder joints for the attachment of components to printed circuit board or lead frames:

I) in solder balls for the attachment of ceramic ball-grid-array (BGA)
II) in high temperature plastic overmouldings (> 220 °C)"

In this respect, UP (The RoHS Umbrella Project 2021e) also explains that LHMPS is also "needed to connect components to multi-stranded connecting cables of high temperature applications such as stoves and ovens. This use that is covered by the current wording must be covered by any Oeko proposed new wording". UP did not provide further detail and it thus remains unclear whether this statement was made to clarify that this application would be covered by the above item (d-II) or not. Though item d-II refers to a connection of "*components to printed circuit board or lead frames",* it is not clear to what cables UP refers, though a cable could be connected to a socket plug on one end and to a PCB or a lead frame on other end.

Hermetic sealing materials

Whereas the initial proposal only referred to hermetic sealings "between a ceramic package or plug and a metal case", Bourns Inc. (2021d) requested an extension of this item to the use of hermetic sealings "between component terminations and an internal sub-part".

The following wording is finally proposed after being confirmed by stakeholders:

"e) as a hermetic sealing material between:

I) a ceramic package or plug and a metal case,
II) component terminations and an internal sub-part"

LHMPs in lamps

A sub-item was initially included under the first item for internal interconnections to cover HID lamps and oven lamps. As the schematic illustrations of lamps (see Figure **10-5**) and their use of LHMPS showed that not all uses of the solder material were internal to the lamp body, stakeholders were asked to consider addressing such applications in a separate item. Stakeholders clarified that the use of LHMPS material for lamps should not be considered as "internal interconnections" in electrical or electronic components, since the solder point connection in many cases is visible from the outside. UP (The RoHS Umbrella Project 2021c) also specified another lamp type that would not be covered by this wording: incandescent reflector lamps for infrared heating. Stakeholders proposed a revised wording for the lamp applications as a separate item as below:

> "for establishing electrical connections (between lamp components) in incandescent reflector lamps for infrared heating or high intensity discharge lamps or oven lamps".

Though the justification for all lamp types is assumed to be similar, it is noted that stakeholders did not provide clarification as to why an infrared lamp or high intensity discharge (HID) lamps are assumed to be exposed to similar temperatures as those that an oven lamp would be exposed to, i.e. temperatures that would melt a bond with alternative solders. The consultant is aware from earlier exemptions that heat may build up in the body of a HID luminaire during operation. However, how these temperatures correspond to the different solders is not known. Nonetheless, it is proposed to include this item in the final exemption, to ensure that such items, understood to currently benefit from the exemption, would still be covered by a future exemption. The differences between the various lamp applications should be considered in the next assessment to ensure that all applications are justified according to the article 5(1)(a) criteria.

Audio transducers

This application area was not initially included in the first proposal but identified as a shortcoming in the first round of comments. After consultation with stakeholders it was considered more appropriate to add this as a separate item, also in light of the expected phase-out of LHMPS in this application within the next five years. After phase-out is accomplished, this approach would allow the removal of such applications from an exemption to remain valid.

The following wording is finally proposed after being confirmed by stakeholders:

“f) for audio transducers where the peak operating temperature exceeds 200°C”

10.5.6. 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.

The information made available to the consultant suggests that the substitution and elimination of lead in LHMPS generally is still scientifically and technically impracticable so that granting an exemption could be justified by Art. 5(1)(a). Though in some cases, information suggests that alternatives could be used in a small set of specific cases, information was not provided to allow demarcating such application areas.

Based on the current evaluation and previous evaluations, it is clear that there is no “one-size-fits-all” solution due to the broad application fields and also the different properties of lead required depending on the applications. As already described in the last evaluation report (Gensch et al. 2016), in the consultant’s understanding, it cannot be concluded that all applications of LHMPS will have a lead-free solution based on the same basic material and technology. The requirements in the various LHMPS applications are different, even though they all use LHMPS at present. For the various applications, different individual or combined properties of LHMPS are relevant to a different degree, and it is reasonable to assume that this requires different alternative solutions and thus also application-specific research to substitute or eliminate lead.

An encouraging example is audio transducers, in which design is being changed to new lead-free solutions. For the use of LHMPS in high power audio transducers, the information submitted plausibly explains that LHMPS is currently still required. Progress was made both in high and low frequency transducers. Substitution of lead may become scientifically and technically practicable over the next five years.

As for other application areas, there are very few prospects that suggest that this situation will change within the next five years, thus it is recommended to continue the exemption for five years.

As it could be understood that for many applications, alternatives were currently not viable, an approach was taken to specify the exemption wording in relation to the various application areas for which information was provided. The consultant understands that specifying the exemption wording is a task of technical complexity due to the large variety of applications in its scope. Industry argues that in some areas substitutes are not yet available. Nonetheless, it can also be understood that where lead-free solders (or solders with less lead) could be used, that these have been applied to substitute LHMPS. The current wording, however, does not differentiate between such cases and could potentially allow misuse. The current wording also does not provide certainty for the market surveillance (or for that matter industrial actors) as to where LHMPS can be used in EEE and where substitutes are available and should be applied (s. chapter 10.5.4). Hence, the assessment tried to demarcate the applications for which the exemption is necessary, in contrast to those where LHMPS is not used. Specifying the wording in a concrete way might not reduce the use of lead under this exemption in the short term (assuming all manufacturers surely differentiate where LHMPs should be used and where not). But without a clear targeted wording, the implementation of market surveillance is very difficult. It is also assumed that an application-based formulation shall also serve to communicate more clearly where additional research into alternatives is needed, motivating the research community to develop substitutes in relevant areas.

In summary, a clear reformulation to specify components and applications where LHMPS is really needed is very difficult due to the complexity of technical issues, broad applications and limited time and resources. However, in the consultant’s opinion, the first step has to be taken after more than ten years usage of this vague formulation of the exemption, especially seeing as certain applications (e.g. lamps, audio transducers) have achieved a clear formulation this time and in the latter also show prospect of a phase-out of LHMPS. The consultant believes that specifying components and applications is an ongoing process. Besides, a clear formulation of applications can facilitate examining the possible potential substitutions in the future review.

Industry has raised concern that in some cases, components exist that make use of different applications of LHMPS. From the various discussions on the scope of the exemption, it is the consultant’s impression that industry’s intent was to retain a situation in which only one of the newly proposed exemption items would cover all uses of LHMPS in a specific component. The motivation for this approach is understood to be the burden of updating compliance declarations for components, where some manufacturers specify all exemptions that apply. The consultant agree that a change from a single simplified exemption to sub-items, where more than one could apply, may result in a burden for updating declarations. Nonetheless, the situation that more than one exemption applies to a single exemption is not new and the consultant sees no limitation to declaring the use of a few of the Ex. 7(a) items when LHMPS is used in multiple applications that have all been shown to be justified.

10.6. Recommendation

10.6.1. Wording of Exemption 7(a)

It is recommended to renew exemption 7(a) with a new and specified wording, given that substitutes are still understood to be mostly unavailable. The proposed split has attempted to incorporate stakeholder proposals as far as possible, provided that it could be followed why various adaptations were needed. Some aspects could be specified further, however this would extend beyond the time restrictions of the assessment. In some cases, changes have been made to the proposed formulation to ensure that items currently benefiting from Ex. 7(a) would still benefit from the new items in the future.

It is noted that though stakeholders confirmed that certain groups of articles would be covered by the new items of the exemption, for the most part they do not support a split of the exemption as explained below (see 10.6.2).

Recognising that there may still be some applications that are not covered by the new items proposed, a short-term exemption is also recommended for the current exemption, to allow stakeholders to submit applications for the inclusion of additional application groups (or for further fine tuning of the existing items), provide that in such cases, it can be shown that the use is justified in relation to Article 5(1)(a).

Exemption formulation 7(a)	Duration
Lead in high melting temperature type solders (i.e., lead-based alloys containing 85 % by weight or more lead) (*excludes those in the scope of exemption 24)*	For all categories except applications covered by point 24 of this Annex, expires on 21 July 2024.
Lead in high melting temperature type solders (i.e., lead-based alloys containing 85 % by weight or more lead) when used for the following applications (excludes those in the scope of exemption 24): *I) for internal interconnections for attaching die, or other components along with a die in semiconductor assembly with steady state or transient/impulse currents of 0.1 A or greater or blocking voltages beyond 10 V, or die edge sizes larger than 0.3 mm x 0.3 mm* *II) for integral (meaning internal and external) connections of die attach in electrical and electronic components, if the thermal conductivity of the cured/sintered die-attach material is >35W/(m*K) AND the electrical conductivity of the cured/sintered die-attach material shall be >4.7MS/m AND solidus melting temperature has to be above 260°C* *III) In first level solder joints (internal or integral connections - meaning internal and external) for manufacturing components so that subsequent mounting of electronic components onto subassemblies (i.e., modules or sub-circuit boards or substrates or point to point soldering) with a secondary solder does not reflow the first level solder. This item excludes die attach applications and hermetic sealings* *IV) In second level solder joints for the attachment of components to printed circuit board or lead frames:*	Applies to all categories except applications covered by point 24 of this Annex, expires on 21 July 2026.

Exemption formulation 7(a)	Duration
1. in solder balls for the attachment of ceramic ball-grid-array (BGA) *2. in high temperature plastic overmouldings (> 220 °C)* *V) as a hermetic sealing material between:* *1. a ceramic package or plug and a metal case,* *2. component terminations and an internal sub-part* *VI)* for establishing electrical connections between lamp components in incandescent reflector lamps for infrared heating or high intensity discharge lamps or oven lamps VII) *for audio transducers where the peak operating temperature exceeds 200°C*	

As raised in Section 10.5.4, should the European Commission decide against such a specification, it is recommended to develop guidance and possibly even a standard to address the many technical aspects and specific properties of the various applications of LHMPS. Although development of such standards is a long process, it would allow a clear communication of application areas, properties and cases where the application of LHMPS is considered to be justified, which would serve both the EEE sector in its communication in the supply chain as well as the enforcement of Ex. 7(a). Such guidance could be referred to in a future exemption to allow retention to a general wording that will limit the administrative burden for the various parties, while also allowing a clear demarcation of areas where LHMPS can be used.

10.6.2. Applicants' statements concerning the split of Exemption 7(a)

The applicants disagree with the splitting of the wording, which has been explicitly expressed in the third, fourth, and fifth questionnaires. Applicants' arguments and concerns are summarised below:

- The LHMPS materials are used in a huge variety of applications. Therefore, it is impossible to list them all and address specifically. In short the requirements are linked to the material itself and not to its application. There is a risk that splitting/renumbering/itemization of the exemptions would unintentionally exclude necessary applications from its current scope.
- Splitting the exemption will not eliminate existing functional requirements for LHMPS, nor will it improve the availability for Pb-free alternatives.
- Stakeholders fear that specifying the wording will lead to significant unnecessary burden for industry including thousands of SMEs (manufacturers and importers) at large without commensurate benefits.
- Any change to the current wording would likely divert resources to rework the existing EEE material content reports and conformity declarations in support of CE marking declaration. This might reduce resources from investigating technical solutions.

- The use of LHMPS is critical to situations were reflow is necessary in PCB build; but is only applied where necessary due to the additional costs, process controls and reliability risks in comparison with the application of a lead-free solder.
- Stakeholders have also identified that this approach will result in a single component claiming multiple exemptions due to the use of LHMPS in different roles within the component. The implications cannot be assessed at the moment and it should be avoided that there is an interruption in availability of electronics in the EU market and competitiveness is damaged.
- As the applicants cannot support this sub-split of a yet sharp cut exemptions and being aware that the demands for each PCB design are different and numerous, they claim that it would be of limited benefit to give examples. In addition, there are different specific PCB requirements in terms of lifetime and temperature and environmental load. This is in our opinion very complex and at the moment we have to state that we are not able to give an expertise, covering all uses. Not all is disclosed by non-EU companies and companies that are not a member of this applicant group. Therefore, it might be that during WTO notification such stakeholders would claim market distortion. The clarification regarding the feasibility of narrowing the scope of the exemption as suggested will require a global dialogue in the world-wide connected and complex supply chain. The applicants estimate that this will take at least 1 year to be realized.
- The RoHS Umbrella Project (2021e) argues that this sub-split will cause a legislation which is not implementable and cause high administrative burden only. UP Exemption #7a WG Participants in view of the implementation of the harmonized standard EN IEC 63000 would like to emphasise that the split of the exemption wording would lead to the situation that more evidence is required whether the application of the solder is justified

Bourns and UP suggest conducting representative material analysis every 5 years, of the end-of-life product stream for electrical and electronic products. They are confident that these procedures will testify that intentional lead uses are on very low levels and continuously decreasing.

10.6.3. Outlook: Further Specification of Exemption 7(a)

The following aspects are considered to be relevant for providing a good basis for the next review of this exemption:

1) More detailed information should be provided on what has been researched in the last 5 years, supported with clear evidence.
2) The consultant has put a large focus on the specification of the scope of the exemption in the current review process due to the limited time and resources. In future assessments, a larger focus could be put on better understanding cases in which the use of alternatives is scientifically and technically practical and where their reliability has been ensured. This would require defining performance benchmarks for available alternatives and where they can be applied so that these can be excluded from the scope of Exp. 7(a).
3) Classification of different individual or combined properties of LHMPS for specific application groups,
4) Following up on the practical implementation of the recommendation of the Umbrella Project, representative material analysis should be conducted by industry on a routine basis to shed light on the amounts of LHMPS found in WEEE, on typical application areas and on the changing trends of use of this material.
5) Threshold set in item a) and b) of the proposed exemption should be considered in relation to the applications making use of these items to consider if they need to be fine-tuned.
6) The differences between the various lamp applications should be considered in the next assessment.

11. Exemption 7(c)-I "for 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"

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

ALD	Atomic layer deposition
Bourns	Bourns Incorporated
CEM	Channel Electron Multipliers
CTE	Coefficient of thermal expansion
EEE	Electrical and Electronic Equipment
EHS	Environmental Health and Safety
LMP	Low-melting point
MCP	Micro-channel plates
Pb	Lead
Photonis	Photonis Scientific, Inc.
PTC	Positive Temperature Coefficient
PZT	Lead zirconium titanate
OFP	Optical Fiber Packaging Ltd
RGP	Resistive Glass Product
RoHS	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment

11.1. Background

Seven organisations (Schott AG, Bourns Inc., COCIR, Optical Fiber Packaging Ltd, Photonis Scientific, Inc. and the RoHS Umbrella Project represented by Murata Electronics Europe B.V. and VISHAY BC components BEYSCHLAG GmbH) have submitted requests for the renewal of the above-mentioned exemption. A few stakeholders submitted applications for the renewal of the exemption as their contribution to the stakeholder consultation that took place in the course of this study. These were submitted by: Branson Ultrasonic Corp., Lucky Forests Corporation Ltd, and Bandelin electronic GmbH & Co. KG.

The applicants apply for exemption 7(c)-I of Annex III of the RoHS Directive:

"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"

> *Applies to categories 1-7 and 10 (except applications covered under point 34) and expires on 21 July 2021.*
>
> *For categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments expires on 21 July 2021.*
>
> *For category 8 in vitro diagnostic medical devices expires on 21 July 2023.*
>
> *For category 9 industrial monitoring and control instruments, and for category 11 expires on 21 July 2024.*

All applicants request the renewal of the exemption with its current wording and for the maximum duration possible (5 to 7 years depending on the EEE category). The applicants identify several applications for which they argue that the exemption is still needed because no lead-free alternatives are currently available, so lead has not yet been replaced or eliminated in applications such as those outlined below.

Applications of **lead-based glass, used to connect and seal** two elements made of glass, metal or ceramic materials are addressed in the applications of Schott AG (Schott 2020), Optical Fiber Packaging (Optical Fiber Packaging Ltd 2020) and the Umbrella Project (2020h). These applications are also termed by some applicants as lead-glass sealing materials, lead-glass solders or low-melting point (LMP) glass solders and are used to connect elements on the one side, but usually also to ensure a hermetic sealing, which protects from ingress of external elements such as humidity, acidity, etc. Schott (2020) explains that lead-glass solders are needed to manufacture high-quality hermetic housing components for optoelectronic applications, for passivation and encapsulation of semiconductor components and to hermetically connect power electronics. OFP (2020), which requests the exemption only for category 3 (IT and telecommunications equipment) use the LMP glass to manufacture miniature hermetic seals to optical fibres contained within small metallic tubes. The small seal subassembly is then used to allow optical fibres to hermetically penetrate into an 'optical module'.

Bourns Inc. (2020b) refers to use of **lead-containing glass in thick film inks/ glazes** used in electronic components. Thick film is a resistive and conductive film greater than 0.0001" thick resulting from firing a paste or ink that has been deposited on a ceramic substrate. This is also called a glass frit and is used in several applications as barrier layers for stopping the migration of silver or as a sealing material for ensuring hermetic packages. The Umbrella Project (2020h) refers to chip resistors, which are widely used in all types of EEE for current control, current detection, voltage division, amplification ratio determination, termination, dumping, pull-up and discharge applications in E&E devices. The resistor elements of these chip resistors consist of mixed sintered bodies of conductive particles which contain lead. In distinction from lead-glass solders, here lead-containing glass is understood to be used for encapsulating semiconductor components, which is also mentioned by SCHOTT (2020).

COCIR (2020) request the exemption for Category 8 medical devices for the use of lead zirconium titanate (PZT) as a **piezoelectric material**. The request mainly deals with the use of PZT in polycrystalline ultrasound transducers but also mentions other electronic components that contain lead in glass or ceramics that are applied in medical devices. The Umbrella Project (2020h) also mentions PZT components used in transducers used in ultrasonic sensor applications for distance measurement to objects, crack detection in concrete and metal, detection of foreign bodies inside food as well as every type of life-saving medical diagnosis.

