Study to assess requests for 29 renewal requests concerning one specific EEE category and two (-2-) new exemption requests under the Directive 2011/65/EU

Under the Framework Contract No ENV.B.3/FRA/2019/0017: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation

Final Report

May 2024

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1. Summary – English

Under Framework Contract no. ENV.B.3/FRA/2019/0017, a consortium coordinated by Bio Innovation Service was requested by DG Environment of the European Commission to provide technical and scientific support for the evaluation of the renewal request of 29 exemptions to Annex III of Directive 2011/65/EU. The work has been undertaken by the Bio Innovation Service, UNITAR and Fraunhofer Institute IZM, and has been peer-reviewed by experts from the three organisations.

1.1. Background and objectives

Directive 2011/65/EU (hereafter "the Directive") on the restriction of the use of certain hazardous substances in electrical and electronic equipment provides "*that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II*" (i.e. lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers and starting July 2019 bis (2-ethylhexyl) phthalate, butyl benzyl phthalate, dibutyl phthalate and diisobutyl phthalate). Article 5(1)(a) provides a basis for excluding certain applications from these provisions through the inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV. This article further specifies the criteria on which such exemptions can be justified: in cases where the environmental and health protection afforded by Regulation 1907/2006/EC (REACH) is not weakened, exemptions can be justified in cases where 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; and
- 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."

Furthermore, the availability of substitutes; the socio-economic impacts of substitution; any potential adverse impacts on innovation and life cycle thinking information can also be considered to determine the duration of exemptions.

Article 5(2) of the RoHS Directive stipulates that exemptions listed in Annexes III and Annex IV shall have an expiration date. Where a specific date is not specified, this article lists provisions to clarify the validity. Article 5(3) requires stakeholders to submit applications for granting, renewing or revoking exemptions to the European Commission. Such applications provide the basis for the Commission to initiate evaluations of the exemptions listed in the annexes (or evaluations of requests for new exemptions).

1.2. Key findings – Overview of the evaluation results

The exemption requests covered in this project and the applicants concerned, as well as the final recommendation and proposed expiry dates are presented in Table 1-1 below.

The reader is referred to the corresponding section of this report for details on the evaluation result. For better readability of the table, the following acronyms are used:

Cat. category, referring to categories of EEE in the scope of the RoHS Directive (Annex I)

MCI monitoring and control instrument

MD medical device

IMCI industrial monitoring and control instrument

Incl. including

IVD in-vitro diagnostic medical device

Notes:

- The terms “cat. 8” and “cat. 9” address all EEE under these categories, respectively. For example, “cat. 8” includes IVD as well as other MD.
- The consultants recommended the COM to allow sufficient time for preparation and timely submission of renewal requests between the official publication of the COM’s decision as to granting exemptions or their renewal and the expiry date of the exemptions. Recommended expiry dates in 2024, 2025 and early/mid 2026 may therefore, actually be shifted at the COM’s discretion.
- The below summary only includes the recommended exemption wordings and scopes for cat. 8, cat. 9 and 11. Recommendations for renewals of these exemptions from recent reviews in 2021 and 2022 by Ramboll/Oeko-Institut and BIO IS/Fraunhofer IZM/UNITAR for other categories of EEE remain valid.

Table 1-1: Overview of exemption requests, recommendations and expiry dates

#	Current exemption requested for renewal (or request for new exemption)	Applicants and recommendation	Recommended wording incl. numbering		Scope and expiry date
III-6(a)	*Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight*	*EUROMOT, TMC*	*6(a)(I)*	**Renew with current wording:** *Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight*	*Expires on 21 July 2024 for cat. 9 and 11*
			6(a)(II)	**Renew with wording recommended in previous review:** *Lead in batch hot dip galvanised steel components containing up to 0,2 % lead by weight*	*Expires on 21 July 2026 for categories 9 IMCI and 11*
III-6(b)	*Lead as an alloying element in aluminium containing up to 0,4 % lead by weight*	*EUROMOT, TMC*	*6(b)(I)*	**Renew with current wording:** *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 on 21 July 2026 for cat. 9 IMCI and 11*
			6(b)(II)	**Renew with current wording:** *Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight*	*Expires on 21 July 2026 for cat. 9 IMCI and 11*
III-7(a)	*Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)*	*EUROMOT, TMC*	*7(a)*	**Renew**	*Expires on 21 July 2026 for cat. 9 IMCI and 11*
III-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*	*EUROMOT, TMC, Werfen*	*7(c)(I)*	**Renew**	*Expires on 21 July 2026 for cat. 9 IMCI and 11*
III-8(b)	*Cadmium and its compounds in electrical contacts*	*TMC*	8(b)(II)	**Renew with wording recommended in previous review:**	*Expires on 31 December 2025 for cat. 9 IMCI*

				Cadmium and its compounds in electrical contacts used in	
				- circuit breakers	
				- thermal sensing controls	
				- thermal motor protectors (excluding hermetic thermal motor protectors)	
				- AC switches	
				- DC switches	
III-13(a)	*Lead in white glasses used for optical applications*	*TMC*	*13(a)*	**Renew with current wording (+ options, cf. recommendation section)**	*Expires on 21 July 2028 for cat. 9 IMCI*
III-13(b)	*Cadmium and lead in filter glasses and glasses used for reflectance standards*	*TMC*	*13(b)(I)*	**Renew with current wording:** *Lead in ion coloured optical filter glass types*	*Expires on 21 July 2028 for cat. 9 IMCI*
			13(b)(II)	**Renew with current wording:** *Cadmium in striking optical filter glass types; excluding applications falling under point 39 of Annex III*	
			13(b)(IV)	**Renew with wording recommended in previous review:** *Cadmium in glazes used for reflectance standards*	
			13(b)(V)	**Renew with wording recommended in previous review:** *Lead compound coatings in infrared interference filters used in infrared gas analysis and mid-far-infrared spectroscopy*	
III-15	*Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages*	*TMC*	*15*	**Renewal not recommended due to lack of evidence required by Art. 5(1)(a).**	Expires on 21 July 2024 for cat. 9 IMCI
III-18(b)	*Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi2O5:Pb)*	*LightingEurope*	*18(b)*	**Renew with current wording.**	Expires on 21 July 2026* for cat. 11.
III-34	*Lead in cermet-based trimmer potentiometer elements*	*TMC*	*34*	**Renew with current wording.**	Expires on 21 July 2024* for cat. 9 IMCI