Photonis Scientific, Inc. (2020) requests the exemption only for medical devices of Cat. 8 and monitoring and control instruments of Cat. 9. The Photonis request focuses on lead-oxide based glasses termed "**electronic glasses**" used to provide the electrical characteristics necessary for electron multiplication to occur. Such materials are needed both for the forming and the proper operation of Microchannel Plates (MCPs), Single Channel Electron Multipliers (CEMs) and Resistive Glass Products (RGPs).

According to the Umbrella Project (2020h) the exemption is also needed for **PTC (Positive Temperature Coefficient) thermistors** which make use of semiconductor ceramics having the property that their electrical resistance increases as temperature rises. These are used for temperature/current control and protection of circuits from abnormal heating and overcurrent. In PTC thermistors, materials become semiconductive by the addition of rare earth elements, etc. to barium titanate, however in order to ensure the thermal characteristics and resistive value stability it is necessary to add lead.

11.2. The history of the exemption

When Directive 2002/96/EC (RoHS 1 2003) was published in 2003, two exemptions covered applications in scope of Ex. 7(c)-I. Exemption 5 allowed the use of lead in glass and exemption 7d covered the use of lead in ceramics of electronic components. An additional exemption for "Lead in cermet-based trimmer potentiometer elements" was added to the Directive as exemption 34 following a request made in 2006, after the applicant argues that the homogeneous material in this case, the thick-film layer containing the lead, in itself is neither a glass nor a ceramic material. Nonetheless, in 2007/2008, Exemption 11 of Annex II in Directive 2000/53/EC (ELV Directive), which is equivalent to exemption 7c-I of RoHS Annex III, was reviewed and it was decided that it also covered lead in cermet-based trimmer potentiometer elements. Following the review of exemption 7d in 2007/2008, the ELV wording was adopted as the current Ex. 7(c)-I to eliminate uncertainties.

Ex. 7(c)-I was last reviewed in 2015/2016 (Gensch et al. 2016). It was concluded that "*the substitution of lead in ceramics is scientifically and technically still impractical in the majority of applications"* though practical to a certain degree in some cases, but it could not be clarified whether this would justify and enable narrowing the scope of the exemption. For lead in glass or in a matrix of glass or ceramic compounds, it was concluded that it was still scientifically and technically impracticable to substitute lead. During the assessment, an effort was made to specify the exemption into these two sub-groups of applications, however the discussions with stakeholders did not allow concluding this process. The following exemption specification was recommended as a starting point for the current assessment of exemption 7(c)-I. Exemptions 7(c)-II, 7(c)-III and 7(c)-IV were integrated into this wording proposal[58]:

Lead in

i) piezoelectric ceramics in electrical and electronic components, i.e.

- ferroelectric ceramics
- pyroelectric ceramics
- other piezoelectric ceramics

ii) positive temperature coefficient (PTC) ceramics in electrical and electronic components

- with TC < 120 °C (TC: Curie temperature) and resistivity of less than < 1000 Ωcm
- with TC < 120 °C and resistivity of 1,000 Ωcm and more
- with TC ≥ 120 °C and resistivity of less than 1,000 Ωcm
- with T_C ≥ 120 °C and resistivity of 1,000 Ωcm and more

iii) dielectric ceramics in discrete capacitor components for a rated voltage of 125 V AC or higher, or for a rated voltage of 250 V DC or higher
iv) dielectric ceramic in discrete capacitor components for a rated voltage of less than 125 V AC, or for a rated voltage of less than 250 V DC; for use in spare parts of EEE placed on the market before 1 January 2013
v) PZT-based dielectric ceramic materials for capacitors which are part of integrated circuits or discrete semiconductors
vi) other ceramics
vii) in glass or in a glass or ceramic matrix compound

- used for protection and electrical insulation

[58] In other words, the formulation includes applications covered by other exemptions listed under Annex III, as part of an effort to ensure that possible overlaps in the various items are avoided.

  - in glass beads of high voltage diodes on the basis of a zinc-borate glass body
  - in other electrical and electronic components
- used as resistance material
  - in cermet-based trimmer potentiometers
  - other *electrical and electronic components*
- *used for bonding purposes in electrical and electronic components*
  - for hermetic sealings between ceramic packages and glass or ceramic lids in electrical and electronic components
  - used *for any other purposes in electrical and electronic components*

11.3. Technical description of the requested exemption

In general, a differentiation can be made between applications where lead is part of a **glass material** or part of a **ceramic material**. In this respect, lead used in a glass atop a ceramic material would be included in the first group:

Lead in glass materials and components:

Low-melting point (LMP) glass solders – SCHOTT (2020) explains that lead is essential for realisation of low working temperatures. In optoelectronic components, solder glasses are needed as otherwise excessive process temperatures would lead to the destruction of the component (glass window or lens, semiconductor and other applications that are manufactured using glass solder). This is also mentioned for the following component encapsulation applications. The Umbrella Project (2020h) specifies that lead-containing glasses have melting temperatures of about 300 to 340°C. Important properties mentioned include excellent wettability with both metals and ceramics which is important for bonding different materials, weather and corrosion resistance due to the chemical stability of lead, less susceptibility to dielectric breakdown under high electric loads and high mechanical strength due to the small thermal expansion coefficients of lead and its crack resistance. OFP (2020) further explains that the presence of lead supports several important functions in such applications:

- Significantly reducing the melting point of the glass (from 1000°C to 270°C), which is important to maintain the optical fibre coating (typically acrylate) during production.
- Significantly reduces the viscosity of glass mix (by about 100 times), allowing melted glass to flow into very tight spaces required for reliable fibre optics glass seal. Furthermore, for achieving a vacuum-tight seal, the seal must not contain bubbles. Low viscosity of PbO based glass mix allows bubbles to escape before solidifying the glass.
- Allows varying and precisely matching the coefficient of thermal expansion (CTE) of the glass to match those of metal and fibre optics glass (or other materials). When the CTEs do not match, this can induce breakage upon cooling or result in a non-hermetic seal.
- Allows wetting of the metal surface (or other materials) to create a proper physical bond and vacuum tight sealing.

Glass frit, chip resistors and lead-containing glass used for encapsulating of semiconductor components – Bourns (2020b) explains that lead oxide is used to lower melting temperature and viscosity for processing below 550°C and to raise dielectric strength. The lead oxide content of the glass can be adjusted to control the CTE which is favourable for high sintering temperature operations.

Electronic glasses used for producing MCPs, CEMs and RGPs - Lead oxide, as a glass constituent, is responsible for providing crucially necessary current flow within signal multiplying detection devices to accomplish electron multiplication, or in other words for providing the electrical properties to the glass. This is provided through positive lead ions which agglomerate on the glass during the production process and later act as electron donors leading to the conduction property. The presence of Pb in the glass melt also decreases the viscosity of the glass at high temperatures, making it suitable for the complex forming operations required to make these products. (Photonis Scientific, Inc. 2020)

Lead in ceramic materials and components:

Piezoelectric materials – COCIR (2020) mentions five properties as important piezoelectric parameters:

- Coupling factor – this is the efficiency of the material's ability to convert mechanical energy from vibrations into an output electrical charge and vice-versa. It is explained as the most critical property as it is impossible to compensate for inferior coupling factors by design change.
- Piezoelectric constant - this defines the properties of the material and thus also its performance.
- Dielectric constant – this affects the impedance of a transducer element. Low values can be somewhat compensated by changing the electrical control circuit design and using multilayer piezoelectric materials. The best single crystal materials have relatively higher values.
- Insertion and other losses - insertion loss is proportional to the material's sensitivity and is thus important for image quality. A loss in performance can be dealt with by increasing power, but this can cause heating which will in turn decreases performance. Losses cannot be zero but should not be greater than 10%.
- Depoling and Curie temperatures - above the Curie temperature, PZT materials lose their ferroelectric properties due to the depoling process, which makes them unusable for ultrasound transducer applications. This can be accompanied by a corresponding strain and results in cracking or change of the PZT properties. Piezoelectric materials with low phase transition temperatures show unstable performance during operation and can depole during shipping or storage in areas with a hot environment, affecting the performance of ultrasound transducer. Curie temperature should be sufficiently high so that solder bonding, use and storage do not degrade performance.
- Velocity - Low ultrasound velocity requires a thinner transducer, but thinner materials have higher capacitance, which is good for smaller piezoelectric elements, however making fabrication more difficult.

Positive Temperature Coefficient thermistors – Lead is added to ensure the thermal characteristics and resistive value stability of the ceramic material, thus also related to the electric resistance of the material remaining stable under changing temperatures (Umbrella Project 2020h).

11.3.1. Amount of lead used under the exemption

Consultants Note: The terms tonne and ton are used below as they appear in the original documents. An American ton consists of ca. 907 kg whereas a British tonne consists of ca. 1016 kg. A metric tonne consists of 1000 kg. It is not clear what units are meant in the entries below and how this would affect the total amount of lead placed on the market through this exemption. This could lead to small variations in the total amount but is considered negligible in the context of the amounts estimated and their effect on the results of this assessment.

Schott (2020) estimates that the lead consists of up to 75% of the glass solder for connecting glass windows and lenses or between 5% and 50% when encapsulating semiconductor components. Schott estimates the lead consumption for industrial applications placed on the European market in 2018 to be between 550t ~ 750t but explains this to be a rough estimation for reference purposes only. The Umbrella Project (2020h) refers to the same reference estimation, but states that up to 93 wt% lead is used for the various applications. The estimation is based on a survey performed by ZVEI in which 14 member companies provided data on lead use in industrial applications.

In its response to first clarification questions consultation, Umbrella Project ((Umbrella Project 2021m) quotes ZVEI and JEITA (2019), who re-estimate the amount of lead used in EEE components for applications under the scope of the RoHS exemption 7(c)-I as in the range of 350 tons to 400 tons per annum in 2018. Around 90% of that figure comprises of lead in ceramic and 10% is lead in glass and glass-ceramic matrix compounds.

Regarding the lead content of glass frit substrate, Bourns Inc. (2020b) states that the homogeneous glass included in thick film ink or encapsulation materials varies and can range from 1-75% of the glass. The total ink/encapsulation including the glass is generally <1% of the finished part. Bourns Inc. was unable to determine the total amount of lead in glass for all EEE products entering the EU market because the company does not have information on how EE components, claiming exemption 7(c)-I, are incorporated in assemblies of other goods and eventually placed on the EU market by downstream actors in the value chain. Bourns Inc. however asserts that a misuse of the exemption 7(c)-I appears unlikely since component manufacturers consider that lead is used only where necessary for given applications.

For medical ultrasound piezoelectric dielectrics, COCIR (2020) estimates that 64 wt% of the PZT is lead. 4.2 kg of lead is estimated by an ultrasound probe manufacturer to enter the EU market annually through the lead in medical ultrasound transducers based on numbers of equipment sold in the EU, average mass of lead per probe and the market share of the manufacturer.

OFP (2020) estimates that 0.1% of lead is contained in the LMP glass used to manufacture miniature hermetic seals for optical fibres and that 50 kg of lead enter the EU market through this application.

Photonis (2020) states that the glass used to make MCPs, CEMs and RGPs are lead silicate glasses containing between 47.5 to 58 % by weight (26.5 to 31.5 % by mol) of lead oxide (PbO) (in another place 44 %-54 % Pb is specified). An estimation of amounts is provided on p. 8 of the application for the three uses. In total, Photonis estimates that 133 kg of Pb are placed on the global market through these applications (in another place 145 kg is mentioned) annually, with a rough estimation of the European share being 25 % or ~36kg per year.

Looking at the various values reported by the various applicants, it is not clear if **750 tons per annum** represents the top range for all possible applications or only for certain applications (i.e. for industrial applications of Ex. 7(c)-I, whereas some of the applicants mention also uses in non-industrial applications i.e., private consumer applications). Nonetheless the above data gives an indication of the amounts placed on the EU market for articles in the scope pf Ex. 7(c)-I.

11.4. Applicants' justification for the requested exemption

11.4.1. Substitution or elimination of lead

Looking at the candidates for substitution, the applicant's argumentation is mainly based on why the lead substitutes investigated so far are not considered sufficient in their intended field of application.

Low-melting point (LMP) glass solders – The Umbrella Project (2020h) mentioned that the melting temperatures of lead-free glasses are about 120-160°C higher than those of lead-based glasses. This means a higher bonding temperature which causes larger stress due to the larger difference in the extent of thermal expansion that will be generated and can result in cracks and difficulties to maintain the sealing/bonding and electrical insulation. This will increase the risk for malfunctions over time. The increase in the glass bonding temperature also has a negative effect on the wettability of the glass on the metal surface resulting in bonding strength degradation and leading to solder bonding failures. OFP (2020) also argues along these lines, explaining that over the last 20+ years multiple attempts to create alternative low melting point glass mixes, such as β-eucryptite, zirconium vanadate (ZrV2C>7), and zirconium tungstate (ZrW208) or BaO(SrO,CaO)-B2O3-Bi2O3 systems, for example, have been made. However, these materials resulted in non-homogeneous or crystalized seals or did not wet to metals, thus not creating reliable seals or actually even vacuum tight seals.

OFP (2021) states that alternatives for the use of lead in such applications currently do not exist and are not expected to become available for many years to come because a substitute needs to meet many important parameters. A reduction of lead in sealings of optical fibers and wires might be achieved by engineering measures, e.g. increasing the efficiency of the use of the leaded glass used per optical or electrical channel.

Schott (2020) mentions two approaches for substitution, though not explaining how they differ. The one refers to the use of BeO or UO_2 and is said to not be functional from an environmental health and safety (EHS) perspective though without detailing why. The other is not specified, though requirements and limitation of various glass alternatives are provided in table on page 6 of the application. For the second approach it is explained that intermediate soldering and high CTE sealing have been found suitable in some cases, due to the general nature of the glasses. Specific compositions are not mentioned in this respect, but it is explained that those with higher melting temperatures generally exhibit a low CTE. Existing PbO-free glasses can be used almost exclusively in specially processed components (extremely fast soldering by induction or laser) and/ or in special, encapsulated environments, but usually do not fulfil all requirements, thus PbO glass solders usually still need to be used.

Glass frit, chip resistors and lead-containing glass used for encapsulating and passivation of semiconductor components - The Umbrella Project (2020h) states that based on research, lead-free resistor element materials have low moisture resistance during load heating and low mechanical strength during overload heating, leading to inferior reliability. Resistance value variations, exceeding those of the present lead-containing resistors, will occur over time or in sudden outbreaks, depending on the resistance value range for the EEE. This is problematic for uses where power is applied at high-temperatures or in a high-humidity environment or where pulse overloads are applied such as in switching power supplies widely used in EEE. In light emitting diodes, this can lead to shortening of service life or to a decrease in illumination intensity. In current detection applications this can lead to heat damage to the motor or complete failure. Solving such issues would require hermetic sealing of the EEE, which however is often not practical due to size, resulting overheating of circuits and the increase in the consumption of energy and resources during the life cycle. Bourns states that it has been experimenting with various non-lead glass formulations. While success for low to mid-level resistance values have been implemented on some individual models, other potential alternatives are still in the design/test stage. Schott explains that for passivation, the glass systems meet a higher tolerance of process temperature (glass systems which have lower CTEs at higher melting temperatures). The ZnO-B2O3 systems are promising candidates but need optimization with regard to their chemical resistance. For diode passivation, the current PbO-free development glasses still show undesirable interactions with the semiconductor, which reduce the electric strength below an acceptable level. A Pb-free glass for bonding NiFe alloys and other materials that meets the requirements for chemical resistance in long-term use at an equivalent level to that of leaded glass is yet to be found.

In a later communication, Bourns Inc. (2021) refers to an example of experimental studies to substitute lead-free glass for leaded substrate in trimming potentiometers. A substitution of lead-containing glass in thick film inks, encapsulating glazes and other similar inks does not appear to be suitable in a variety of applications, such as chip arrays, chip resistors, diodes, other trimming potentiometers, precision potentiometers, resistor networks, power resistors and other Bourns' products. It is also noted that the results of those experiments are at a very early testing stage and cannot be generalized or utilised for other models.

Schott (2021) provides additional information following clarification questions, where it specifies the technical properties that are required of passivation glasses and soldering applications. A comparison of lead-containing glass types and lead-free candidates for substitution materials (see Table **11-1**) shows that "*none of the characterized glass families has so far shown a sufficiently adapted property profile that a complete substitution can be regarded as successful even in only one field of application. Even the overall consideration of partial solutions via the coupling of different new families cannot yet completely cover all applications*." Despite partial successes in lead substitution having been demonstrated for some soldering applications, "*complete substitution of all lead-containing glass families in the scope of RoHS is unfortunately not to be expected*." The applicant stresses that several lead-free candidate materials themselves pose environmental and health risks, making them unacceptable as substitutes for lead.

Table 11-1: Comparison of properties of glass types in combination with their fillers

Glass family	CTE	Melt-down temperature	Remarks
Lead-Borates	5 - 15 ppm/K	< 500°C	Due to sufficient crystallization stability the addition of CTE-reducing fillers is possible.
Lead-Alkaline-Phosphates	13 - 20 ppm/K	< 500°C	No fillers needed due to intrinsically matching CTE
Zinc-phosphates	13 – 16* ppm/K	450 - 600 °C	Crystallization tendency is inacceptable high that not even a minimum process window would be left

Source: (SCHOTT AG 2021)

*no filler

Electronic glasses – Photonis (2020) details limitations of alternatives in relation to the three application types. For micro channel plate (MCP) in particular the high length to diameter ratios and the small channel size (2.5 to 25 microns) required cannot be achieved with non-glass material. A few alternatives for substituting the type of glass, explaining their limitations, are presented. These include the use of soda-lime glass, borosilicate glass, crystalline or amorphous silicon and ceramics. Only borosilicate glass allows producing applicable alternatives for MCP. Despite the hollow-draw process used for production leading to hexagonal channel shapes and significant channel deformation at the boundaries of the multifibres, these glasses are still suitable for large area MCPs, however these are explained to cover only a small share of all MCPs. Most of MCPs are 25mm diameter small channel MCPs used for image intensifier tubes.