III-42	*Lead in bearings and bushes of diesel or gaseous fuel-powered internal combustion engines applied in non-road professional use equipment:* *- with engine total displacement ≥ 15 litres;* *or* *- with engine total displacement < 15 litres and the engine is designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds; or regular maintenance is typically performed in a harsh and dirty outdoor environment, such as mining, construction, and agriculture applications;*	*EUROMOT*	*42(a)*	**Renew with modified wording:** *Up to 95 % of lead in overlay coatings and/or up to 33 % of lead in linings of bearings and bushes of diesel or gaseous fuel-powered internal combustion engines applied in non-road professional use equipment:* *- with engine total displacement ≥ 15 litres;* *or* *- with engine total displacement < 15 litres and the engine is designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds; or regular maintenance is typically performed in a harsh and dirty outdoor environment, such as mining, construction, and agriculture applications;*	Expires on 21 July 2029 for cat. 11
III-44	*Lead in solder of engine control units of combustion engines within the scope of Regulation (EU) 2016/1628 of the European Parliament and of the Council[(1)], installed in equipment used at fixed positions while in operation, which is designed for professionals, but also used by non-professional users;*	*EUROMOT*	*44*	**Renew with current wording.**	*Expires on 21 January 2027 for cat. 11*

[1] Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53).

III-X	**New exemption:** *Optical components made of mercurous chloride monocrystal (calomel)*	*BBT*	*X*	**Grant with below wording:** *Mercury in optical materials made of mercurous chloride monocrystal (calomel) for use in applications requiring a polarizing material or in acousto-optic applications, if at least one of the below properties is required:* *a) A crystal material is required for the specific application, and its transmission must include[1] at least one wavelength in the spectrum from more than 8 µm up to 17 µm.* *b) Indices of refraction of n_o > 1,89 and n_e > 2,44 at 10,6 µm wavelength, and n_o > 2,11 and n_e > 3,18 at 0,38 µm wavelength, as well as a birefringence of more than +0,5 at any part of the wavelength spectrum from 0,38 µm to 17 µm.* *c) Extinction ratio of more than 1:20 000 in the infrared wavelength spectrum between 3 µm and 17 µm.* *d) Velocity of elastic wave propagation of less than 400 m/s* *e) Value for acousto-optical figure of merit M2 = 640 x 10^{-15} s^3/kg at 632,8 nm wavelength* *f) Damage threshold of more than 5 x 10^5 W/cm^2 at 1.064 nm*	*Expires on (date of official publication + 5 years) for cat. 3 and 9 IMCI*
IV-1(a)	*Lead and cadmium in ion selective electrodes including glass of pH electrodes*	*COCIR*	*1(a)(I)*	**Renew with below wording:** *Lead and cadmium in thick film pastes in ion selective electrodes used for blood gas systems.*	*Expires on 31 August 2026 for cat. 8 IVD*

IV-1(b)	*Lead anodes in electrochemical oxygen sensors.*	*Alphasense, Ametek Mocon, Draeger, Honeywell,*	*1(b)(I)*	**Renew with below wording:** *Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and/or exhaled air for patients and that are intended to be used as consumables in medical devices put on the market before 26 May 2024.*	*Expires on 21 July 2025 for cat. 8 MD other than IVD*
			1(b)II)	**Renew with wording recommended in previous review:** *Lead in galvanic oxygen sensors in instruments that are designed for the measurement of dissolved oxygen in concentrations below 30 ppb.*	*Expires on 21 July 2025 for cat. 9*
			1(b)(III)	**Renew with modification of wording recommended in previous review:** *Lead anodes in galvanic capillary oxygen sensors in instruments that are designed for the measurement of oxygen in gases.*	*Applies to cat. 9 IMCI and expires on* *- 21 January 2027 for general applications* *- 21 July 2028 for ATEX-rated products*
			1(b)(IV)	**Renew with wording recommended in previous review:** *Lead anodes in Hersch cells for oxygen sensors where sensitivity below 100 ppm is required.*	*Expires on 21 July 2028 for cat. 9 IMCI*
			1(b)(V)	**Renew with wording recommended in previous review:** *Cadmium anodes in Hersch cells for oxygen sensors where sensitivity below 100 ppm is required.*	*Expires [7 years after official publication of the COM's decision] for cat. 9 IMCI*
			1(b)(VI)	**Renew with wording recommended in previous review:** *Lead anodes in permeable membrane oxygen sensors in instruments that are designed for the measurement of oxygen in gases.*	*Expires on 31 December 2025 for cat. 9 IMCI*
IV-1(c)	*Lead, cadmium and mercury in infra-red light detectors.*	*Bruker, PPTF*	*1(c)(I)*	**Renew with wording recommended in previous review:** *Cadmium and mercury in mercury cadmium telluride (MCT) of infrared light detectors*	*Expires on 21 July 2028 for cat. 8 and 9*