On the technological level, atomic layer deposition (ALD) is mentioned as a prospective candidate for MCP. In this process a series of independent, self-terminating gas reactions of alternating precursor gases are used to build up a film with a desired chemistry one atomic layer at a time. The composition of the film is determined by the chemical components of the precursor gases, and these precursors must be carefully selected to produce films with the desired final chemistry. For lead glass MCPs, the manufacturing steps for producing the resistive and emissive layers are inter-dependent processes, so that properties of resistive and emissive layers can be selected and adjusted independently. Though promising developments are mentioned, these are still being researched. Progress has been made in the last ten years. The projected future of ALD development leads Photonis to estimate that it will take at least 5 more years for this process to become sufficiently reliable for commercial manufacturing of MCPs as particle detectors. Applications for night vision equipment are estimated to require a longer time to develop. (Photonis Scientific, Inc. 2020)

Photonis (2020) has also used the ALD technology to create functional CEMs as part of its research and development programs. These detectors demonstrate that ALD can be used to make CEMs, but the full range of characteristics for this type of CEM have not yet been studied. Photonis mentions limitations of ALD, which are not reproduced here as the technology is understood to be under development.

Additional technological alternatives (discrete dynode multiplier, photodiodes, photomultiplier tube and Electron-bombarded CCD) are compared in relation to application areas of MCPs and CEMs in table 1 of section 6.1.3 of the application. Unique properties of MCPs are shown on p. 15, explaining that alternate detectors do not possess all of these properties, but could eventually allow for eliminating the need for lead-glass MCPs. (Photonis Scientific, Inc. 2020)

ALD is also considered for resistive film for resistive glass capillary inlet tubes (RGP). The ALD coating of resistive glass capillaries inlet tubes has produced tubes with poor resistance uniformity along the length of the inlet tube. The films produced by ALD deposition on capillary inlet tubes were not stable over the broad temperature range (350°C-450°C) and eventually failed and became non-conducting after a few hours at temperatures >200°C. There are three main alternatives to resistive glass capillary inlet tubes, non-conducting glass tubes, metal tubes, and orifices. Non-conducting glass tubes transport ions in a similar fashion to resistive glass tubes, but the fact that they do not conduct electricity limits their performance in two key areas. The first is that the build-up of charge on the inside of the tube leads to decreased ions transmission compared to resistive glass capillary inlet tubes. The second is the speed at which the inlet can be electrically switched between positive and negative ion modes. Metal tubes and orifices do not have the switching time limitations of the glass tubes, but cannot support a voltage drop, which means the two sides must be at the same potential. This can complicate the post capillary ion-neutral atom separation process. (Photonis Scientific, Inc. 2020)

In a late communication Photonis (2021c) states that "it is conceivable that some lead-glass components could be made with thin functional lead-glass surfaces rather than fabricated entirely out of lead-glass. The rationale would be that only a few microns of material near the surface are responsible for the electrical conductivity and enhanced electron emission properties of reduced lead-glass". This option is however understood to refer to a possible future development and not an alternative already applied on the market.

To summarise, though Photonis (2020) shows that many candidates are under consideration, it is explained that none are currently mature enough to allow for substitution in most of the application range of MCPs, CEMs and RGPs.

Piezoelectric materials – On the substance substitution level, COCIR (2020) states that extensive research has been carried out into lead-free piezoelectric materials, but still giving very inferior performance. Table 1 of the application compares properties of possible PZT alternatives and Figure 1 of the application compares the dielectric constant of lead-free and lead based materials. Reference to a review by Taghaddos is also made, which looks at additional materials and devices. The bottom line is that these are inferior to PZT in performance, whereas there is a risk that the use of lead-free transducers might entail medical misdiagnosis and is thus not practical for medical applications.

An alternative technology mentioned by COCIR (2020) is capacitive Micromachined Ultrasonic Transducers (cMUT), which do not contain lead. cMUTs have the potential to be a lead-free alternative for ultrasound imaging with potentially wider bandwidths and smaller feature size. However, cMUT technology has yet to overcome significant technical limitations necessary to be a clinically viable alternative, including output pressure, reliability and linearity. Information from studies is provided to allow a comparison between the technologies in relation to insertion loss and reliability results. Recognizing these limitations, researchers have focused their investigations on applications that play to the strengths of cMUTs, namely their ability to produce small feature sizes and wide bandwidths. These applications include catheters, endoscopic probes, high frequency linear arrays and probes with wide clinical coverage. Transducers for these applications cannot be fabricated easily using PZT or single crystal technology and therefor accept the reduced acoustic output performance associated with cMUTs. This technology is still in development, but it is considered highly unlikely by COCIR that sufficient performance will be obtained in the next 5-10 years (COCIR 2020).

The Umbrella Project (2020h) refer to the MRS Bulletin[59] and explains that though it would be scientifically and technically possible to use lead-free piezoelectric material, the actual physical properties such as dielectric properties and elasticity as well as their temperature dependence will be significantly different to those of lead-containing material. There are two prominent lead-free piezo materials: Potassium Sodium Niobate (KNN) and Bismuth Sodium Titanate (BNT) / Sodium Bismuth Titanate (NBT). Compared to PZT, lead-free piezoelectric ceramics like (K,Na)NbO3 (KNN) ceramics have several disadvantages:

- Low piezoelectric performance (piezoelectric constant), so in order to achieve equivalent electrical performance it is necessary to increase the element size several times (i.e. component will not fit in current designs of printed wiring boards, a particular disadvantage for medical devices that need to be inserted into the body);

[59] Cited as: MRS Bulletin, 43 (8). pp. 581-587, A. J. Bell and O. Deubzer

- Low depolarization temperature, so operating temperatures must be lowered in order to achieve the required electrical functions. (e.g. cooling of EEE will be necessary);
- Inferior fatigue properties and mechanical strength result in the reduction of the service life of EEE within a range from several tens to several hundreds of times (e.g. a few months service time instead of 10 years approximately).
- A more complex sintering process with lower yields is necessary. Moreover, niobium is a critical raw material and presents a supply risk.

To further support the justification for the exemption, two stakeholders that produce PZT components stated in confidentiality that ceramic materials tend to be the costliest components in an application. Their long-time experience shows that if there is a non-ceramic solution that can be realised, it will be applied.

Positive Temperature Coefficient (PTC) thermistors - The Umbrella Project asserts that industry has conducted research and development activities to find materials that are candidates for lead-free PTC thermistors, such as alkali metals, alkali earth metals and bismuth as additive elements in substitution of lead. Under actual operation conditions, part of the alkali metals will precipitate in the crystal grain boundary and cause the electrical resistance to change, hindering the long-term stability of electrical functions and reliability. Service life is also reduced to one tenth of the original lifespan (Umbrella Project 2020h).

11.4.2. Environmental arguments

The Umbrella Project (2020h) assures that the use of lead-containing glass and ceramics helps saving energy and resources along the entire product lifecycle. This encompasses the production and use phase of EEE, where lead-containing ceramics show high efficiency even when reduced in size and thickness. The use of lead also achieved long service life and high reliability, which results in higher resource efficiency. Results of a Life Cycle Assessment of lead-free piezo-electrics (by Ibn-Mohammed et al.) are quoted to illustrate some of the environmental impacts of PZT and its alternatives, referring to strengths and weaknesses of the alternatives compared.

11.4.3. Socioeconomic impacts

COCIR (2020) explains that, if the exemption was withdrawn, some uses of ultrasound transducers could be substituted by MRI. However, this would impose additional costs to medical facilities and is not considered a practical solution (MRI typically cost €2 million each compared to less that €20,000 for ultrasound, MRI also requires more space and have much higher running costs). This could affect the level of available services for some EU patients possibly also with impacts on diagnosis and treatment.

Optical Fiber Packaging Ltd (2020) warns that its core business would be badly affected if the exemption is not renewed with over 100 jobs at stake. More than 90% of OFP’s products use the current low melting point glass.

DxTx Medical (DxTx Medical 2021) expresses its concern that without the exemption, the quality of medical diagnostic equipment could be compromised if certain EEE components have to be replaced. This could lead to compatibility problems with existing devices.

SEMI (SEMI EUROPE 2021b) notes that replacing lead-containing parts with RoHS-compliant parts would impose an additional administrative burden on industry. The simultaneous redesign of several products would require the industry to implement significant engineer projects.

11.4.4. Road map to substitution

Bourns Inc. (Bourns Inc. 2021a), points out that a roadmap for lead-substitution in glass cannot be provided because the research and development of lead-free substitutes has not yet resulted in a suitable candidate material. While some lead-containing component types might be phased out of current production during the next years there is still a need to maintain the availability of spare parts for servicing EEE products.

11.4.5. The scope of the exemption

The current exemption formulation is understood to be relatively broad, allowing any kind of application of lead in glass, ceramic or glass-ceramic matrix materials in EEE. Considering that a specification of the exemption could prevent its misuse, applicants were asked to propose possible approaches, either referring to specific properties or to specific application areas. The following reproduces some of the aspects mentioned in this respect.

COCIR (2021) specifies that in relation to PZT materials the exemption renewal is only requested for medical ultrasound transducers, though piezoelectric ultrasound transducers may also be used in Cat. 9 EEE. Furthermore, PZT materials are explained to also be used in types of electronic components used in all EEE such as ceramic filters, ceramic resonators, buzzers, etc. Reference is made to SVHC statement submitted by MURATA with regards to other components. COCIR also need the exemption for leaded glass hermetic encapsulation which is used in high voltage diodes of Cat. 8 devices: Defibrillator / Monitor and Automated External Defibrillators.

Photonis (2021b) emphasizes that CEMs and RGPs (and also MCPs) are all applications based on resistive glass, where lead is necessary to realize stable quality for the resistive properties required in current market applications. Lead also enables the provision of current flow, the crack resistance of the glass, and the reduced melting temperature and viscosity of the glass.

Later Photonis (Photonis 2021a) explains the primary technical specifications for the use of the lead glass in the production of chemically modified surfaces for MCPs, CEMs and RGPs. Photonis does not see a way to exclude such applications from the exemption or provide examples of applications falling in the scope of exemption 7(c)-I where the use of lead is avoided. A possibility to reduce the lead content of these components could be to fabricate few microns-thick functional lead-glass layers on the surfaces of lead-free glass components to create electrical conductivity and enhanced electron emission properties. However, this option is currently at a low technology readiness level.

OFP (2021b) request the exemption for hermetic sealing and Cat. 3 and Cat. 8 applications of fixing of optical fibers and electrical conductors into metal alloys, ceramics and other glasses. OFP further explains its technologies to rely on: Lead in glass matrix materials with melting points of 270-320°C, containing a 70% to 85% lead oxide formulation for the purpose of hermetically sealing of optical fibers and electrical conductors into metal alloy, ceramics and glass components.

In a later correspondence, OFP (OFP 2021a) disagrees with a proposed wording for 7(c)-I because it narrows that scope of Low Melting Point glass (LMP) material in a way that would exclude OFP's products, specifically hermetic sealing and fixing of optical fibers and electrical conductors into metal alloys, ceramics and other glasses. The applicant cannot provide an adequate wording proposal that narrows the scope of 7(c)-I without excluding the use of lead in above mentioned applications.

Umbrella Project (2021m) stated that they do not believe the exemption is misused, since the addition of lead causes variations in the electrical/mechanical functions/properties of electrical and electronic components, making them incompatible with the relevant EEE specification requirements, component manufacturers consider that lead is used only where necessary for given applications.

The Umbrella Project (Umbrella Project 2021a) later stresses that the current wording of exemption 7(c)-I covers a plethora of technical applications of lead in glass or ceramic materials in EEE relevant for their proper function. In a legal text, the complex interrelations of various technical parameters cannot be described in a more specific language as it is deemed impossible in practice to exhaustively present all applications and cases. In support of this point of view, Bourns Inc. presents a non-exhaustive selection of examples where the required technical performance parameters necessitate the continued use of lead-containing materials in EEE-components under 7(c)-I (Bourns Inc. 2021b). It is emphasized that it is considered impractical to define specific technical parameters in the wording of 7(c)-I because they are too heterogeneous.

11.5. Stakeholder contributions

The following 6 organisations have expressed their support of the request for renewal of this exemption in the course of the stakeholder consultation:

- A manufacturer of finished medical devices that asked to remain anonymous supports the exemption request for 7(c)-I. It has identified a few EE-components within its product portfolio, that depend on Ex. 7(c)-I. Efforts have been made in the past to replace or eliminate lead-containing components, but no lead-free substitute could be found. At present, the company has no defined roadmap to substitute the parts.
- **Fresenius Kabi** USA, LLC (Fresenius Kabi 2021) agrees with the exemption request for 7(c)-I. No substitution or elimination possibilities for lead containing components have been identified.
- **Japanese electric and electronic industrial associations** (Japan 4EE 2021) agrees with the exemption request for 7(c)-I and suggests that the current legal text should be maintained. Japan 4EE has not found materials for which lead elimination or substitution is scientifically or technically feasible, or a substitute for

which reliability can be ensured. Since there is a huge number of EE components that require lead in glass or ceramics, only examples can be provided for materials that depend on Ex. 7(c)-I. Japan 4EE sees no prospect of replacing the lead-containing parts with lead-free ones and therefore cannot provide a roadmap for the further substitution of lead in the field of EE components in the scope of 7(c)-I.

- **SEMI** (SEMI EUROPE 2021b) notes that replacing lead-containing parts with RoHS-compliant parts would impose an additional administrative burden on industry, including the assignment of a new part number, revision of related drawings and bill of materials. SEMI estimates that "*even one such simple change could require 8 to 32 or more hours of engineering time [...], which could require one to three weeks of real calendar time*." Depending on the role of the part within the equipment, redesign of surrounding components might also be required. The simultaneous redesign of several products would require the industry to implement significant engineer projects.
- **Test and Measurement Coalition** (2021), see chapter 5.1
- **YAGEO Corporation** (Yageo 2021) states, that at the present stage, market-available lead-free raw materials do not fulfil all required technical performance parameters. Several of Yaego,s product series in mass production are already compliant with RoHS (Lead content <1000 ppm) or samples available. However, the majority of components are still in a stage of feasibility study based on the progress of raw material development.

11.6. Critical review

11.6.1. REACH compliance – Relation to the REACH Regulation

See section 4.1 for details.

11.6.2. Scientific and technical practicability of substitution

Six applicants have requested the renewal of Ex. 7(c)-I and multiple stakeholders provided information in support of the renewal for a few application groups in the scope of the exemption that can be categorised into two groups:

- Lead used in glass or in a glass matrix:
  - Lead-based glass, used to connect and seal, also referred to as low-melting point (LMP) glass solders,
  - Lead-containing glass in thick film inks/glazes, also referred to as glass frit, chip resistors and lead-containing glass used for encapsulating of semiconductor components,
  - Electronic glasses
- Lead in ceramic or in a ceramic matrix:
  - Piezoelectric materials,
  - Positive Temperature Coefficient thermistors

In **lead-based glass**, used **for connecting** components, for **sealing** and for **encapsulation and passivation**, the presence of Pb lowers the processing temperature of the glass and thus ensures that the components being connected or coated are not destroyed during the manufacturing process. Lead-containing glasses are said to have melting temperatures of about 300 to 340°C, good wettability with both metals and ceramics which is important for bonding different materials, weather and corrosion resistance due to the chemical stability of lead, high mechanical strength due to the small thermal expansion coefficients of lead and its crack resistance and less susceptibility to dielectric breakdown under high electric loads. The Umbrella Project states that lead-free alternatives have melting temperatures that are about 120-160°C higher than that of lead glasses, affecting the process window and the wettability of the glass to other materials. Use of such alternatives could result in stress in the connecting material due to the differences in CTE of the lead-free glass and the materials it is used to bond or coat. This can lead to cracking and malfunction of the bond or seal or faults in its electrical insulation properties. OFP mentions low melting point glass mixes, such as β-eucryptite, zirconium vanadate (ZrV2C>7), and zirconium tungstate (ZrW208) or BaO(SrO,CaO)-B2O3-Bi2O_3 that have been experimented with, but that did not provide comparable performance to that of lead-based glasses, affecting the reliability of the bond or coating. Schott explains that PbO-free glasses can be used in specially processed components (extremely fast soldering by induction or laser) or in special, encapsulated environments, but claim that such alternatives usually do not fulfil all requirements, thus PBO glass solders usually still need to be used. As for glasses used for encapsulation and passivation, the Umbrella Project contends that lead-free resistor element materials have inferior reliability due to low moisture resistance during load heating and low mechanical strength during overload heating. This is not suitable for applications where power is applied at high-temperatures or in a high-humidity environment or where pulse overloads are applied such as in switching power supplies widely used in EEE or in light emitting diodes where this may shorten the service life through the decrease in illumination intensity. The moisture resistance can be increased through sealing of the EEE, however this is often not practical and also increases the use of resources. Bourns explains that its investigation of possible alternatives shows some success for low to mid-level resistance values, however this refers to solutions for specific elements that could not be applied in other cases without requiring further adjustments. Schott mentions that glass systems with lower CTEs at higher melting temperatures like ZnO-B_2O_3 systems as promising candidates but need optimization of their chemical resistance. PbO free glasses experimented with for diode passivation are said to have undesirable interactions with the semiconductor, which reduces the electric strength below an acceptable level.