IV-4	*Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons.*	*TMC*	*4(a)*	**Renew with below wording:** *Lead in glass frit binders for assembly of HeNe gas lasers used in heterodyne interferometry calibration and heterodyne interferometry positioning applications.*	*Expires on 21 July 2026 for cat. 9 IMCI*
IV-9	*Cadmium in helium-cadmium lasers*	*JBCE*	*9*	**Renewal not recommended due to lack of substantiated evidence required by Art. 5(1)(a).**	*Expires on 21 July 2024 for cat. 9 IMCI*
IV-10	*Lead and cadmium in atomic absorption spectroscopy lamps*	*Perkin Elmer, Agilent Technologies, JBCE, Analytik Jena, Heraeus*	*10(a)*	**Renew with current wording until 24 February 2027, thereafter with below wording:** *Lead, cadmium, and mercury in electrodeless discharge lamps for atomic absorption spectroscopy*	*Applies to cat. IMCI from 25 February 2027 on;* *Expires on 21 July 2031*
IV-46	*Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils*	*COCIR*	*46*	**Renew with current wording.**	*Expires on 31 December 2026*
IV-X	**New exemption:** *Cadmium in Hersch cells for oxygen sensors used in industrial monitoring and control instruments, where sensitivity below 100 ppm is required*	*AMETEK MOCON*	*1(b)(V)*	**Grant with below wording:** *Cadmium anodes in Hersch cells for oxygen sensors where sensitivity below 100 ppm is required*	*Expires on [7 years after official publication of COM decision]*

Note: Like 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. Note De Synthèse : Français

Au titre du contrat-cadre n°. ENV.B.3/FRA/2019/0017, un consortium coordonné par Bio Innovation Service a été sollicité par la DG Environnement de la Commission Européenne pour fournir un soutien technique et scientifique pour l'évaluation de la demande de renouvellement de 29 exemptions à l'annexe III de la directive 2011/65/UE. Le travail a été entrepris par le Bio Innovation Service, UNITAR et le Fraunhofer Institute IZM, et a été revu par des experts des trois organisations.

2.1. Contexte et objectifs

La Directive 2011/65/UE (ci-après « la Directive ») relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques prévoit « que les EEE mis sur le marché, y compris les câbles et les pièces détachées destinées à leur réparation, à leur réemploi, à la mise à jour de leurs fonctionnalités ou au renforcement de leur capacité, ne contiennent aucune des substances énumérées à l'annexe II » (à savoir le plomb, le mercure, le cadmium, le chrome hexavalent, les polybromobiphényles, les polybromodiphényléthers et, à partir de juillet 2019, le phtalate de bis(2-éthylhexyle), le phtalate de butylbenzyle, le phtalate de dibutyle et le phtalate de diisobutyle). L'article 5(1)(a), fournit une base pour exclure certaines applications de ces dispositions par l'inclusion de matériaux et de composants d'EEE destinés à des applications spécifiques dans les listes des annexes III et IV. Cet article précise en outre les critères sur lesquels ces exemptions peuvent être justifiées : dans les cas où la protection de l'environnement et de la santé assurée par le règlement 1907/2006/CE (REACH) n'est pas affaiblie, les exemptions peuvent être justifiées dans les cas où au moins un des critères suivants est rempli :

- « leur élimination ou leur remplacement sur la base de modifications de la conception, ou par des matériaux et composants ne nécessitant aucun des matériaux ou substances énumérés à l'annexe II, est scientifiquement ou techniquement impraticable,
- la fiabilité des produits de substitution n'est pas garantie,
- il est probable que l'ensemble des incidences négatives sur l'environnement, sur la santé et sur la sécurité du consommateur liées à la substitution l'emportent sur l'ensemble des bénéfices qui en découlent pour l'environnement, la santé et la sécurité du consommateur. »

En outre, la disponibilité des substituts, les impacts socio-économiques de la substitution, tout impact négatif potentiel sur l'innovation et les informations sur le cycle de vie peuvent également être pris en compte pour déterminer la durée des exemptions.

L'article 5(2), de la Directive RoHS stipule que les exemptions énumérées à l'annexe III et à l'annexe IV ont une date d'expiration. Lorsqu'aucune date spécifique n'est spécifiée, cet article énumère les dispositions permettant d'en clarifier la validité. L'article 5(3), exige que les parties prenantes soumettent à la Commission européenne des demandes d'octroi, de renouvellement ou de révocation des exemptions. Ces demandes servent de base à la

Commission pour lancer les évaluations des exemptions énumérées dans les annexes (ou les évaluations des demandes de nouvelles exemptions).

2.2. Principales conclusions - Aperçu des résultats de l'évaluation

La demande d'exemption couverte par ce projet et le demandeur concerné, ainsi que la recommandation finale et la date d'expiration proposée sont présentés dans le Tableau 2-1 ci-dessous. Plus de détail sur le résultat de l'évaluation est présenté dans le chapitre correspondant à chaque évaluation. Pour une meilleure lisibilité du tableau, les acronymes suivants sont utilisés :

cat. catégorie de produit électriques et électronique tel que c'est défini dans l'annex I de la directive RoHS

COM Commission européenne

MCI instrument de contrôle et de surveillance

MD dispositifs médicaux

IMCI instrument de contrôle et de surveillance industriel

Incl. inclus

IVD appareil médical de diagnostic in vitro

NB :

- Les termes « cat. 8 » et « cat. 9 » appliquent à tous les EEE sous ces catégories. Par exemple, « cat. 8 » inclut l'IVD ainsi que d'autres MD.
- Les consultants suggèrent à la COM de prévoir un délai suffisant pour la préparation et la soumission dans les délais des demandes de renouvellement entre la publication officielle de la décision de la COM relative à l'accord des dérogations ou à leur renouvellement et la date d'expiration des dérogations. Les dates d'expiration recommandées en 2024, 2025 et début/mi-2026 peuvent donc effectivement être décalées à la discrétion de la COM.
- Le résumé ci-dessous présent uniquement les formulations et les champs d'exemption recommandées pour le cat. 8, cat. 9 et cat.11. Les recommandations de renouvellement de ces exemptions issues des récents examens effectués en 2021 et 2022 par Ramboll/Oeko-Institut et BIO IS/Fraunhofer IZM/UNITAR pour d'autres catégories d'EEE restent valables.

Tableau 2-1 : Aperçu des demandes d'exemption, des recommandations et des dates d'expiration.

Ex. no	Formulation actuelle de l'exemption (ou la nouvelle demande d'exemption)	Candidats	Recommandation		Date d'expiration et champ d'application
III-6(a)	*Le plomb comme élément d'alliage dans l'acier destiné à l'usinage et dans l'acier galvanisé contenant jusqu'à 0,35 % de plomb en poids*	*EUROMOT, TMC*	*6(a)(I)*	**Renouveler avec la formulation actuelle :** *Le 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 cat. 9 et 11*
			6(a)(II)	**Renouveler avec la formulation recommandée dans l'évaluation précédente :** *Le plomb dans les composants en acier galvanisé à chaud en lots contenant jusqu'à 0,2 % de plomb en poids*	*Expire le 21 juillet 2026 pour cat. 9 IMCI et 11*
III-6(b)	*Le plomb comme élément d'alliage dans l'aluminium contenant jusqu'à 0,4 % de plomb en poids*	*EUROMOT, TMC*	*6(b)(I)*	**Renouveler avec la formulation actuelle :** *Le plomb comme élément d'alliage dans l'aluminium contenant jusqu'à 0,4 % de plomb en poids, à condition qu'il provienne du recyclage de déchets d'aluminium contenant du plomb*	*Expire le 21 juillet 2026 pour cat. 9 IMCI et 11*
			6(b)(II)	**Renouveler avec la formulation actuelle :** *Le plomb comme élément d'alliage dans l'aluminium destiné à l'usinage avec une teneur en plomb allant jusqu'à 0,4 % en poids*	*Expire le 21 juillet 2026 pour cat. 9 IMCI et 11*
III-7(a)	*Le plomb dans les soudures à haute température de fusion (c'est-à-dire les alliages à base de plomb contenant 85 % en poids ou plus de plomb)*	*EUROMOT, TMC*	*7(a)*	**Renouveler.**	*Expire le 21 juillet 2026 pour cat. 9 IMCI et 11*
III-7(c)(I)	*Composants électriques et électroniques contenant du plomb dans un verre ou une céramique autre que la céramique diélectrique dans les condensateurs, par ex. dispositifs piézoélectroniques, ou dans un composé à matrice de verre ou de céramique*	*EUROMOT, TMC, Werfen*	*7(c)(I)*	**Renouveler.**	*Expire le 21 juillet 2026 pour cat. 9 IMCI et 11*

III-8(b)	*Le cadmium et ses composés dans les contacts électriques*	*TMC*	8(b)(II)	**Renouveler avec la formulation recommandée dans l'évaluation précédente :** *Le cadmium et ses composés dans les contacts électriques pour*	*Expire le 31 décembre 2025 pour cat. 9 IMCI*
				- disjoncteurs,	
				- contrôles de captage thermique,	
				- dispositifs thermiques de protection des moteurs (sauf protecteurs thermiques des moteurs type hermétique)	
				- Interrupteurs CA	
				- interrupteurs CC	
III-13(a)	*Le plomb dans les verres blancs utilisés pour les applications optiques*	*TMC*	*13(a)*	**Renouveler avec la formulation actuelle (+ options, cf. le sous chapitre recommandation)**	*Expire le 21 juillet 2028 pour cat. 9 IMCI*
III-13(b)	*Le cadmium et le plomb dans les verres filtrants et les verres utilisés pour les normes de réflectance*	*TMC*	*13(b)(I)*	**Renouveler avec la formulation actuelle :** *Le plomb dans les verres à filtres optiques colorés*	*Expire le 21 juillet 2028 pour cat. 9 IMCI*
			13(b)(II)	**Renouveler avec la formulation actuelle :** *Le cadmium dans les types de verres à filtres optiques frappants ; à l'exclusion des demandes relevant du point 39 de l'annexe III*	
			13(b)(IV)	**Renouveler avec la formulation recommandée dans l'évaluation précédente :** *Le cadmium dans les émaux utilisés pour les normes de réflectance*	
			13(b)(V)	**Renouveler avec la formulation recommandée dans l'évaluation précédente :** *Revêtements composés de plomb dans les filtres interférentiels infrarouges utilisés dans l'analyse des gaz infrarouges et la spectroscopie infrarouge moyen et lointain*	
III-15	*Le plomb dans les soudures pour réaliser une connexion électrique viable entre la puce semi-conductrice et le support dans les boîtiers de puces retournées de circuits intégrés*	*TMC*	*15*	**Renouvellement non recommandé en raison du manque de preuves requises par l'art. 5(1)(a).**	Expire le 21 juillet 2024 pour cat. 9 IMCI

III-18(b)	*Le plomb comme activateur dans la poudre fluorescente (1 % de plomb en poids ou moins) des lampes à décharge lorsqu'elles sont utilisées comme lampes de bronzage contenant des luminophores tels que le BSP (BaSi2O5:Pb)*	*LightingEurope*	*18(b)*	**Renouveler avec la formulation actuelle.**	Expire le 21 juillet 2026* pour cat. 11.
III-34	*Le plomb dans les éléments de potentiomètre trimmer à base de cermet*	*TMC*	*34*	**Renouveler avec la formulation actuelle.**	Expire le 21 juillet 2024* pour cat. 9 IMCI
III-42	*Le plomb dans les roulements et les bagues des moteurs à combustion interne alimentés au diesel ou au carburant gazeux utilisés dans les équipements à usage professionnel non routier :* *- avec cylindrée totale du moteur ≥ 15 litres;* *or* *- avec une cylindrée totale du moteur < 15 litres et le moteur est conçu pour fonctionner dans des applications où le temps entre le signal de démarrage et la pleine charge doit être inférieur à 10 secondes ; ou un entretien régulier est généralement effectué dans un environnement extérieur difficile et sale, comme dans les applications minières, de construction et agricoles ;*	*EUROMOT*	*42(a)*	**Renouveler avec une formulation modifiée :** *Jusqu'à 95 % de plomb dans les revêtements de recouvrement et/ou jusqu'à 33 % de plomb dans les garnitures de roulements et de coussinets de moteurs à combustion interne fonctionnant au diesel ou à carburant gazeux, utilisés dans des équipements non routier à usage professionnel :* *- avec cylindrée totale du moteur ≥ 15 litres;* *ou* *- avec une cylindrée totale du moteur < 15 litres et le moteur est conçu pour fonctionner dans des applications où le temps entre le signal de démarrage et la pleine charge doit être inférieur à 10 secondes ; ou un entretien régulier est généralement effectué dans un environnement extérieur difficile et sale, comme dans les applications minières, de construction et agricoles.*	Expire le 21 juillet 2029 pour cat. 11
III-44	*Le plomb dans la soudure des unités de commande des moteurs à combustion relevant du champ d'application du règlement (UE) 2016/1628 du*	*EUROMOT*	*44*	**Renouveler avec la formulation actuelle.**	*Expire le 21 janvier 2027 pour cat. 11*