To summarise, available substitutes are understood not to provide comparable performance, not allowing application or resulting in bonds and seals of lower reliability. Some of these may still have potential to develop into practical alternatives in some applications, however the properties of the material or of how it is applied must still be optimised. This is not expected to happen in the short-term. It can also be assumed from the information provided that a single solution shall probably not be suitable for all applications of Pb-glasses used for connecting, sealing, encapsulation or passivation and rather that specific solutions will need to be developed on a case-by-case basis.

The lead present in **electronic glasses** provides the property of current flow to the glass, which is necessary in applications based on signal multiplication and detection.

Positive lead ions agglomerate on the glass during the production process and later act as electron donors leading to this conduction property. The presence of lead also contributes to glass viscosity which supports the complex forming of such components. Photonis claims that for MCPs in particular the high length to diameter ratios and the small channel size (2.5 to 25 microns) required cannot be achieved with non-glass material. Technological alternatives for MCPs and CEMs (discrete dynode multiplier, photodiodes, photomultiplier tube and Electron-bombarded CCD) do not possess all of the unique properties of MCPs and CEMs and would not allow elimination at present. Though borosilicate glass is explained to allow fabrication of the channel form, these show deformation at the outer boundaries and are only suitable for large area MCPs said to have only a small market share. Atomic layer deposition is under investigation for both MCP and CEM applications but explained to still require five years or more for development before commercialisation may be possible.

To summarise, though many candidates are under consideration, none is understood to currently be mature enough to allow for substitution in most of the application range of MCPs, CEMs and RGPs. The arguments of the applicant can be followed.

The use of lead in **piezoelectric materials** is explained to be important for provision of five main properties: the coupling factor of the glass; the piezoelectric constant; the dielectric constant; low insertion losses (between 0-10%); high Curie temperature to avoid depoling and performance degradation during solder bonding, storage and use; and suitable velocity. COCIR states that though extensive research has been carried out into lead-free piezoelectric materials, these still give inferior performance. Using such alternatives in existing applications, e.g., the use of lead-free transducers in existing devices, could entail medical misdiagnosis and is thus not practical for medical applications. On the technical level, though COCIR mentions capacitive Micromachined Ultrasonic Transducers as a possible lead-free alternative for ultrasound imaging, it is explained to still have limitations hindering its clinical application including output pressure, reliability, and linearity. Though this technology has been applied in some areas, these are areas where PZT materials cannot be fabricated easily and thus where the lower performance is acceptable. The Umbrella Project explains that though lead free PZT materials exist, these differ from lead-based ones in dielectric properties, elasticity, and temperature dependence. Both technical properties and manufacturing limitations are mentioned as some of the areas where such substitutes cannot compare with lead-based PZTs.

To summarise, though various materials for substitution of lead in piezoelectric materials have been considered, at present none is comparable in terms of performance to provide a suitable substitute.

In **positive temperature coefficient thermistors**, lead enables the thermal characteristics and resistive value stability of the ceramic material, which allow the material to remain stable under changing temperatures. Alkali metals, alkali earth metals and bismuth can be used as additive elements to substitute of lead. However, the Umbrella Project explains that under actual operation conditions, part of the alkali metals will precipitate in the crystal grain boundary and cause the electrical resistance to change. This subsequently affects the long-term stability of electrical functions and also reduces service life, meaning that the reliability of such substitutes is inferior to the use of lead in these ceramic materials.

To summarise, for the various application groups mentioned, though various alternatives have been investigated, it can be followed that these could not be applied at present to substitute lead-based applications due to inferior performance in relation to various properties. The consultant concludes that in some cases, such alternatives will not allow the fabrication of the applications mentioned above, whereas in others, fabricated elements have a lower reliability and lead to early malfunction. Both of these result in the situation in which lead-based applications must still be placed on the market to allow the production of various EEE.

11.6.3. Environmental arguments and socioeconomic impacts

The Umbrella Project refers to the environmental advantages of lead in terms of energy and resource consumption. In some cases, examples are given to substantiate these claims, referring for example to components that would need to be fabricated in larger size, leading to a need for additional resources and/or cooling requirements. These arguments may be plausible, but have not been reviewed in detail, seeing as the main justification for the exemption relates to the lack of available substitutes or their inferior reliability.

11.6.4. Socio economic impacts

Some of the applicants provide indication as to possible socio-economic costs in the case that the exemption was to be revoked. The information is partial and has not been reviewed in detail seeing as the main argumentation to justify the exemption is not focused on socio-economic arguments.

11.6.5. Roadmap to substitution

Neither the applicants nor any other interested parties have provided a roadmap for the substitution of lead in the applications covered by exemption 7(c)-I. Nonetheless, available publications show that the research community is still active in developing materials that could provide substitutes for the applications of lead in scope of Ex. 7(c)-I in the future.

Research and development in the **piezoelectric materials family** has been documented over the past decade in the form of books and publicly available research reports as well as patents. (Wu 2018) p34 for example points out that "*some physical properties* [of lead-free piezoelectric materials] *are comparable to those of PZT*" and that their key properties have been greatly enhanced, such as piezoelectric coefficients (d_{ij}), electromechanical coupling (*kij*), ferroelectric remanent polarization (P_r) and dielectric permittivity (ε_r)." (Wu 2018) believes "*that these advances in lead-free piezoelectric materials can transfer them into the real practical applications in the future*."

Asked to comment on these findings, industry still maintains that the materials under consideration do not match the specific performance characteristics of PZT. Although applicants and stakeholders point to ongoing and future research projects in materials science, they seem to have little optimism that viable substitutes for PZT will be ready for the market in the short term.

As far as lead-containing electronic glasses for frit sealing, soldering, passivation and resistive coatings, etc. are concerned, material research and development has been carried out and reported in a large number of papers and reports. However, there does not appear to be a breakthrough solution in terms of viable, general-purpose substitute materials for leaded glass in the 7(c)-I application area. According to the applicants and other interested parties, it seems to be difficult to match the properties of substitute materials with the technical performance requirements of EE components, as the latter are very heterogeneous. While lead-containing glasses cover a broad range of parameters, the lead-free substitutes would need to be identified and tested one-by-one for each application. From the background of the plethora of EE components affected, their lead-free redesign would require industry to allocate substantial capital and human resources.
It can be followed that possible candidates will still require research and development before they can be applied in applications to be placed on the market and that this could require additional time, particularly as development and optimisation will probably need to be approached on a case-by-case basis. Nonetheless, the multitude of applications and the limited data as to the set of properties and the respective performance window needed for different applications make it difficult to consider if in some areas lead-free alternatives might come to market faster than others.

11.6.6. Scope of the Exemption

The exemption is currently formulated as follows:

> *"Electrical and electronic components containing lead in a **glass** <u>or</u> **ceramic** other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, <u>or</u> in a **glass <u>or</u> ceramic matrix** compound"*

This formulation exempts the use of lead where it is used in one of a few materials: glass, glass matrix, ceramic, ceramic matrix. Though it can be followed that the properties of lead of relevance to these applications are similar, in each area, the applications necessitate a different set of properties, as observed in Table **11-2** below.

Table 11-2: Comparison of properties of glass types in combination with their fillers

	Low melting point glass solders	Glass frit, chip resistors, encapsulation	Electronic glasses (MCPs, CEMs and RGPs)	Piezoelectric materials	Positive temperature coefficient thermistors
Reducing melting temperature of glass	X	X	X		
Improving wettability of glass to metals and ceramics (ensuring strong and hermetic bond and preventing ingress of moisture, chemicals)	X	X			
Reducing the viscosity of the glass	X	X	X		
Adjusting the CTE of the glass to that of the materials being bonded	X				
Chemical and corrosion resistance of the bond	X	X			
Less susceptibility to dielectric breakdown under high electric loads/raise dielectric strength/ High dielectric constant	X	X		X	
High mechanical strength / high crack resistance;	X		X	X	
Provision of current flow within the glass			X		
High curie temperature and depolerisation temperature /stability of material properties under changing temperature conditions		X (>100°C)		X (>100°C)	X
High piezoelectric property constants (charge and voltage)				X	
High coupling factor				X	

Source: Information compiled by Oeko from the various applicant documents

According to the information provided by the various parties, the technical justification in each of these application areas is different and it stands to reason that substitutes will also differ in this respect. Furthermore, the current wording would also allow the use of lead in other areas, provided it is in a glass or ceramic material. The applicants and stakeholders involved in the assessment claim, as in the past review, that the list of applications is not exhaustive, and they recommend not changing the wording so as not to deny market access to such applications. However, the input received in the current assessment and in the past does not provide sufficient evidence why the exemption would be justified in other application areas. Options have therefore been considered to narrow the scope of exemption 7(c)-I to applications for which a plausible justification has been specified. Based on the available information and on past efforts in this direction, the following formulation was devised as an alternative to the current wording of Ex. 7(c)-I. It is based on an initial split of the current exemption into two exemptions, one for lead in glass and glass matrix materials and one for lead in ceramic and ceramic matrix materials:

1) "Electrical and electronic components containing lead in a glass or glass matrix compound that fulfils the following functions:
   a) protection and electrical insulation in glass beads of high voltage diodes on the basis of a zinc-borate glass body,
   b) for hermetic sealings between ceramic packages and glass or ceramic lids

   c) for bonding purposes in a process parameter window for [PLEASE SPECIFY TEMPERATURE AND VISCOSITY]
   d) used as resistance material in cermet-based trimmer potentiometers in a parameter window [PLEASE SPECIFY RESISTIVITY]
   e) used in chemically modified glass surfaces for Microchannel Plates (MCPs), Single Channel Electron Multipliers (CEMs) and Resistive Glass Products (RGPs).

2) "Electrical and electronic components containing lead in a ceramic that fulfils the following functions:
   a) piezoelectric lead zirconium titanate (PZT) ceramics for polycrystalline ultrasound transducers in medical devices (Category 8).
   b) piezoelectric lead zirconium titanate (PZT) ceramics for ultrasonic sensor applications
   c) providing ceramics with a positive temperature coefficient (PTC)
      i) with TC < 120 °C (TC: Curie temperature) and resistivity of less than < 1000 Ωcm
      ii) with TC < 120 °C and resistivity of 1,000 Ωcm and more
      iii) with TC ≥ 120 °C and resistivity of less than 1,000 Ωcm
      iv) with TC ≥ 120 °C and resistivity of 1,000 Ωcm and more

Stakeholders and applicants were asked to comment on this proposal and also to provide input as to the performance window for which the exemption would be needed. The following summarises their comments and the consultant's conclusions for each article. Six stakeholders provided information in confidentiality. This has been taken into consideration below where the information could be specified in an anonymous way.

The Umbrella Project (2021a) provide a general statement on the effort to specify the current exemption wording, explaining that the wording should provide "*a sound basis for communication between stakeholders, consultants and finally the legislators:*

I. An attempt to change structure or wording of RoHS exemptions shall be done under due consideration that the RoHS and its Annexes are a legal text and not a scientific or technical publication, thus, the wording shall:

- *be unambiguous and inclusive, creating legal certainty,*
- *not discriminate or exclude market participants,*
- *enable transparency along the supply and value chain, and finally,*
- *enable producers of EEE and authorities to provide the proof of compliance of products.*

II. In addition, such changes should:

- *create environmental, health and consumer safety benefits*
- *take into account the availability of substitutes and the socioeconomic impact of substitution.*

III. In order to achieve the above targets, the structure of exemptions had been successfully set: as to

- *provide a generic exemption for a material in a group of applications as a first step,*
- *exclude specific applications, where substitution is scientifically and technically possible in a second step.*

[…] The current wording of the exemption reflects the reality, and does not "appear to be too broad, as the technical requirements that can only be met by using lead-containing materials are described too generically." Specifically, lead is used, if an essential technical need for it exists to fulfil the required characteristics, performance, and reliability". The UP provide an overview of the various types of EE components used in EEE of which Exemption 7(c)-I is relevant for many categories. This overview is reproduced in Appendix A.3.0) to this report. The UP further explain that "Details of material composition and properties, processing parameters, etc. normally are company secrets and not available in public specifications. Thus, these data cannot be used to assess the compliance to RoHS, as such information is not publicly available".

1) "Electrical and electronic components containing lead in a glass or glass matrix compound that fulfils the following functions:

a) protection and electrical insulation in glass beads of high voltage diodes on the basis of a zinc-borate glass body,

Schott (2021) propose to make a few changes in item 1(a) so that it would read "*protection and electrical insulation in glass beads of high voltage diodes and glass layers for wafer on the basis of a lead-(zinc/silica)-borate glass body*".

Further comments were not proposed for this entry. Though the consultant appreciates the further specification of the type of glass bead, the glass type is not completely clear, and it is thus proposed to specify the two glass types, i.e., lead-zinc-borate and lead-silica-borate. The opposite is true for the reference to glass layers for wafer, which is understood to extend the scope to an additional application area.

It is noted that Ex. 37 of Annex III of the Directive currently reads "*Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body*" (time of writing 14.12.2021). This exemption is understood to have expired for all categories on 22 July 2021, except for Cat. 8-in-vitro, Cat. 9-industrial and Cat. 11, for which the exemption will remain valid until July 2023 and 2024, respectively. Looking at the similarity of these exemptions, the consultant assumes that Ex. 37 as a minimum would overlap with Ex. 7(a) in relation to high voltage diodes when these are protected or insulated with a glass bead with a zinc-borate composition. Ex. 37 applications could be excluded from the current exemption to avoid uncertainties resulting of an application covered under two exemptions. It is however not clear if Ex. 37 is still used to place articles on the market in practice or rather that stakeholders make use of Ex. 7(c)-I instead for such applications. Rather than excluding Ex. 37 applications of Cat. 8-in-vitro, Cat. 9-industrial and Cat. 11, it would be recommended to merge Ex. 37 into Ex. 7(a) if industry requests the renewal of Ex. 37 for these categories or the renewal of Ex. 7(a) for high voltage diodes with a zinc-borate body.

This would avoid the situation of having two exemptions that cover the same applications depending on the category of use and would ensure that future assessments are conducted together.

b) for hermetic sealings between ceramic packages and glass or ceramic lids

OFP (2021c) explains that this formulation would not cover their use of the exemption in optical fibre applications. OFP defines its application of the exemption as "hermetic sealing and fixing of optical fibers and electrical conductors into metal alloys, ceramics and other glasses." It explains that "*the wording being proposed will exclude the use of LMP glass for hermetic sealing with metal alloys and other glasses. This would result in catastrophic damage to OFP's core business with closure of the company's manufacturing and the loss of over 100 jobs. More than 90% of OFP's overall, products use the current low melting point glass for the applications described above*". This would furthermore subsequently affect OFP's OEM customers and the products, many of with are understood to be telecommunication application in scope of RoHS.

Schott (2021) also refer to the formulation of item 1(b), and provide the following proposal: "*for hermetic sealings between ceramic, metal and/or glass parts*".

The consultant can follow the need to extend the formulation so that it allows sealing applications of lead-based glass between the three materials and does not exclude the introduction of a hermetic seal and bond between metal and glass or between these materials and ceramic parts. The consultant is of the opinion that this proposed formulation would cover both the sealing of such parts and their fixing but does not think that this needs to be made explicit in the formulation.

A further response made in confidentiality also supports that this entry should cover also hermetic sealings between metal and glass.

c) for bonding purposes in a limited process parameter window

Bourns (2021) confirms that lead in glass is used for bonding purposes but contends that limiting the scope to specific temperatures and/or viscosity will greatly limit the use of this entry. "*Depending on component type and materials included in that component makes it difficult to create a viable range of temp and viscosity that will not exclude existing products*".

In contrast, Schott (2021) provide a proposal for item 1(c) that would limit the scope to a certain performance range for temperature and viscosity. "*for bonding purposes in a process parameter window for < 500°C and $10^{13,3}$ dPas*[60] *(so called "glass-transition temperature*")". Nonetheless, this is explained to be a process window for the glass itself, whereas inclusion of possible additives may "*have an impact on the process parameters specified here*".

[60] The specified unit $10^{13.3}$ dPas indicates the viscosity of the molten glass, i.e. the shear pressures required to move the melt at a certain temperature. Since glass does not have a melting point (solid glass is, in a sense, also liquid) its "melting point" is called glass transition temperature Tg. The unit dPas indicates the force required to deform the melt at the glass transition temperature: dPas = deci Pascal * second.

It is not clear whether the parameters specified by Schott would be sufficient to cover applications using glass-lead for bonding purposes. Though it is assumed that Schott is aware of the temperatures applied in its own glasses, it is possible that where other suppliers use other glasses, i.e., with other additives, that this parameter window may not suffice. This is also reflected in Bourn's appeal not to specify the temperature and viscosity parameters. Though the proposed thresholds could be tested in a further consultation, this could also be investigated in more detail in a future assessment where only this item is under assessment.

d) used as resistance material in cermet-based trimmer potentiometers

According to Bourns (2021) the scope of this entry needs to allow the use of lead not just in cermet-based trimmer potentiometers but also in other resistor applications used in other parts including: Resistor Networks, Power Resistors, Chip Resistors/Arrays, Fuel cards, PTCs, Sensors, and Diodes to name some examples of other Bourns applications. This is not an exhaustive list and does not leave room for new products. For these examples the ink resistivity range may be from 1 Ohms/square to 1 Mega Ohms/square but again is just an example of other resistive products outside of the cermet-based trimming potentiometers that need to be included in the definition of resistance material.