	Parlement européen et du Conseil[(2)], installées dans des équipements utilisés à des positions fixes en fonctionnement, destinés aux professionnels, mais également utilisé par des utilisateurs non professionnels ;				
III-X	**Nouvelle exemption:** *Composants optiques en monocristal de chlorure mercureux (calomel)*	*BBT*	*X*	**Accorder avec la formulation ci-dessous :** *Le mercure dans les matériaux optiques constitués de monocristal de chlorure mercureux (calomel) à utiliser dans les applications nécessitant un matériau polarisant ou dans les applications acousto-optiques, si au moins une des propriétés ci-dessous est requise :* *a) Un matériau cristallin est requis pour l'application spécifique, et sa transmission doit inclure[1] des longueurs d'onde dans le spectre allant de plus de 8 µm à 17 µm.* *b) Indices of réfraction de n_o > 1,89 et n_e > 2,44 à une longueur d'onde de 10,6 µm et n_o > 2,11 et n_e > 3,18 à une longueur d'onde de 0,38 µm ainsi qu'une biréfringence supérieure à +0,5 à n'importe quelle partie du spectre de longueur d'onde de 0,38 µm à 17 µm.* *c) Taux d'extinction supérieur à 1:20 000 dans le spectre des longueurs d'onde infrarouges comprises entre 3 µm et 17 µm.* *d) Vitesse de propagation des ondes élastiques inférieure à 400 m/s*	*Expire le (date officiel de publication + 5 ans) pour cat. 3 et 9 IMCI*

[2] èglement (UE) 2016/1628 du Parlement européen et du Conseil du 14 septembre 2016 relatif aux exigences concernant les limites d'émission pour les gaz polluants et les particules polluantes et la réception par type pour les moteurs à combustion interne destinés aux engins mobiles non routiers, modifiant les règlements (UE) n° 1024/2012 et (UE) n° 167/2013 et modifiant et abrogeant la directive 97/68/CE (JO L 252, 16.9.2016, p. 53).

				e) Valeur du facteur de mérite acousto-optique M2 = 640 x 10^{-15} s^3/kg à une longueur d'onde de 632,8 nm	
				Seuil de dommage supérieur à 5 x 10^5 W/cm^2 à 1.064 nm	
IV-1(a)	*Le plomb et le cadmium dans les électrodes sélectives d'ions, y compris le verre des électrodes de mesure du pH*	*COCIR*	*1(a)(I)*	**Renouveler avec la formulation ci-dessous :** *Le plomb et le cadmium dans les pâtes à film épais des électrodes sélectives d'ions utilisées pour les systèmes de gaz du sang.*	*Expire le 31 août 2026 pour cat. 8 IVD*
IV-1(b)	*Les anodes en plomb dans les capteurs électrochimiques d'oxygène*	*Alphasense, Ametek Mocon, Draeger, Honeywell,*	*1(b)(I)*	**Renouveler avec la formulation ci-dessous :** *Les anodes en plomb dans les capteurs électrochimiques mesurant la concentration de l'oxygène de l'air inspiré et/ou expiré par les patients, et qui sont des consommables dans des dispositifs médicaux mis sur le marché avant le 26 mai 2024.*	*Expire le 21 juillet 2025 pour cat. 8 MD autres que l'IVD*
			1(b)II)	**Renouveler avec la formulation recommandée dans l'évaluation précédente :** *Le plomb dans les capteurs d'oxygène galvaniques dans les instruments conçus pour mesurer l'oxygène dissous dans des concentrations inférieures à 30 ppb.*	*Expire le 21 juillet 2025 pour cat. 9*
			1(b)(III)	**Renouveler avec la formulation recommandée dans l'évaluation précédente :** *Anodes en plomb dans les capteurs d'oxygène capillaires galvaniques dans les instruments conçus pour la mesure de l'oxygène dans les gaz.*	*Applique à la cat. 9 IMCI et expires*
					- le 21 janvier 2027 pour des applications générales
					- 21 juillet 2028 pour des produits certifiés ATEX
			1(b)(IV)	**Renouveler avec la formulation recommandée dans l'évaluation précédente :** *Anodes en plomb dans les cellules Hersch pour capteurs d'oxygène où une sensibilité inférieure à 100 ppm est requise.*	*Expire le 21 juillet 2028 pour cat. 9 IMCI*
			1(b)(V)	**Renouveler avec la formulation recommandée dans l'évaluation précédente :** *Anodes en cadmium dans les cellules Hersch pour capteurs d'oxygène où une sensibilité inférieure à 100 ppm est requise.*	*Expire [7 ans après la publication officielle de décision de la COM] pour cat. 9 IMCI*