The consultant can follow that additional applications aside from cermet-based trimmer potentiometer rely on the use of lead in glass for resistance materials. Adding the parameter specification of the resistivity could allow confining this entry to some degree, though it is not clear whether this range is suitable or not.

It is noted that in a separate study, exemption 34 is also under assessment for possible renewal. This exemption reads as follows:

- "Lead in cermet-based trimmer potentiometer elements"

Bournes has signalled that it places trimmer potentiometers on the market through Ex. 7(c)-I and not through Ex. 34, this despite the wording of Ex. 34 which clearly addresses such applications. The assessment of Ex. 34 among others investigated whether lead must indeed be used in all cermet-based trimmer potentiometers or not (the assessment refers to two types of applications for which the justification of an exemption may differ). A first recommendation is to renew the exemption for a short period until July 2024 to allow "*the industry to compile input that would allow narrowing the scope of the exemption to specific use conditions or type of equipment*", however a decision as to this exemption is currently pending.

Depending on the conclusions of this process, it may be relevant to exclude cermet-based trimmer potentiometers or a sub-group thereof from Ex. 7(c)-I to eliminate possible overlaps. Should the exemption be requested for renewal, it could be added in the future as a further item of Ex. 7(c) to ensure mutual assessments in the future. This would ensure that the specification achieved through exemption 34 is not lost (in line with the current effort to specify the exemption). In parallel, assuming that some stakeholders did not participate in the assessment as they assumed that Ex. 7(c)-I covered this application, they would still benefit from the exemption for a short time to allow further substantiation of its justification.

e) used in chemically modified glass surfaces for Microchannel Plates (MCPs), Single Channel Electron Multipliers (CEMs) and Resistive Glass Products (RGPs).

Photonis (2021c) suggests removing the word "Single" from the text in article 1(e), explaining that "*the term Single Channel Electron Multipliers should be changed to Channel Electron Multipliers since there is a long established history of channel electron multipliers with more than one channel*." Photonis further details two primary technical specifications for the use of lead glass under this entry:

- An electrically conductive surface with sheet resistance values that can be varied between 1E4 and 1E18 ohms.
- An electron emission coefficient >1.5 for primary electrons with energies of 30eV or higher.

The consultant can follow the removal of the word "Single" from the formulation in light of the existence of both single and multiple channel electron multipliers. As to the further proposed specifications, though the add to the confinement of the wording, in the consultants view the entry refers already to very specific applications. The additional detail would add to the complexity of the formulation, and in considered to only become relevant in the future as a means of further specification when certain parts of the application range maybe no longer need the use of lead in glass and when this can be described with the above parameters.

2) "Electrical and electronic components containing lead in a ceramic that fulfils the following functions:

a) piezoelectric lead zirconium titanate (PZT) ceramics for polycrystalline ultrasound transducers in medical devices (Category 8).
b) piezoelectric lead zirconium titanate (PZT) ceramics for ultrasonic sensor applications

A response provided by a manufacturer of ultrasonic cleaning devices was made in confidentiality and clarifies that PZT ceramics are used also in such devices. For this purpose, high-power transducers use PZT ceramic rings clamped between metal front and back masses. The stakeholder stresses the importance of PZT ceramics in transducer applications which are used not only for medical applications.
A further confidential response clarifies that PZT ceramics are also used in vortex meters. The component is detailed as an accelerometer, which was also mentioned by a further stakeholder as a component using PZT ceramics. This suggests that PZT components may be needed for other than ultrasonic sensor and ultrasound transducer applications. The stakeholder mentions additional applications where it uses PZT components in additional EEE such as electrical and ultrasonic transducers, ultrasonic level switch and density meters and in ultrasonic flow meters. Other confidential inputs refer not only to ultrasonic cleaning but also to ultrasonic welding and cutting as areas of PZT applications

The above information refers to both item 2(a) and 2(b) and clarifies that there may be other applications of PZT beyond those described in the proposed items. PZT ceramics can be understood to be used in ultrasound transducers both in medical and in other equipment, whereas it is not clear that all of these are polycrystalline ultrasound transducers. Additional applications are also understood to be relevant such as accelerometer. Based on the understanding that PZT materials are relatively costly and thus used only where other alternatives do not exist, it is considered more appropriate at this time not to confined the use of PZT materials to specific applications but rather to focus on this in the future when the item is assessed as a single exemption.

c) providing ceramics with a positive temperature coefficient (PTC)
   i) with TC < 120 °C (TC: Curie temperature) and resistivity of less than < 1000 Ωcm
   ii) with TC < 120 °C and resistivity of 1,000 Ωcm and more
   iii) with TC ≥ 120 °C and resistivity of less than 1,000 Ωcm
   iv) with TC ≥ 120 °C and resistivity of 1,000 Ωcm and more

Bourns (2021) refers to item 2(c) and states that the various items include the various temperature and resistivity values. Though item 2(c)-i fits to many of Bourns PTCs, concern is raised that the specificity of the exemption language may exclude new innovative products or specific needs of customer applications.

The consultant does not share the opinion that the four sub-items would exclude certain applications seeing as the reference to the parameters at his time would still allow the use of lead-based ceramics in all combinations. Nonetheless, the consultant is of the opinion that this added complexity should only be included after a specific assessment of this article in the future, should it be shown that the actual range of applications is more confined, i.e., eliminating one of the sub-items or confining its parameters further.

As a last point it is noted that Annex III of RoHS includes the following three exemptions that may have some overlap with the proposed specification:

- Ex. 7(c)-II: Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher – this exemption has also been assessed as part of the current study.
- Ex. 7(c)-III: Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC – this exemption expired in 2013 and is only available for spare parts.
- Ex. 7(c)-IV: Lead in PZT based dielectric ceramic materials for capacitors which are part of integrated circuits or discrete semiconductors – a request for renewal has not been submitted for this exemption and it is understood to only be valid for Cat. 8-in-vitro, Cat. 9-industrial and Cat. 11 EEE.

To avoid possible overlaps, it is recommended to exclude these items from the future item for ceramic materials ether by referring to the exemptions or by excluding capacitors altogether.

11.6.7. 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 can be concluded that for a number of applications, lead is used in glass or glass ceramic materials as well as in ceramic or ceramic matrix materials. The different applications depend on various properties of lead to provide certain functions or properties to the material in which it is being used.

This includes in the case of lead-based glass applications:

- reduction of the material melting point,
- improved wettability of the glass to various materials,
- decreased viscosity,
- adjustment of the CTE of glass to the materials it is used to bond or coat,
- dielectrical strength,
- increased chemical and corrosion resistance
- and higher strength and crack resistance,
- provision of current flow within the glass,
- high curie temperature.

Different applications of glass are based on different combinations of these properties, also making the identification and implementation of substitutes a complex and case sensitive process. It can be followed that though research continues to find various candidates that could be considered as potential substitutes for lead in glass applications in the future, at present lead-free glass materials available on the market would not provide suitable substitutes for most of the applications for which such materials are used.

The situation is similar for applications in which lead is applied in a ceramic or ceramic matrix material. Here lead is added to achieve combinations of the following properties in the ceramic material:

- dielectric strength (decreased susceptibility to dielectric breakdown),
- higher strength and crack resistance,
- high curie temperature and depolarisation control under changing temperature conditions,
- high piezoelectric constants (charge and voltage), and
- high coupling factor.

Overall, the consultants conclude that the exemption is justified as available substitutes are either not suitable and cannot be fabricated into lead-free components that could be used in the same applications, or such components provide an inferior reliability leading to malfunctions that would not be acceptable in the respective EEE.

That said, in the consultant's view, the current exemption wording is not confined to specific applications and furthermore leads to uncertainty as to whether lead can be used only in glass or ceramic materials or also in ceramic-glass matrix materials. The existence of many different applications results in the assessment focusing on how these relate to each other and to the properties that lead enables in the applications of the various materials. An application specific assessment would allow a stronger focus on each of the applications and its specific obstacles to substitution. Specifying the exemption to a confined set of application would allow a more detailed assessment in the future and shall also add certainty to market surveillance in considering in which cases the exemption is applied properly. That said, it is difficult to conclude as to the degree of detail that would result in a clear demarcation of applications where lead is actually needed and used and where it is not. A proposal for exemption specification was circulated to stakeholders and after integrating their views, a more detailed exemption formulation could be as follows:

Option 1

1) "Electrical and electronic components containing lead in a glass or glass matrix compound that fulfils the following functions:
   a) 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,
   b) for hermetic sealings between ceramic, metal and/or glass parts
   c) 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")
   d) used as resistance materials such as ink, with a resistivity range from 1 Ohms/square to 1 Mega Ohms/square, excluding trimmer potentiometers*
   e) used in chemically modified glass surfaces for Microchannel Plates (MCPs), Channel Electron Multipliers (CEMs) and Resistive Glass Products (RGPs).

2) "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):
   a) piezoelectric lead zirconium titanate (PZT) ceramics
   b) providing ceramics with a positive temperature coefficient (PTC)

*The exclusion of trimmer potentiometers is under the assumption that Ex. 34 shall be renewed for a short period and covers these applications. Nonetheless, for some items it is not completely clear if the last adjustments could exclude applications in which lead cannot be avoided. The following formulation is a bit more simplified. Though it might leave more room for using the exemption where it is not necessarily needed, this could be focused on more carefully in future assessments while reducing the risk of certain applications where lead cannot be avoided being denied market entry:

Option 2

1) "Electrical and electronic components containing lead in a glass or glass matrix compound that fulfils the following functions:
    a) protection and electrical insulation in glass beads of high voltage diodes and glass layers for wafer on the basis of a lead-zinc-borate and lead-silica-borate glass body,
    b) for hermetic sealings between ceramic, metal and/or glass parts
    c) for bonding purposes
    d) used as resistance material, excluding trimmer potentiometers*
    e) used in chemically modified glass surfaces for Microchannel Plates (MCPs), Channel Electron Multipliers (CEMs) and Resistive Glass Products (RGPs).

2) "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):
    a) piezoelectric lead zirconium titanate (PZT) ceramics
    b) providing ceramics with a positive temperature coefficient (PTC)

The exclusion of trimmer potentiometers is under the assumption that Ex. 34 shall be renewed for a short period and covers these applications.

The first alternative specifies process windows for some of the application areas and in this sense is considered to be narrower in scope. As the duration of the assessment did not allow a final check of this formulation with industry, it is not completely certain that the specific thresholds may not exclude certain articles where lead is not avoidable. Coupling this formulation with a short-termed renewal for the current formulation of Ex. 7(c)-I would give industry time to apply for the exemption for additional applications or for applying for amendments of the current proposal. Alternatively, the second formulation which is considered to have more certainty in relation to covering the various applications that make use of Ex. 7(c)-I could be applied, not renewing the current exemption for categories where it is currently specified to be valid until July 2021.

11.7. Recommendation

Lead provides glass and ceramics with unique properties for various application. Given that for many of these, substitutes are understood not to be available (or to provide inferior performance and reliability, it is recommended to grant the exemption with the following formulation:

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.*

12. Exemption 7(c)-II "for lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher"

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

AC	Alternating Current
CRM	Critical raw materials
DC	Direct current
EEE	Electrical and Electronic Equipment
GDP	Gross domestic product
LCA	Life cycle assessment
ZrSrTi	Zirconium strontium titanate
ZrBaTi	Zirconium barium titanate
Pb	Lead
RoHS 2	Directive 2011/65/EU on the Restriction of Hazardous Substances in Electrical and Electronic Equipment
UP	A large number of company/business organizations/business associations that are participants in the RoHS Umbrella Industry Project, also referred to as the Umbrella Project
V	Volt

12.1. Background

Discrete ceramic high voltage capacitors (with a rated voltage ≥ 125 V AC / 250 V DC) are incorporated in a wide range of EEE to store and release electric charges. This function is necessary for the products to function as needed. Capacitors are electronic components that can store electrical charge in the form of an electric field between electrodes. The components are used in EEE to add capacitance to an electric circuit. A capacitor consists in principle of two electrically conductive electrodes that are separated by an electrically insulating spacer, a so-called dielectric material. The latter can consist of various non-conductive substances. Ceramics represent one class of materials generally used in capacitors as a dielectric. Ceramics based dielectrics, such as lead-containing ones, provide very good charge separating properties so that the electric field is enhanced and this enables for small package volumes of such capacitors.

The current state of technology is that most ceramic capacitors are already produced from lead-free dielectric materials. The applicant informs that "*industry managed to substitute an estimate of 99% 'lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC' by lead free alternatives*" (Umbrella Project 2019b). However, for some applications, capacitors are needed that provide specific properties. High voltage rating ceramic capacitors require a dielectric material that provides high dielectric constant at high operating voltage. High dielectric constant and low leakage at high temperatures are necessary properties of the material in order to obtain components with high energy storage capability. Such properties can currently only be achieved by using lead titanate as a constituent of the dielectric ceramic (ibid).

Murata Electronics Europe B.V, on behalf of 37 industry organisations, which are part of the RoHS Umbrella Industry Project requests the extension of the existing exemption with its current wording for the maximum duration allowed by Article 5 of the Directive (Umbrella Project 2019b).

"Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher"	***Does not apply to applications covered by point 7(c)-I and 7(c)-IV of this Annex. Expires on:*** ***— 21 July 2021 for categories 1-7 and 10;*** ***— 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;***

The applicant addresses lead-containing ceramic capacitors for a rated voltage of 125 V AC or 250 V DC or higher. The original application submitted 19 December 2019 has been extended (submitted 9 October 2020) to cover Category 11 (other EEE), in addition to Categories 1-10 for which the renewal was originally requested.

Such capacitors are used in various categories of EEE, including consumer and household equipment as well as monitoring and control instruments in industry and medical devices. Discrete ceramic capacitors for high voltage are used in high voltage electronic circuits, usually power electronic inverters, power electronics and specific appliances (Umbrella Project 2019b).

The Umbrella Project asserts, that there are currently no alternative materials available that provide the same combination of dielectric properties and thermal stability as lead titanate (Umbrella Project 2021o). Up to now and within the foreseeable future, alternatives to allow substitution are not expected to become available on the market. Thus, the applicant asks for an extension of the existing exemption in Annex III for the respective maximum validity periods foreseen in the RoHS 2 Directive.

12.2. History of the exemption

The exemption for lead in dielectric ceramic capacitors has been evaluated twice since the Directive2002/96/EC (RoHS 1) was first published in 2003. The original exemption 7d was entitled "Lead in electronic ceramic parts (e.g. piezo electronic devices)". In 2008/2009, the first review of this exemption concluded that lead can be substituted in low voltage dielectric ceramic capacitors. As a consequence, a change in the title and the number of the exemption was adopted to the Annex of RoHS 1. Since then, high voltage capacitors were addressed by the new exemption 7(c)-II titled: "Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher". The low voltage ceramic capacitors were addressed by exemption 7(c)-III titled: "Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC". Exemption 7c-III was transferred without changes from the Annex of RoHS 1 to Annex III of RoHS 2 and expired on 1 January 2013 because lead-free alternatives have become available for low-voltage ceramic capacitors. Exemption 7c-II was transferred without changes from the Annex of RoHS 1 to Annex III of RoHS 2 because lead-free alternatives were not available for high voltage dielectric ceramic capacitors. In 2015, Murata Elektronik GmbH applied for a further extension of exemption 7c-II. A change in the wording of exemption 7c-II was requested to disambiguate the scope from exemption 7(c)-I. The assessment of the request (Gensch et al. 2016) concluded that the exemption was still justified, as substitutes were not available for application in high voltage ceramic capacitors. However, the extension of the exemption was recommended for only three years because the applicant could not demonstrate that the substitution of lead in the applications concerned was scientifically and technically impracticable. The 2016 evaluation concluded that "Should industry fail then again to provide substantiated information about specific research and available lead-free HVC in the future, the consultants recommend cancelling the exemption in the next review." The wording of the exemption has not changed since 2016. The present request, submitted on 19 December 2019 by Murata Elektronik GmbH on behalf of 37 industry organisations, aims at extending the existing exemption for lead in high voltage ceramic capacitors for the second time (Murata Electronics Europe B.V. 2019). A change in the wording is not proposed again.

12.3. Technical description of the requested exemption

Discrete ceramic high voltage capacitors (>= 125 V AC / 250 V DC) are incorporated in a wide range of EEE to store and release electric charges, which is necessary for the products to function as needed. The capacitors provide their function (capacitance) in high voltage circuits and withstand also elevated temperature without drop in energy storage capability and leakage of the stored charge (Umbrella Project 2019b).

Application areas of high-voltage capacitors are mainly power supply devices and protection devices that are stated to be part of almost all of the RoHS Annex I EEE categories. UP refers to the following EEE as examples where the Exemption is needed: power electronic inverters, pulsed power electronics, pulse forming networks, capacitive discharge units, transient high voltage suppression, magnetization / demagnetization devices, plasma generators, high-energy flash lamps, radio frequency interference suppression and electrical safety devices.

The RoHS substance in question – lead (Pb) - influences the electromagnetic properties of the solid-state dielectric (ceramic material), in particular capacitance and dielectric losses of capacitors. The ceramics contain lead in concentrations of 0.1- 60 wt% (% weight) of the homogeneous material. Lead-containing ceramic high voltage capacitors are explained to be indispensable components in EEE that provide stable electric properties even at high voltage and frequencies as well as elevated temperatures. In high-temperature applications, the component must withstand elevated temperatures that build up inside the EEE housing. In the design of electrical and electronic equipment, a safety margin of 1.5 to 2 times the nominal temperature is usually applied to safeguard against abnormal operating conditions. This requires high temperature components that operate safely at 130 °C or higher (ibid).

12.3.1. Amount of lead used under the exemption

According to the applicants, there is an annual amount of 7 tonnes of lead placed on the EU market in the form of **lead titanate ceramics** as a constituent of capacitors, used in EEE (Umbrella Project 2019b). The amount is calculated based on economic allocation of global amounts to the EU market (global GDP ratio of Europe (22%)). Concrete EU-specific consumption data is difficult to calculate as most of the lead-containing high-voltage capacitors are produced and incorporated into EEE outside the EU so that data are not readily available.

The previous exemption request from 2015 estimated the amount of lead placed on the EU market in the form of ceramic capacitors (as of 2013) as 11.3 tons per year. This was already a lower amount compared to 30 t of lead placed on the EU market in the same application area in 2007. (Gensch et al. 2016)

The applicant (Umbrella Project 2019b) further states that the overall use of lead-containing high-voltage capacitors is expected to have declined over the past decade as a result of technical trends in the design of electrical and electronic equipment (reduction of the operating voltage of mounted devices). However, for certain areas or applications, such as power supplies and inverters in high voltage energy systems, lead containing high voltage capacitors gains importance. Thus, a further reduction of the amount of lead in this application area is not expected from today's perspective because practical substitution technologies are not available at the present stage (see section 12.4.1).

The #7(c)-II technical Working Group of the Umbrella Project (Umbrella Project 2021o), notes that EU-specific consumption data for lead in high-voltage capacitors falling within the scope of exemption 7(c)-II is difficult to calculate, as most lead-containing components are manufactured outside the EU and then placed on the EU market as part of EEE. Therefore, the consumption estimates provided in the application form (Umbrella Project 2019b) cannot be further substantiated. The decline in the use of lead-containing capacitors observed since 2013 can be attributed to the technical trends in EEE design to reduce the operating voltage of the mounted devices. As a result, the number of high-voltage devices installed in EEE appears to have decreased, which has led to a proportional decrease in the number of high-voltage capacitors containing lead. Hence, the Umbrella Project concludes that previous lead reductions have been the result of technical design changes rather than a replacement of lead-containing high-voltage capacitors by lead free high-voltage dielectrics.

12.4. Applicants' justification for the requested exemption

The applicant explains that, to date, no lead-free dielectric ceramics have been found for high-voltage capacitor applications that have the required technical characteristics (Umbrella Project 2019b). According to the applicant, lead-free substitutes are not considered to provide the same performance as compared to lead-containing ceramics, specifically:

- High dielectric constant at high operating voltage,
- High energy storage capability (also at high temperatures),
- Low leakage at high voltage and high temperatures, and
- Low loss at high current, frequency, and temperatures.

The applicant asserts that since 2015, industry, represented by the Umbrella Project, has been investigating the availability of lead-free materials that could replace lead in dielectric ceramics. Thus far, no technical alternative has been found for this application and there are no indications that lead-free ceramic materials will be found for high-voltage capacitors in the near future.

The exemption request specifies the unique properties of lead-containing dielectric ceramics, which makes their use in high voltage capacitors indispensable (Umbrella Project 2019b):

- Low Energy Loss Properties: The use of leaded ceramic suppresses thermal vibration of the dielectric material, especially if high-frequency alternating currents are applied. Lead-free dielectrics vibrate stronger at high-frequencies and thus cause larger energy dissipation in the form of heat. This would be detrimental to the proper function of modern telecommunications and computing equipment that work at high frequency.
- Thermal Properties: Leaded dielectric ceramics exhibit both low capacitance variation with temperature changes and high Curie temperatures[61] (above 130°C). Lead-free materials do not allow the design of high-voltage devices for high-temperature operating conditions because the capacitance decreases at higher temperature. Regarding the specific performance parameters that can only be achieved with leaded dielectrics, the UP states in a later communication that the dielectrics of high-voltage capacitors must have a high temperature stability, which

[61] The „Curie Temperature" refers to a material-specific temperature at which the materials' magnetic properties change abruptly.

is 1.5 to 2 times the rated temperature stability of the entire component (Umbrella Project 2021p). This operating safety margin requires the use of leaded dielectrics that can withstand a temperature of 130 °C or more.

- Capacitance: At a high voltage, the dielectric is subject to mechanical stress due to its piezoelectric properties. This effect (electrostriction) causes lead-free dielectric ceramics to become destabilized and in the worst case lose their functions. In contrast, lead-containing dielectric ceramics suppress this effect so that they can be safely used for high-voltage devices even if they have high capacitance.

12.4.1. Substitution or elimination of lead

According to the Umbrella project, no suitable substitutes are available that combine the required properties: high dielectric constant, high energy storage capability, low leakage, and low loss at high current, frequency, and temperatures (Umbrella Project 2019b; 2021o).

The applicant explains that initial efforts of industry accomplished the substitution of approximately 99% of lead in dielectric ceramic high voltage capacitors after the adoption of the RoHS Directive in 2003 (ibid). Ever since, the remaining uses of lead-containing ceramic high voltage capacitors remained largely unchanged because industry has not been able to find lead-free substitute materials that provide the same combination of desired properties. Thus, no further efforts have been made to phase-out lead-containing ceramic high voltage capacitors from EEE products despite industry having continued to monitor publicly available scientific literature that address possible substitute candidates. The applicant also asserts that industry-run substitution research has continued with no viable results. Evidence of unsuccessful search for technical alternatives cannot be published because of the competitive disadvantage of such disclosure. The exemption request illustrates the industries' unsuccessful efforts in lead-free substitution research by means of illustrative cases:

- Addition of zirconium to ceramics consisting of strontium titanate or barium titanate: the dielectric constant decreased so that the resulting capacitance was less than one-tenth that of the leaded capacitors. ZrSrTi or ZrBaTi based capacitors would therefore require a tenfold larger package volume.
- Strontium titanate has been investigated as a potential lead-free dielectric ceramics substitute, since it has small energy loss and no electrostriction. However, the capacitance is less than one tenth that of lead-added barium titanate. Attempts to use strontium titanate for the design of high-voltage capacitors failed to provide the desired capacitance at small size required for applications in power supplies for household and industrial electrical equipment. The power output of the attached AC adapters becomes unstable and can cause the EEE to malfunction.
- Technical redesign of EEE towards the usage of lead-free high-voltage capacitors: The consequences would be increased product size and weight due to the necessity to size up not only the capacitors but also circuit boards, cooling mechanisms etc. This would contradict the overarching trend towards device miniaturisation in the EEE sector.

In addition to the above-mentioned substitution approach at the material level, there are further possibilities to reduce the use of lead-containing capacitors at the technical level or at the level of circuit development. The applicant points to technical options that have been explored to design EEE in such ways to avoid the build-up of high temperatures (i.e. >130°C) in the proximity of high voltage capacitors within EEE housing. The (Umbrella Project 2021o) specifies the following possibilities, but refrains from outlining their practical relevance in the industry and giving a timetable for implementation:

(1) Reduction of the operating current/voltage of the device - Joule heat decreases, and operating temperature is lowered,

(2) Increase of the distance between electronic components heated to high temperatures and the other electronic components,

- This option may not be applicable since it may have an adverse effect on control in analogue circuits.
- It may not be applicable to heat-generating parts themselves either.

(3) Passive cooling: Addition of heat sinks and heat dissipation sheets to components and boards,

(4) Forced cooling: Wind blowing with a blower or fan.

A non-exhaustive online literature review, conducted by the consultant, showed that numerous ceramic capacitors, advertised as lead-free and RoHS-compliant, are commercially available on the market covering a wide range of technical specifications. For instance, the product portfolio of a major component supplier contains data sheets for various types of lead-free ceramic capacitors in a wide range of technical parameters (see Table **12-1**).

Table 12-1: Examples of lead-free ceramic capacitors offered by Vishay

Type	Capacitance	Rated voltage	Operating temperature range (°C)
AC Line Rated Ceramic Disc Capacitor [62]	9 nF to 0.1 µF	400 V_{AC}, 50 Hz	-30 to +125
High Voltage Class 1 Ceramic AC and DC Disc Capacitors [63]	560 pF to 1700 pF	10 kV_{DC} to 50 kV_{DC} / 7 kV_{AC} to 34 kV_{AC}	-30 to +85
High Voltage Ceramic DC Disc Capacitors [64]	100 pF to 3300 pF	10 kV_{DC} to 15 kV_{DC}	-25 to +105
Surface Mount Multilayer Ceramic Chip Capacitors for High Temperatures [65]	0.1 pF to 3300 pF	25 kV_{DC} to 500 kV_{DC}	-55 to +200

[62] https://www.vishay.com/docs/23107/20vl.pdf
[63] https://www.vishay.com/docs/22210/715c-kt.pdf
[64] https://www.vishay.com/docs/23119/615rseries.pdf
[65] https://www.vishay.com/docs/45239/vjhifreqht.pdf

Type	Capacitance	Rated voltage	Operating temperature range (°C)
AC Line Rated Ceramic Disc Capacitors Class X2, High reliability [66]	9000 pF to 100000 pF	400 V_{AC}	-25 to +125
AC Line Rated Disc CapacitorsClass X1, Y2 [67]	1.0 nF to 0.01 µF	250 V_{AC} to 400 V_{AC}	-30 to +125

Source: (Vishay)

The above shown examples illustrate the principal availability of lead-free ceramic high voltage capacitors on the industrial supply market. They cover a wide spectrum of technical specifications, including capacitance, frequency, sizes and temperature rating. However, the rated temperature of lead-free capacitors appears to be limited to a maximum of 125° C, which does not meet the necessary temperature requirements in all EEE applications. As the Umbrella Project explained upon request, high voltage capacitors can heat up internally due to energy dissipation through electric current flows. This can cause the internal temperature (inside the component housing) to exceed the rated temperature in the EEE housing, as specified in the technical data sheets, by factor 1.5 to 2 (Umbrella Project 2021o). Therefore, UP argues that "*components that can withstand a high temperature environment of 130° C or higher are required*" for safety reasons.

Another brief review of the scientific literature carried out by the consultant identified a wealth of research and development work that has been carried out in the field of advanced materials over the last decade, addressing candidate lead-free dielectric ceramics. This is evidenced by numerous publications in peer-reviewed scientific journals. To name a few, below are some examples of lead-free dielectrics reported in the scientific literature.

- (Dittmer et al. 2011) investigated a group of materials 1−x $0.94Bi_{1/2}Na_{1/2}TiO_3$ – $_{0.06}BaTiO_3$_−x$K_{0.5}Na_{0.5}NbO_3$ (BNT−BT−xKNN) as potential candidates for high-temperature capacitors with a working temperature far beyond 200 °C. The researchers conclude that the tested compositions present a good starting point for the development of high-temperature capacitor materials.
- (Correia et al. 2013) demonstrate a very high energy density and high temperature stability capacitor based on $SrTiO_3$ substituted $BiFeO_3$ thin films. The lead-free material is evaluated as a promising candidate for high temperature applications in power electronics up to 200 °C.
- (Kumar et al. 2015) report the development of multilayer ceramic capacitors based on relaxor $BaTiO_3$-$Bi(Zn_{1/2}Ti_{1/2})O_3$ (BT-BZT) for high temperature applications, which were evaluated in a temperature range of 50 to 350 °C.
- (Sun et al. 2017) describe the fabrication of lead-free $BaZr_{0.2}Ti_{0.8}O_3$ epitaxial thin films on Nb doped $SrTiO_3$ substrates. The authors assert that this material exhibits good properties (referring to thermal stability, break down voltage and fatigue endurance) compared to other $BaTiO_3$-based energy storage capacitor materials

66 https://www.vishay.com/docs/23107/20vl.pdf
67 https://www.vishay.com/docs/23104/30lvs.pdf

and even Pb-based systems, making it a good candidate in the application of modern EEE.

- (Yang et al. 2017) present results for the lead free ceramics (1-x)$SrTiO_3$-$xBi_{0.5}(Na_{0.82}K_{0.18})_{0.5}Ti_{0.96}Zr_{0.02}Sn_{0.02}O_3$. These results indicate that the (1-x)ST-xBNKTZS ceramics may be promising lead-free materials for high energy storage capacitors.
- (Correia et al. 2017) investigate a lead-free $BiFeO_3$-$SrTiO_3$ ceramic that exhibits low dielectric loss and high thermal stability, while maintaining high energy density and fast discharge rates up to 200 °C. The researchers conclude that these unique properties clearly outperform other state of the art ceramics and potentially create significant new markets for high capacity ceramic capacitors at high frequencies and high temperature operations.
- (Jia et al. 2018) review various contemporary lead-free dielectrics for ceramic capacitors with upper operating temperatures far beyond 200°C. The authors compare various lead-free perovskite capacitor dielectrics based on BT, BNT, BKT, and KNN and summarise their properties. They discuss the trade-offs between frequency stability, loss factor and resistivity at high temperature. An outlook on further research needs is provided to overcome prevailing obstacles in their technical applicability and fabrication technologies.
- (Cai et al. 2019) describe a two-step sintering process for the production of lead-free multilayer capacitors based on lead-free relaxor ferroelectric ceramic $0.87BaTiO_3$-$0.13Bi(Zn_{2/3}(Nb_{0.85}Ta_{0.15})_{1/3})O_3$ (BT-BZNT). The fabricated dielectric exhibits high energy density of 8.13 J cm^{-3} and a high efficiency of 95% at a temperature range up to 170 °C.
- (X. Li et al. 2020) prepare a novel lead-free $0.88BaTiO_3$-$0.12Bi(Li1/3Zr_2/3)O_3$ (0.12BLZ) relaxor ferroelectric ceramic for dielectric capacitor application. The material reportedly shows good frequency and temperature stability in different frequencies and temperatures (25–140 °C).
- (Wang et al. 2020a) demonstrate that lead-free capacitors can be made from (0.7 x)$BiFeO_3$–$0.3BaTiO_3$–$xBi(Li_{0.5}Nb_{0.5})O_3$ (BF–BT–xBLN). The multilayer ceramics show promise for practical use in capacitors for pulsed power systems.
- (Wang et al. 2020b) describe a method for the fabrication of $Ca_{0.5}Sr_{0.5}Ti_{0.97}Sn_{0.03}O_3$ (SnCST3) ceramics with enhanced energy storage performance. The material is a competitive candidate for the application in lead-free high-power capacitors.

While the research cited above does not suggest that these lead-free dielectric ceramics are immediately suitable for the substitution of lead-containing dielectrics addressed in the current 7(c)-II exemption, it does show that a variety of promising candidate materials and fabrication methods are available.

In a second round of consultation, stakeholders were asked to explain the relevance of the various candidate materials, identified in materials research literature, to the industrialisation of lead-free substitutes for capacitors in the scope of Ex. 7(c)-II.

The Umbrella Project (Umbrella Project 2021p) replied in summary that the above cited examples of scientific materials research results on the development of lead-free substitution candidates for lead-containing dielectrics represent a very low level of technological maturity (laboratory-scale). None of the lead-free substitution candidates is considered practically ready for industrial use for several reasons:

- The candidate materials have not been evaluated as materials in terms of the full electromechanical property matrix, the aging characteristics, electrode compatibility, machinability, and process costs.
- The materials in question have not yet been brought to a higher technological level and there is no mass production to ensure a stable supply of commercially available semi-finished products.
- The materials under consideration have several physical-technical deficiencies, including being highly volatile and volatilising alkali metal elements, which lead to a change in composition during ceramic production, which in turn leads to a change in the electronic properties of the ceramics.
- Further, some of the candidate materials contain critical raw materials (CRM), such as niobium and bismuth, which have a resource supply problem.
- Some of the manufacturing processes used in the fabrication of capacitor from candidate materials are extremely poor in productivity which would be an obstacle to mass production.
- As supplementary information, UP provides a number of technical data sheets for capacitors out of the product portfolio of its participant organizations. The data sheets are for fast-switching semiconductors and ceramic insulated disc type capacitors for low dissipation. These data sheets show some of the properties of components for which the exemption is made use of but do not suffice to allow an overview of such a range of properties.

12.4.2. Environmental arguments

The exemption request suggests that the use of lead-containing high voltage capacitors helps lowering the resource and energy consumption throughout the lifecycle of an EEE product (Umbrella Project 2019b).

- Leaded dielectric ceramics can be sintered at even lower temperatures than lead-free alternatives (1000°C instead of 1300°C). This reduces the energy consumption for production and allows for a reduced carbon footprint. The exemption request specifies the energy saving potential with 1 MWh per million components produced (in total 220 MWh for all components placed on the EU market per year)
- The reduced size and thickness of leaded high voltage capacitors is explained to save the use of resources in comparison to the production of larger sized lead-free components. The miniaturisation also helps to design smaller printed wiring boards and housings, which contributes to material savings.

It is also stated (Umbrella Project 2019b) that the separate collection and recycling of discrete ceramic high voltage capacitors is considered unfeasible because these components are closely incorporated into WEEE. There is no practical way to identify and recover capacitors exclusively during the end of life treatment of WEEE.

12.4.3. Socioeconomic impacts

No detailed socioeconomic assessment is provided, however the applicant refers to the rule of diminishing return on investment, explaining that "*the efforts still necessary in order to substitute all devices incorporating lead in the scope of 7(c)-II will be many times what has already been spent in materials research*." (Umbrella Project 2019b).

12.4.4. Road map to substitution

Neither the applicants nor other interested parties have provided a roadmap for the substitution of lead in the applications covered by exemption 7c II.