			1(b)(VI)	**Renouveler avec la formulation recommandée dans l'évaluation précédente :** *Anodes en plomb dans les capteurs d'oxygène à membrane perméable dans les instruments conçus pour la mesure de l'oxygène dans les gaz.*	*Expire le 31 décembre 2025 pour cat. 9 IMCI*
IV-1(c)	*Le plomb, le cadmium et le mercure dans les détecteurs à infrarouges*	*Bruker, PPTF*	*1(c)(I)*	**Renouveler avec la formulation recommandée dans l'évaluation précédente :** *Le cadmium et le mercure dans le tellurure de mercure et de cadmium (MCT) des détecteurs de lumière infrarouge*	*Expire le 21 juillet 2028 pour cat. 8 et 9*
IV-4	*Le plomb dans la fritte de verre des tubes à rayons X et les intensificateurs d'images et le plomb dans liant de fritte de verre au plomb pour l'assemblage de lasers à gaz et de tubes à vide qui convertissent le rayonnement électromagnétique en électrons.*	*TMC*	*4(a)*	**Renouveler avec la formulation ci-dessous :** *Le plomb dans les liants de fritte de verre pour l'assemblage de lasers à gaz HeNe utilisés dans les applications d'étalonnage d'interférométrie hétérodyne et de positionnement d'interférométrie hétérodyne.*	*Expire le 21 juillet 2026 pour cat. 9 IMCI*
IV-9	*Le cadmium dans les lasers hélium-cadmium*	*JBCE*	*9*	**Renouvellement non recommandé en raison du manque de preuves motivées requises par l'art. 5(1)(a).**	*Expire le 21 juillet 2024 pour cat. 9 IMCI*
IV-10	*Le plomb et le cadmium dans les lampes de spectroscopie d'absorption atomique*	*Perkin Elmer, Agilent Technologies, JBCE, Analytik Jena, Heraeus*	*10(a)*	**Renouveler avec la formulation actuelle jusq'au 24 février 2027, ensuite la formulation ci-dessous** *Le plomb, le cadmium et le mercure dans les lampes à décharge sans électrode pour la spectroscopie d'absorption atomique.*	*Applique à la cat. IMCI à partir du 25 février 2027 ; Expire le 21 juillet 2031*
IV-46	*Bis(2-ethylhexyl) phtalate (DEHP) dans les composants en plastique des bobines de détection IRM*	*COCIR*	*46*	**Renouveler avec la formulation actuelle.**	*Expire le 31 décembre 2026*
IV-X	**Nouvelle exemption :** *Le cadmium dans les cellules Hersch pour les capteurs d'oxygène utilisés dans les instruments de surveillance et de contrôle industriels, où une sensibilité inférieure à 100 ppm est requise*	*AMETEK MOCON*	*1(b)(V)*	**Accorder avec la formulation ci-dessous :** *Anodes en cadmium dans les cellules Hersch pour capteurs d'oxygène où une sensibilité inférieure à 100 ppm est requise.*	*Expire le [7 ans après la publication officielle de décision de la COM]*

3. Introduction

The consortium for the Framework Contract Assistance to the Commission on technological, socio-economic and cost benefit assessments related to the implementation and further development of EU waste legislation (ENV.B.3/FRA/2019/0017) coordinated by Bio Innovation Service (BioIS) was mandated by the European Commission with the "Study to assess requests for a renewal of eleven exemptions of Annex III of Directive 2011/65/EU" performed under the study request No 090202/2023/900216/ENV.B.3.

3.1. Project scope

The Commission needs clear technical and scientific evidence and an assessment of these requests for granting, renewing or revoking exemptions in the light of the criteria listed in the Directive, notably the provisions cited above, taking into consideration the differing validity periods and expiry dates for the various product categories 1-11 of Annex I of the RoHS Directive. During the evaluation, a public online stakeholder consultation was also organised.

This study will provide the Commission required technical and scientific support for the evaluation of the requests for renewal and amendment of the exemptions displayed in the below table. The number of exemptions in the table less than 29 since the exemptions were regrouped for the review.

Abbreviations used in the below table:

Cat. Category
IMCI Industrial monitoring and control instruments
IVD In vitro diagnostic medical devices

Table 3-1: Overview of exemptions to be reviewed

Exemp. entry	Requested for cat.	Exemption wording	Current expiry dates for categories relevant for the request
III-2022-1	9, 11	Request for new exemption: Optical components made of mercurous chloride monocrystal (Calomel)	Requested for 7 years
IV-2022-2	9	Request for new exemption: Cadmium in Hersch cells for oxygen sensors used in industrial monitoring and control instruments, where sensitivity below 100 ppm is required	Requested for 7 years
III-6(a)	9 IMCI, 11	Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight	21 July 2024 for cat. 9 IMCI and for cat. 11

Exemp. entry	Requested for cat.	Exemption wording	Current expiry dates for categories relevant for the request
III-6(b)	9 IMCI, 11	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight	21 July 2024 for cat. 9 IMCI and 11
III-6b(I)	11	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight, provided it stems from lead-bearing aluminium scrap recycling	Currently not applicable to cat. 11
III-6b(II)	11	Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight	Currently not applicable to cat. 11
III-7(a)	9 IMCI, 11	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)	21 July 2024 for cat. 9 IMCI and 11
III-7(c)(I)	8 IVD, 9 IMCI, 11	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	- 21 July 2023 for cat. 8 IVD - 21 July 2024 for cat. 9 IMCI and 11
III-8(b)	9 IMCI	Cadmium and its compounds in electrical contacts	21 July 2024 for cat. 9 IMCI and 11
III-13(a)	9 IMCI	Lead in white glasses used for optical applications	21 July 2024 for cat. 9
III-13(b)	9 IMCI	Cadmium and lead in filter glasses and glasses used for reflectance standards	21 July 2024 for cat. 9
III-15	9 IMCI	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	21 July 2024 for cat. 9
III 18b	11	Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi2O5:Pb)	21 July 2024 for cat. 11.
III 34	9 IMCI	Lead in cermet-based trimmer potentiometer elements	21 July 2024 for cat. 9 IMCI
III 42	11	Lead in bearings and bushes of diesel or gaseous fuel-powered internal combustion engines applied in non-road professional use equipment: - with engine total displacement ≥ 15 litres; or - with engine total displacement < 15 litres and the engine is designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds; or regular maintenance is typically performed in a harsh and dirty outdoor environment, such as mining, construction, and agriculture applications	21 July 2024 for cat. 11

Exemp. entry	Requested for cat.	Exemption wording	Current expiry dates for categories relevant for the request
III 44	11	Lead in the solder of sensors, actuators, and engine control units of combustion engines within the scope of Regulation (EU) 2016/1628, installed in equipment used at fixed positions while in operation, which is designed for professionals, but also used by non-professional users	21 July 2024 for cat. 11
IV 1a	8 IVD	Lead and cadmium in ion-selective electrodes, including glass of pH electrodes	21 July 2023 for cat. 8 IVD
IV 1b	9 IMCI	Lead anodes in electrochemical oxygen sensors	21 July 2024 for cat. 9 IMCI
IV 1c	9 IMCI	Lead, cadmium and mercury in infra-red light detectors	21 July 2024 for cat. 9 IMCI
IV 4	9 IMCI	Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons	21 July 2024 for cat. 9 IMCI
IV 9	9 IMCI	Cadmium in helium-cadmium lasers	21 July 2024 for cat. 9 IMCI
IV 10	9 IMCI	Lead and cadmium in atomic absorption spectroscopy lamps	21 July 2024 for cat. 9 IMCI
IV 46	8	Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils	21 July 2024 for cat. 8 other than IVD

3.2. Overview: 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 an 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 also has 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 in the Annexes related to the 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.

Substances for which an authorisation or restriction process is underway may be discussed in some cases in relation to a specific exemption 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.[3]

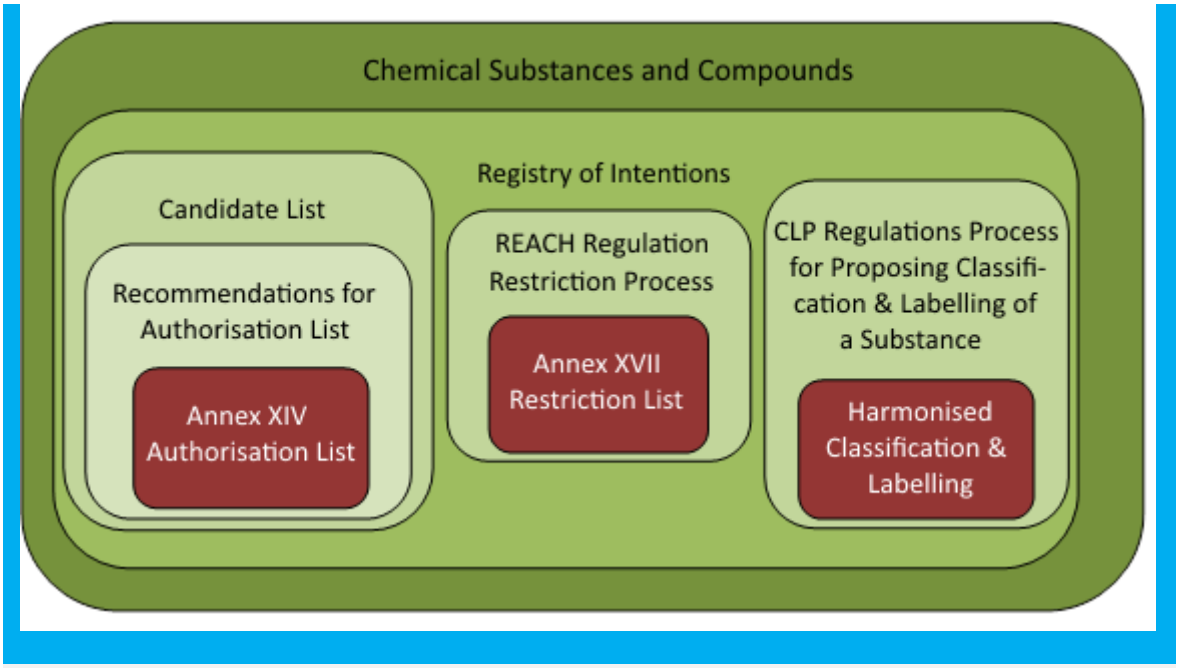
When evaluating the exemption requests, with regard to REACH compliance, we have checked whether the substance / or its substitutes are:

- 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.

Figure 3-1: Relation of REACH categories and lists to other chemical substances



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

[3] 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

conducted by the ECHA together with the Member States and different ECHA Expert Groups.[4] If a Member State evaluates a 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).[5] 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) analysis 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 submit Annex XV dossiers and, therefore, to facilitate timely preparation of the interested parties for commenting later in the process. It is also important to avoid duplication of work and encourage co-operation between Member States when preparing dossiers. Note that the Registry of Intentions is divided into three separate sections: listing new intentions; intentions still subject to the decision-making process; and withdrawn intentions. The registry of intentions is available at the ECHA website at: https://echa.europa.eu/registry-of-intentions;
- The identification of a substance as a Substance of Very High Concern and its inclusion in the Candidate List is the first step in the authorisation procedure. The Candidate List is available at the ECHA website at https://echa.europa.eu/candidate-list-table;
- The last step of the procedure, prior to the 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;

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

[5] 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

- In parallel, if a decision is made concerning the restriction on the use of a substance in a specific article or concerning the restriction of its provision on the European market, then a restriction is formulated to address the specific terms, and this shall be added to Annex XVII of the REACH Regulation. The Annex can be found in the consolidated version of the REACH legal text; and

The ECHA web page was used to reference Annexes XIV and XVII:

- Annex XIV: https://echa.europa.eu/authorisation-list
- Annex XVII: https://echa.europa.eu/substances-restricted-under-reach

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. cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) as well as bis (2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DiBP).[6]

4. Specific REACH-related information for substances of relevance for the exemption requests of this review

The exemption requests to be reviewed included the following substances:

- *Cadmium (Cd)*
- *Lead (Pb)*
- *Mercury (Hg)*
- *DEHP*

4.1. Cadmium

Annex XIV

Cadmium and several of its compounds are classified as substances of very high concern but so far are not adopted to Annex XIV as substances that require authorisation for use.

[6] 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.

Annex XVII

Cadmium is mentioned in a few of the listed restrictions.