Upon request (clarification questions), the applicant provided a confidential response outlining several approaches to developing lead-free dielectric ceramics for use in high-voltage capacitors. The first example showcases a comparison of the electrical performance parameters of a lead-containing versus a lead-free sample material. UP concludes that the lead-free material exhibits poor performance characteristics, which render it inadequate for the intended application in high-voltage capacitors. In a second example that concerns a different physical parameter, a lead-free dielectric ceramic sample with a different composition is compared with a lead-containing sample. The results show that the lead-free dielectric has inferior properties. Supplementary information provided by (Umbrella Project 2021n) illustrates highly aggregated results from research projects on internal materials, conducted to develop lead-free dielectrics for use in high-voltage applications. The information presented indicates that it is possible in principle to improve certain properties of lead-free materials, but generally at the expense of other important characteristics.

The (Umbrella Project 2021o) emphasizes that the past trend of lead-reduction in high-voltage capacitors has now come to an end, as industry has not been able to develop practical technologies that can replace specific areas and applications of power supplies and inverters in high voltage energy systems. UP concludes that "*a further reduction of the amount of lead is not expected from today's perspective*".

A stakeholder manufacturing components states that "a feasible alternative to solve our technical issues is not in sight and we expect that an undefined period of time is still ahead of us until practical solutions come on the horizon."

12.5. Stakeholder contributions

During the stakeholder consultation, the following organisations have expressed their support of the request for renewal of this exemption.

- **Fresenius Kabi** (Fresenius Kabi 2021) supports the application for a renewal of the exemption (see chapter 5.1) but does not provide specific information concerning Ex. 7(c)-II. When asked for further detail, (Fresenius Kabi USA 2021) assures that the use of lead-containing capacitors in medical devices is not a necessity per se but they are contained in certain commoditised sub-assemblies. Fresenius specifies five EE assemblies used in the manufacture of its product portfolio that invoke exemption 7(c)-II for compliance with the RoHS Directive. The assemblies are sourced from several suppliers and Fresenius Kabi relies on the suppliers' technical data sheets for information on the content of lead-containing components. Enquiries with the respective suppliers revealed that one of the assemblies in question had since been redesigned using lead-free components, making the need for a renewal of Exemption 7c-II obsolete in this particular case. Another supplier provided technical considerations for a possible redesign of its assemblies. Fresenius Kabi points out that it would not be a problem to incorporate redesigned lead-free assemblies into medical devices if suppliers were able to redesign their assemblies so that they did not invoke Exemption 7(c)-II.

- **SEMI** (SEMI EUROPE 2021b) supports the application for a renewal of the exemption (see chapter 5.1) because the exemption is actively used for the manufacturing of tower computers but no more specific information concerning Ex. 7(c)-II were provided.
- **Test and Measurement Coalition** (2021) supports the application for a renewal of the exemption (see chapter 5.1) but does not provide specific information concerning Ex. 7(c)-II.

After the consultation closed, a further stakeholder understood to be a member of the Umbrella Project initiative provided information independently as a response to clarification questions sent to UP:

- A stakeholder manufacturing components states that efforts have been made to develop lead-free alternatives with the same main composition as existing lead-containing dielectric materials. However, the results obtained during material research have shown inferior properties, such as relative permittivity and self-heating characteristics, compared to currently used lead-containing material. Therefore, TDK has been unable to progress to further development steps, such as reliability evaluation under continually applied high-frequency voltage. Hence, TDK sees no perspective for a lead substitution in dielectric ceramics in the foreseeable future.

12.6. Critical review

12.6.1. REACH compliance – Relation to the REACH Regulation

See section 4.1 for details.

12.6.2. Scientific and technical practicability of substitution

Based on the information provided by the applicant and the stakeholder contributions received in the course of the consultation, the consultant concludes that the market availability of lead-free ceramic capacitors for a rated voltage of 125 V AC or 250 V DC or higher appears to be very limited so far. This indicates that suppliers are still actively using Ex. 7c-II, although only few electrical and electronic devices[68] seem to contain capacitors based on the Ex. 7c-II. For example, according to SEMI (SEMI EUROPE 2021b) such capacitors are used in only two parts known to be used in semiconductor-manufacturing and related equipment. Fresenius Kabi USA (2021) also refers to only five EE assemblies where such capacitors are used in the manufacture of

[68] SEMI indicates that only two types wo tower computers are reliant to Ex. 7(c)-II

its product portfolio, for which it is later understood that one has been substituted with a lead-free capacitor.

The pace of innovation in the development of lead-free substitutes for capacitors under Ex. 7(c)-II appears to be slowing after earlier successes in developing lead-free substitutes for ceramic dielectrics for low-voltage capacitors with rated temperatures below 130°C having been adopted by industry. There are several possible explanations:

- First, in the applicant‘s point of view (Umbrella Project 2019b; 2021o), the development of lead-free dielectrics that can replace for lead-containing dielectrics is challenging. It can be deduced from this that the industry is looking for materials that have the same or a similar combination of physical/chemical and electronic properties as lead-containing ceramics. So far, however, the industry has not succeeded in finding a universal substitute that matches the wide range of properties known from lead-containing dielectrics. The candidate materials investigated so far provide promising results in terms of some of the desired properties, but not in their combination.
- Second, documented information on attempts to ramp up the industrial manufacturing of high-voltage ceramic capacitors based on lead-free substitution candidates was not found in the public domain. Therefore, such components are not readily available on the market. As the Umbrella Project (Umbrella Project 2021p) points out, the materials under consideration have in some cases physical and technical problems that stand in the way of reliable and competitive mass production. In other cases, it can be understood that a full evaluation of suitability has not been undertaken or that the materials would need further development and research to allow mass production. It is also stated that some of the manufacturing processes used in the production of capacitors from lead-free materials “are extremely unproductive”.

Nevertheless, there are examples of successful eliminations of lead-containing capacitors under the scope of 7(c)-II from EE devices that contained them prior to a redesign. (Fresenius Kabi USA 2021) explains that inquiry with a supplier of sub-assemblies revealed that parts of newer design no longer contain leaded capacitors, so that use of the Ex 7(c)-II is no longer necessary in this case. It can be understood from the Fresenius information that at least some suppliers are proactive in phasing out the use of lead containing capacitors from their products. This illustrates that a substitution of such components is possible. It is not clear if this is specific to the application area or if further research and testing of candidate alternatives, possibly on a case-by-case basis would also allow further progress in other application areas.

In summary, the combination of the above reasons appears to have stalled the innovation process towards further reducing the lead content of capacitors in the scope of Ex. 7(c)-II. The consultation process for this assessment revealed little evidence of proactive and supply chain-wide R&D efforts to develop and industrialize substitutes. It is not clear if this means that only few EE component suppliers and manufacturers are active in such efforts or rather that it is not reported on in the publicly available literature. Apart from general information provided by the applicant on a confidential basis, there was nothing to suggest that the diverse research results on a laboratory scale have been followed up and developed to a higher technology readiness level that would be a prerequisite for their practical use in EEE. The answers provided by UP make the impression that may be monitoring the international market for lead-free EE high-voltage capacitors to become available, however it is not clear how active the various stakeholders are in the development of such solutions.

Though not necessarily of technical relevance, it should also be noted that the information provided in technical datasheets of ceramic capacitors is often not free of ambiguity. Several component suppliers advertise high-voltage ceramic capacitors as "RoHS-compatible" or "conform to RoHS Directive". This wording is understood to refer to the applicability of Ex. 7(c)-II rather than the lead-free nature of the component. In some cases, the technical data sheet specifies that the capacitor contains a lead-based material, however also stating that the component is "RoHS-compatible". The use of these terms differs among suppliers and may also contribute to the use of Ex. 7(c)-II capacitors in applications where they are not necessarily needed, i.e., as it is warranted by the current exemption formulation. This aspect is further touched upon in section 12.6.4.

12.6.3. Environmental arguments and socioeconomic impacts

With regard to the environmental impact of replacing lead in high-voltage capacitors with currently available substitute materials, the applicant argued that this would make EEE larger and less energy efficient as lead free dielectric ceramics tend to heat up when a high voltage is applied (Umbrella Project 2019b). This would lead to an increase of the environmental load due to the consumption of energy and resources related to the production and disposal of larger equipment. UP extrapolates the additional power consumption due to a substitution of lead-containing capacitors in EEE to rise by 220 MWh per year in Europe (ibid). Almost all types of EEE would be affected, as the capacitors covered by Ex.7(c)-II are mainly used in power supply equipment and protective devices. The information is not further substantiated to allow an understanding of the range of actual environmental impacts that lead-free substitutes would result in. This aspect was not further investigated seeing as the main argumentation to justify the exemption is focused on the lack of suitable substitutes on the market.

Socioeconomic aspects have not been addressed in detail and are also not further reviewed.

The Umbrella Project (Umbrella Project 2021p) noted that some substitution candidate materials rely on the use of critical raw materials (CRM), such as niobium and bismuth, which have a resource supply problem. In relation to the critical raw material character and scarcity of these materials, which has been acknowledged by the EC[69], the consultant understands this to refer mainly to the risk of future supply as the applicants did not raise particular environmental aspects in this concern. The consultant considers the identification of CRM as a serious issue. Nonetheless, the economic aspects that are understood to contribute to the categorisation of a material as having supply risks do not relate to the three main criteria of Article 5(1)(a) but rather only to the secondary criteria of availability. The information provided furthermore does not

69 See: https://ec.europa.eu/growth/sectors/raw-materials/specific-interest/critical_en

allow to assess the severity of this risk and how it could affect the market in the future should such CRMs be found beneficial as substitutes for lead in Ex. 7(c)-II capacitors used in certain applications. In so far, the political relevance of the identification of certain substitute candidates as CRMs is not further investigated as it is considered to be beyond the mandate of this review which is based on the Article 5(1)(a) criteria for justifying exemptions.

12.6.4. Scope of the Exemption

The current formulation of exemption 7(c)-II covers a wide scope of ceramic high-voltage capacitors for a rated voltage of 125 V AC or 250 V DC or higher. The formulation limits the use of lead to the dielectric ceramic material. While the focus of this exemption on the ceramic dielectric materials appears unambiguous, the second condition "*for a rated voltage of 125 V AC or 250 V DC or higher*" leaves some room for potential misuse of the exemption. The technical justification for the use of leaded dielectrics in high-voltage capacitors does not sufficiently exclude the use of a high-voltage rated component in low-voltage circuits. In addition, research results indicate that there are lead-free ceramic dielectrics that could, in principle, be used for high-voltage capacitors, even if these materials do not achieve all the performance parameters of leaded ceramics (such as high temperature stability). However, the current wording of the exemption does not specify any parameters other than the rated voltage. Thus, leaded capacitors, which could be replaced by lead-free ones in certain applications (e.g. devices operating at low temperatures), continue to fall under the current exemption. This does not give priority to avoid the use of lead-containing capacitors in EEE in areas where it is technically possible.

Given the wide range of technical parameters, such as relative dielectric constant and self-heating characteristics, which determine the applicability of high-voltage capacitors in concrete EEE products, as well as the specific design parameters of how the high-voltage capacitors are integrated into the EEE, it is not clear if demarcating specific application areas where lead can be avoided and where it cannot be would be possible. It seems more plausible that the approach to substitution needs to be more case by case oriented, allowing not just for the phase-in of lead-free ceramic dielectric materials, but also for small adaptations in the design of the specific EE assembly. For example, the replacement of lead-containing high-voltage capacitors with larger lead-free capacitors could be considered for internal power supplies of large household appliances, while external power supplies are less likely to be accepted in the market if this makes them bulkier. Whether such aspects could be considered to exclude certain areas of application from the scope of the exemption remains unclear. When asked for example in which high temperature applications the use of leaded high voltage capacitors remains essential and whether such high temperature applications (i.e. >130°C) are relevant across all EEE categories, UP answered (Umbrella Project 2021o) the following: "*high temperature applications refer to the temperatures that the component must withstand inside the equipment housing. When an electric current flows through a conductor, Joule heat is generated. If heat dissipation does not occur, the interior of the EEE housing will inevitably reach high temperatures. The rated temperature of the high-voltage device inside the EEE housing is generally between 60°C and 100°C, but since the amount of heat generated increases in case an abnormality occurs, the designer must use components that can withstand* *temperatures from 1.5 to 2 times that of the rated temperature. Therefore, components that can withstand a high temperature environment of 130°C or higher are required. This is common for all categories of EEE. High voltage capacitors have to fulfil the safety requirements related to the EEE where they are incorporated even in case of fault condition, e.g. short circuit or overheating. Thus, high temperature performance is essential for electrical safety of the EEE*."

To conclude, the information provided by the Umbrella Project does not allow demarcating between applications for which the use of lead is needed and those where alternatives could be applied. This is not clear in relation to alternatives currently available on the market, nor in relation to those that would require further development.

The consultant recommends maintaining the existing formulation of Ex. 7(c)-II. However, consideration should be given as to how industry could be further motivated to phase-out lead where can be avoided through a combination of other materials and design adaptations.

12.6.5. 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, the following conclusions can be drawn in the case of exemption 7(c)-II:

The **substitution** of lead in ceramic dielectrics for high-voltage capacitors is scientifically possible in some cases, but not yet practicable from an industrialised technical point of view. The lead-free dielectric ceramics available to date, such as zirconium added strontium titanate ceramics and barium titanate ceramics, have several shortcomings when it comes to the full range of properties to be used as a replacement material for high-voltage capacitors. Although design changes in high-voltage circuits could circumvent some of the disadvantages of lead-free dielectrics (e.g., compensating for the low dielectric constant by using larger components), this does not appear to be practical for many modern EEE. To this end, the first criterion of Article 5(1)(a) is understood to be fulfilled, at least in some cases.

The second criterion of Article 5(1)(a) - lacking **reliability** of substitutes – is concluded to also apply in this case. This is against the understanding that lead-free capacitors heat up when high voltage is applied. As a consequence, they become unstable above 130°C and, in the worst-case lead to premature failures (e.g. the ceramic cracks) in EEE.

The **third criterion** of Article 5(1)(a) has not been assessed in detail due to lack of information regarding the environmental, health and consumer safety impacts of candidate materials. However, it is plausible that the design of small and energy-efficient power supply units, especially for mobile devices, requires the use of high-voltage capacitors that have low internal energy dissipation, i.e., lead-containing capacitors, in order to meet their functional requirements (long term reliability in use) as well as the design expectations of contemporary users on external power supplies (e.g. small, lightweight, no bulky ventilation).

Overall, the consultants conclude that though it may be possible to develop lead-free dielectric ceramic solutions for capacitors with a higher rated voltage, at least in some cases, this would probably need to be performed on a case-by-case basis. The current state of the market does not allow for a short-term phase-out of lead in the full range of this application, seeing as specific materials and probably also design adjustments would need to be tested before lead-free alternatives could be applied. As UP points out "*candidate materials have not been evaluated as materials in terms of the full electromechanical property matrix, the aging characteristics, electrode compatibility, machinability, and process costs*" It is also plausible that this development still needs time.

Nonetheless, in the consultants' view, the argumentation brought forward by the stakeholders is not new. The same argumentation was brought forward in the last assessment performed in 2015-2016, and yet it remains generic and does not provide specific detail to allow clarifying in which types of applications substitution could be addressed with materials and technologies on the market (as is understood to be the case for one of the Fresenius assemblies) as opposed to where the differences between lead-based and lead free materials make substitution challenging also in the long term. The criteria specified in the Article 5(1)(a) criteria and the need to arrive at a wording that is practicable for enforcement seem to support the low activity from industries' side to develop substitutes. Currently, there seems to be too little proactive effort towards further innovation in substitution development. The criteria used to justify an exemption under Article 5(1)(a) quoted above act as a barrier to further innovation, as the extended granting of exemption 7(c)-II does not put pressure on industry to invest more in substitution efforts. The fact that the use of lead-containing dielectrics in the application area of high-voltage capacitors is exempt from the substance restrictions under RoHS may further discourage innovators from investing in the research, development, testing and industrial upscaling of lead-free substitutes. This is especially of note for those candidate substitutes whose properties fulfil only a subset of the properties of lead-based dielectrics. Since such lead-free dielectrics can only be considered for a small number of uses, their potential market size is smaller and thus less economically attractive in a competitive market. Though this aspect does not play a role in the justification of exemptions per se, it inevitably leads to the situation where a "one size fits all solution" or in some cases a few sizes solution is sought but does not promote search for case specific solutions in most cases. Were a long-term transition period possible, this might on the one side put pressure on industry to consider and implement case by case solutions given the expected expiration of the exemption where possible and on the other side enable submission for requests for new exemptions for applications where technical evidence can be provided in more detail as to the obstacles to substitution.

Although a long transition period may be helpful to put pressure on industry to further develop and apply substitutes and later to apply for more specific exemptions in cases where substitution is not possible, the Directive does not provide a transition period of more than 18 months, which would not be sufficient to allow industry to make progress and identify which areas are not yet covered by available substitutes. Therefore, a duration of 5 years is recommended for all EEE categories.

While the consultants recommend renewing the exemption due to the lack of sufficient alternatives, it must also be considered how the exemption mechanism could be rethought to encourage innovation and industrial uptake of lead-free substitutes in areas where the low-hanging fruits have been harvested. This is of particular importance in cases where the exemption wording is not specific enough to limit use only to areas where the RoHS substance cannot be avoided, but specification of the exemption is communicated to be too complex.

12.7. Recommendation

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

Exemption formulation	Duration
"Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher"	Does not apply to applications covered by point 7(c)-I and 7(c)-IV of this Annex. Expires on 21 July 2026 for all categories

While for most categories exemption 7(c)-II 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. As explained in Section 5, the applicability of these recommendations to EEE in categories which benefit from the validity of Ex. 7(c)-II beyond July 2021 is not completely clear from a legal perspective. To avoid future co-existence of several sub-items with slightly different scopes it is recommended to align all categories in terms of the validity period, seeing as stakeholders did not provide information to show that technical differences existed between categories regarding the substitution of lead in steel. 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.

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

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

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

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

Table 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.
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. 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.

5. For the purpose of this entry, 'cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface.

	Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications: (a) equipment and machinery for: — food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] — agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] — cooling and freezing [8418] — printing and book-binding [8440] [8442] [8443] (b) equipment and machinery for the production of: — household goods [7321] [8421 12] [8450] [8509] [8516] — furniture [8465] [8466] [9401] [9402] [9403] [9404] — sanitary ware [7324] — central heating and air conditioning plant [7322] [8403] [8404] [8415] In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited. 6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below: (a) equipment and machinery for the production of: — paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] (b) equipment and machinery for the production of: — industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431] — road and agricultural vehicles [chapter 87] — rolling stock [chapter 86] — vessels [chapter 89] 7. However, the restrictions in paragraphs 5 and 6 shall not apply to: — articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. 8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight.

<table>
<tr><td></td><td>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.</td></tr>
<tr><td>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.</td><td rowspan="3">Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:
1. Shall not be placed on the market, or used,
— as substances,
— as constituents of other substances, or,
— in mixtures,
for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:
— either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,
— the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008.
Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:
‘Restricted to professional users’.
2. By way of derogation, paragraph 1 shall not apply to:
(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;
(b) cosmetic products as defined by Directive 76/768/EEC;</td></tr>
<tr><td>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.</td></tr>
<tr><td>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.</td></tr>
</table>

	(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. 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	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.

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	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; (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).'
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 (*); (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; (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. 11. Doing either of the following acts after 15 February 2023 in or within 100 metres of wetlands is prohibited: (a) discharging gunshot containing a concentration of lead (expressed as metal) equal to or greater than 1 % by weight; (b) carrying any such gunshot where this occurs while out wetland shooting or as part of going wetland shooting. For the purposes of the first subparagraph: (a) "within 100 metres of wetlands" means within 100 metres outward from any outer boundary point of a wetland; (b) "wetland shooting" means shooting in or within 100 metres of wetlands; (c) if a person is found carrying gunshot in or within 100 metres of wetlands while out shooting or as part of going shooting, the shooting concerned shall be presumed to be wetland shooting unless that person can demonstrate that it was some other type of shooting.

	The restriction laid down in the first subparagraph shall not apply in a Member State if that Member State notifies the Commission in accordance with paragraph 12 that it intends to make use of the option granted by that paragraph. 12. If at least 20 % in total of the territory, excluding the territorial waters, of a Member State are wetlands, that Member State may, in place of the restriction laid down in the first subparagraph of paragraph 11, prohibit the following acts throughout the whole of its territory from 15 February 2024: (a) the placing on the market of gunshot containing a concentration of lead (expressed as metal) equal to or greater than 1 % by weight; (b) the discharging of any such gunshot; (c) carrying any such gunshot while out shooting or as part of going shooting. Any Member State intending to make use of the option granted by the first subparagraph shall notify the Commission of this intention by 15 August 2021. The Member State shall communicate the text of the national measures adopted by it to the Commission without delay and in any event by 15 August 2023. The Commission shall make publicly available without delay any such notices of intention and texts of national measures received by it. 13. For the purposes of paragraphs 11 and 12: (a) "wetlands" means areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water the depth of which at low tide does not exceed 6 metres; (b) "gunshot" means pellets used or intended for use in a single charge or cartridge in a shotgun; (c) "shotgun" means a smooth-bore gun, excluding airguns; (d) "shooting" means any shooting with a shotgun; (e) "carrying" means any carrying on the person or carrying or transporting by any other means; (f) in determining whether a person found with gunshot is carrying gunshot "as part of going shooting": (i) regard shall be had to all the circumstances of the case; (ii) the person found with the gunshot need not necessarily be the same person as the person shooting. 14. Member States may maintain national provisions for protection of the environment or human health in force on 15 February 2021 and restricting lead in gunshot more severely than provided for in paragraph 11. The Member State shall communicate the text of those national provisions to the Commission without delay. The Commission shall make publicly available without delay any such texts of national provisions received by it. --- (*) 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: (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).
72. The following substances which are classified as carcinogenic, mutagenic or toxic for reproduction, category 1A or 1B The substances listed in column 1 of the Table in Appendix 12.	1. Shall not be placed on the market after 1 November 2020 in any of the following: (a) clothing or related accessories; (b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing; (c) footwear; if the clothing, related accessory, textile other than clothing or foot wear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12. 2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50 -00 -0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter. 3. Paragraph 1 shall not apply to: (a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide; (b) non-textile fasteners and non-textile decorative attachments; (c) second-hand clothing, related accessories, textiles other than clothing or footwear(d)wall-to -wall carpets and textile floor coverings for indoor use, rugs and runners. 4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council or Regulation (EU) 2017/745 of the European Parliament and of the Council. 5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose. 6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation. 7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly.

As of July 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).

A.2.0 Appendix 2: Exemption 7(a)

A.2.1 Intended Use and Examples for Related Products in which HMP lead (Pb) solders are utilized

Table 2 from the Umbrella Project application (Umbrella Project 2020d; 2020e) (reproduced as is):

Intended HMP solder use	Examples of related products	Reasons for necessity
– For combining elements integral to an electrical or electronic component: - a functional element with a functional element; or, - a functional element with wire/terminal/heat sink/substrate, etc.	– Resistors, capacitors, chip coil, resistor networks, capacitor networks, leaded inductors, power semiconductors, discrete semiconductors, microcomputers, ICs, LSIs, chip EMI, chip beads, chip inductors, chip transformers, power transformers, lamps, resistance temperature devices (RTD), electromechanical relays for automotive (just as reference) and industrial use, etc. – [See Figure 1, Figure 2, Figure 3, Figure 4, Figure 5 & Figure 8]	– Stress relaxation characteristic with materials and metal materials at the time of assembly is needed – When it is incorporated in products, it needs heatproof characteristics to temperatures higher than 250 to 260°C (this is the typical solder reflow temperature used for PCBs and wave soldering) – It is needed to achieve electrical characteristics and thermal characteristics during operation, due to high electric conductivity, high heat conductivity/ thermal dissipation, etc. – It is needed to gain high reliability for temperature cycles and power cycles due to stress relaxation from higher ductility material, etc.
– For mounting electronic components onto sub-assembled modules or sub-circuit boards	– Hybrid IC, modules, optical modules, etc. – [See Figure 6]	
– As a sealing material between a ceramic package or plug and a metal case	– SAW (Surface Acoustic Wave) filter, crystal resonators, crystal oscillators, crystal filters, etc. – [See Figure 7]	
– For connecting magnet wire coil to flexible conductor	– High power transducers (both low and high frequency) used for Professional Sound application [See Figure 9]	– Sustain the heat dissipation, the high temperatures of the magnet wire and the proximity to the magnet wire coil

Table 2: Intended Use and Examples for Related Products in which HMP lead (Pb) solders are utilized

A.2.2 Properties of relevance to applications in scope of Ex. 7(a) (Umbrella Project 2021e)

	Required performance (threshold/range)	For combining elements integral to an electrical or electronic component		For mounting electronic components onto sub-assembled modules or sub-circuit boards	As a sealing material between a ceramic package or plug and a metal case	For high power transducers (both low and high frequency in professional sound applications
		Functional element with a functional element	Functional element with wire/terminal/heat sink/substrate			
High melting point (liquidus line)	200 - 300 C	X	X	X	X with specific, limited applications with 280-300°C	X
High softening temperature (solidus line)	not lower than 260 C	X	X	X	X	X
Strong thermal conductivity		X	X	X	X	X
Good thermal fatigue resistance		X	X	X	X	X
Good wettability		X	X	X	X	X
Good ductility		X	X	X	X	X
Corrosion-resistivity		X	X	X	X	X
Appropriate oxidation nature		X	X	X	X	X
Electrical conduction		X	X	X	X	X
Stress relief		X	X	X	X	X
Heatproof to reflow temperatures	reflow at 260 C	X	X	X	X	X
Moisture sensitivity		X	X	X	X	X
Sustaining of heat dissipation		X	X	X	X	X
Manufacturability		X	X	X	X	X
High reliability		X	X	X	X	X

A.2.3 Advantages and Disadvantages of High Temperature Lead-free Solutions

Table 5 from the Umbrella Project application (Umbrella Project 2020d; 2020e) (reproduced as is):

Candidate for Substitution		Advantages	Disadvantages
	Bi system	· Solidus line is high · Joint operating temperature is comparable with conventional high temperature type solders. · Relatively low-cost	· Low ductility (very brittle) · Low strength · High electrical resistivity
	BiAgX®	· Easy drop in replacement for Pb-containing solder paste · Relatively low cost	· Brittle solder joints (solder cracks) · poor wetting, solder voids (can cause bond failure and other reliability issues) · thermal impedance increases (so unsuitable where heat conduction is required) · Melting temperature is 263°C
	Au-Sn	· Solidus line is high · Joint operating temperature is comparable with conventional high temperature type solders. · Strength is high	· Low ductility (too hard, so when used between parts with different CTE, this causes high strain leading to bond failure) · Lower melting point compared to HMP lead (Pb) solder
	Sn-high Sb	· Solidus line is high	· Low ductility · Concern of Sb toxicity (on REACH CoRAP list) · Temperature required to solder is ~50°C higher than Pb-based HMP solder and is too hot for some processes (as this will damage most polymers and possibly the silicon chip)
	Zn-Al system	· Solidus line is high	· Brittle and low ductility · Susceptible to corrosion and early failure · Temperature required to solder is significantly higher than Pb-based HMP solder and is too hot for some processes

Sn system + High melting temperature type metal	· It is still retentive even if it is remelted. The joint operating temperature is comparable with that of conventional high temperature type solder, depending on a combination of remelting. · Solidus line is high if all can be made inter-metal compounds	· For a resin mold, there is fear that a molten part may exude to outside of a component · Joint operating temperature is high, extending solder duration which might lead to high intermetallic growth which is often brittle and leads to a reliability issue · Fragile or low ductility because joint is mainly made of brittle inter-metallic compounds
Electrically conductive adhesive system	· No concern of remelting due to thermal hardening	· Poor heat conductivity · Poor electrical conductivity which can deteriorate with age · Susceptible to humidity · Difficult to repair · Insufficient reliability when qualifying for higher (Tjmax=175°C or above) junction temperature · Concern of some components' toxicity (classified as CMR)
Ag sintering systems	· No concern of remelting due to thermal hardening and/or pressure assisted sintering · High electrical and thermal performance	· Additional stress during processing (pressure assisted sintering) on the chip · Susceptible to humidity (porosity of Ag sponge) · High stress on chip due to stiff die-attach material · Concern of some components' toxicity (classified as CMR)

***Table 5**: Advantages and Disadvantages of High Temperature Lead-free Solutions*

Evaluation results concerning lead free materials replacing lead HTM internal solder by Vishay

The following tables are from the Umbrella Project application (Umbrella Project 2020d; 2020e) (reproduced as is):

VISHAY

EVALUATION RESULT SUMMARY (1)

Material Type	Solder paste			
Series	Pb-Sn Alloy (Reference)	Bi-Ag Alloy	ESL 3601 NF	J-alloy
Product	PbAg2.5Sn5	BiAgX®	Au80Sn20	Sn65Ag25Sb10
Lead contain/free	Lead contain	Lead free	Lead free	Lead free
Vishay application	In use	Evaluation	Evaluation	Was in use / stopped
Component (after)	Pb-Sn-Ag Alloy	Bi-Ag Alloy	Au-Sn Alloy	Sn-Ag-Sb Alloy
Dispensing applicable or not	Printing/dispensing	Dispensing	Dispensing	Solder wire
Working condition	Reflow Peak temp. 360-400℃	Reflow Peak temp. 320-380℃	Reflow Peak temp. 320℃	Heat station Peak temp. 300-350℃
Metal layer	Bare Cu is possible	Bare Cu is possible	Au/Au-Alloy (Bare Cu tested)	Bare Cu is possible
Advantage	-	• Soldering reflow profile is comparable • Relatively low cost • Pass reliability test	• Acceptable electrical and thermal conductivity	• No need of flux cleaning • Comparable costs • Die attach process can be optimized to achieve very low void-rate
Disadvantage	-	• Low solder liquid point and solder re-melting concern • Low electrical conductivity • Low ductility and solder crack concern • Poor wettability and high solder void rate • Low thermal conductivity	• Lower eutectic temperature (280℃) • Low ductility • Transfers most of the thermo-mechanical strain to the die -> risk of die cracks especially with increasing die size • Risk of cracked solder joints • High costs (>400x compared to Pb-solder paste)	• Very brittle, transfers lots of stress to the die • Was in use for die attach in the TO-247 package with various diode and thyristor chips. Finally needed to be changed back to Pb-containing solder because of ongoing / not resolvable die crack issues

Conclusion: Bi-AgX® and J-alloy so far assessed as not capable to replace current based solder. No final conclusion yet for Au80Sn20, but extremely high costs, also major technical concerns because of brittleness of the material.

VISHAY

EVALUATION RESULT SUMMARY (2)

Material Type	Sinter paste		Conductive adhesive
Series	Silver sinter paste	Silver sinter epoxy	Silver epoxy
Product	ASP295-79P2	XH9890-6	EN-4620K
Lead contain/free	Lead free	Lead free	Lead free
Vishay application	Evaluation	Evaluation	Evaluation
Component (after)	Silver (sintered)	Silver (sintered) & epoxy	Silver particle & epoxy
Dispensing applicable or not	Dispensing	Dispensing	Dispensing
Working condition	Curing Peak temp. 230℃	Curing Peak temp.200℃	Curing Peak temp.180℃
Metal layer	Ag/Au layer is must	Ag/Au layer is must	Ag/Au layer is suggested
Advantage	• Thermal and electrical conductivity better than Pb-solder • Low void rate • No re-melting concern	• Thermal and electrical conductivity comparable to Pb-solder • Low void rate • No re-melting concern • Pass reliability test	• Electrical conductivity comparable to Pb-solder • Low void rate • No re-melting concern
Disadvantage	• Additional Ag/Au plating is required • Low dispensability • Pressure sintering is suggested • Poor sintering on clip attach • Failed reliability testing • High cost	• Additional Ag/Au plating is required • Pressure sintering is suggested • Poor sintering on clip attach • Poor actual thermal performance • High cost	• Additional Ag/Au plating is suggested • Poor joint capability on clip attach • High cost

Conclusion: Above Lead free materials were evaluated as not capable to replace current Lead based solder paste.

A.2.4 Summary of strategies considered in the current review in order to specify the scope

- Strategy 1: the application approach
  - Connecting applications of parts integral or external to an electrical or electronic component or connecting components;
  - Mounting applications of electronic components onto other assemblies;
  - Sealing applications between various materials.
- Strategy 2: the functional purpose of lead (properties, performance) approach
  - Melting temperatures; thermal conductivity; electrical conductivity, ductility; electrical resistivity, corrosion resistance; resistance to thermal oxidation
- Strategy 3: Category approach: Restriction to specific Annex I categories (e.g., 8 and 9 with requirement on high reliability) or exclusion e.g. consumer products

Strategy 2 is difficult to be followed, since underlying information on LHMPS and lead-free solders is missing. The idea of strategy 2 was to identify the essential physical properties of LHMPS (Note: not elemental Pb) with corresponding technical parameters. As described previously, Pb in LHMPS makes these alloys very unique and reliable based on many properties: high melting point, thermal conductivity, ductility, electrical conductivity, electrical resistivity, corrosion resistance, resistance to thermal oxidation. Hence, understanding physical parameters of these high lead-containing solders would be an underlying basis to identify the applications. However, stakeholders provided the physical properties for the most part on the element basis (e.g. Pb vs. other single elemental metals). On the level of comparison of one solder to another (e.g. Sn-85Pb vs. Lead-free alternatives) only partial information is available. Substantiation was requested but not received and thus this direction was abandoned.

Strategy 3 was found to be unpractical, since the components in which LHMPS must be applied could be distributed in different categories. For instance, stakeholders were asked to explain whether LHMPS are applied in consumer equipment or whether such equipment (or equipment with lower service life) could be excluded from the scope of the exemption. The RoHS Umbrella Project (2021b) explains that LHMPS are used often in low-level electrical and electronic components. UP provides an example that the same SMD fuse may be used in a medical device as well as in consumer products. Thus, UP is against an approach to exclude EEE categories from the scope.

A.3.0 Appendix 3: Umbrella Project overview of various types of Exemption 7(c)-I EE components used in EEE for many categories

The following list was provided in a communication from Umbrella Project (2021a) commenting on the option of specifying the wording of exemption 7(c)-I:

A.3.1 Annex I – Categorization of electric and electronic components

A rough categorization can be found for example in catalogues of component distributors, like Digikey, as shown in the example below, copied from Website: https://www.digikey.de/en. In total ("View All") it lists more than 42 000 different items:

Products View All

Semiconductors

- Development Boards, Kits, Programmers
- Discrete
- Embedded Computers
- Integrated Circuits (ICs)
- Isolators
- LED/Optoelectronics
- RF, Wireless
- Sensors, Transducers

Passives

- Capacitors
- Crystals, Oscillators
- Filters
- Inductors, Coils, Chokes
- Potentiometers, Variable Resistors
- Resistors
- Thermal Management

Electromechanical

- Audio

- Fans
- Motors, Solenoids, Driver
- Relays
- Switches

Power, Circuit Protection

- Battery Products
- Circuit Protection
- Line Protection
- Power Supplies
- Transformers

Automation and Control

Connectors, Interconnect

Cables, Wires

Test Products

Tools