Entry 23

This entry refers to cadmium and its compounds. Under this entry, several restrictions are mentioned for cadmium and the compounds. The restrictions for cadmium and its compounds with potential relevance for EEE are listed in the following paragraphs[7]:

1. *They shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material) unless they contain cadmium for safety reasons:*

    - *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.

In the exemptions that were reviewed in pack 27, cadmium or any of its compounds are not used in any of the above materials. The above restriction is thus not applicable.

2. *Cadmium and its compounds shall not be used or placed on the market in certain paints with specific coces in concentrations of more than 0.01 % (mass), or 0.1 %*

7 Missing numberings refer to uses of cadmium in mixtures and arcticles whose relevance for EEE can be excluded.

(mass) if they colour contains more than 10 % (weight) of zinc, unless they contain cadmium for safety reasons.

In the exemptions that were reviewed in pack 27, cadmium or any of its compounds are not used in paints. The above restriction is thus not applicable.

3. *Cadmium and its compounds shall not be used for cadmium plating[8] metallic articles or components of articles used in*
   a. *equipment and machinery in the following sectors/applications:*
      - *Food production*
      - *Cooling and freezing,*
      - *Printing and book-binding*
   b. *Equipment and machinery for the production of :*
      - *Household goods*
      - *Furniture*
      - *Sanitary ware*
      - *Central heating and air conditioning plant*
      - *Paper and board*
      - *Textiles and clothing*
      - *Industrial handling equipment and machinery*

   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.

In the exemptions that were reviewed in pack 27, cadmium is not used in metallic cadmium platings. In the exemption 8(b) series, cadmium is applied as silver cadmium-oxide and hence as an alloy, not in metallic form as cadmium. The above stipulation is thus not applicable. Any other uses of cadmium in exemptions reviewed in pack 27 cannot be related to the plating of elemental cadmium on metallic surfaces.

Overall, the above stipulations do not apply to the use of cadmium in any of the exemptions of pack 27.

4. *Cadmium and its compounds shall not be used in brazing fillers in concentrations of 0.01 % (mass) or higher unless used for safety reasons. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C.*

None of the exemptions reviewed in pack 27 includes uses of cadmium or its compounds in brazing fillers.

8 'Cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface.

5. *Cadmium and its compounds 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 parts of jewellery and imitation jewellery articles, e.g. in wristwatches and wrist-wear.*

While the exemptions reviewed in pack 27 do not imply the use of cadmium or its compounds in jewellery or imitation jewellery, cadmium could, in principle, be used in electrical contacts of wristwatches according to the wording of exemption III-8(b). The applicability of the exemption is, however, limited to use in EEE of cat. 8, 9 and 11, like the scope of exemption 8(b)(II) recommended by (Deubzer et al. 2022c) as renewal of exemption 8(b). Further on, the switches in the scope of exemption 8(b)(II) can be reasonably excluded from occurring in wristwatches.

Entry 23 is not applicable to the exemptions in the scope of the pack 22 review.

Entries 28 and 30

These entries refer to substances which are

- *classified as carcinogen category 1A or 1B, and/or as reproductive toxicants in Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP-Annex VI), and*
- listed in Appendices 1, 2, 5 or 6.

The placing on the market, or use of various substances as such, as constituents of other substances, or in mixtures, for supply to the general public is restricted.

Lead and lead compounds are mentioned in the related appendices 2 and 5, as well as in part 3 of CLP-Annex VI with the above-mentioned classifications. Entry 72 defines the thresholds for these substances as 1 mg/kg.

The use of cadmium or cadmium compounds in exemptions that were reviewed in pack 27 does not imply the supply of such substances in any of the above described forms to the general public. Cadmium or its compounds are used in articles, i.e. in electrical and electronic equipment.

Entry 72

Entry 72 lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction in entries 28, 29 and 30. It stipulates that the substances listed in column 1 of the table in Appendix 12 shall not be used in textiles, clothing and footwear. The table lists cadmium and its compounds as listed under entries 28, 29 and 30.

Like entries 28 and 30, this entry does not address the use of cadmium in the scope of any of the requested new exemptions or exemption renewal requests.

4.2. Lead

Annex XIV

Lead and several of its compounds, e.g. lead zirconium oxide and lead monoxide, are substances of very high concern.[9] So far, lead has not been adopted to REACH Annex XIV

[9] Cf. ECHA, https://echa.europa.eu/candidate-list-table

as an element. The fact that substances are candidate substances therefore does not weaken the *environmental and health protection afforded by*" the REACH Regulation until they are also adopted to Annex XIV.

Annex XIV lists lead compounds, the placing on the market and use of which would require authorisation in the European Economic Area:

- *Entry 10: Lead chromate;*
- *Entry 11: Lead sulfochromate yellow;*
- *Entry 12: Lead chromate molybdate sulphate red;*
- *Entry 55: Tetraethyllead*

Some of the above substances could in principle be of relevance for exemptions III-13(a) and III-13(b) (glasses for optical applications). Exemption 13(a) does not refer to coloured glasses, and the applicants do not mention any relevance of substances on Annex XIV in their renewal request. For 13(b) dealing with coloured glasses, the applicants confirmed the absence of these substances in the products in the scope of these exemptions.

For other exemptions in the scope of this review, the above substances are not relevant.

Annex XVII

Annex XVII contains entries restricting the use of lead compounds:

- *Entry 16 restricts the use of lead carbonates in paints;*
- *Entry 17 restricts the use of lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*

None of the above entries is applicable to the use of lead and its compounds in the scope of the exemptions that were reviewed in pack 27.

Entry 23

Entry 23 restricts the use of lead in certain types of plastics (see respective paragraph for cadmium in this chapter). This includes the cadmium compound cadmium copper lead zinc sulfide.

This substance is not relevant for the exemptions to be reviewed in pack 27, and lead is not used in plastics in the context of any of these exemptions. Entry 23 is, therefore not applicable.

Entry 27

Entry 27 restricts the use nickel in "post assemblies" inserted into pierced parts of the human body and in articles intended to come into direct and prolonged contact with skin, such as, among others, wristwatches. Lead nickel silicate is mentioned in entry 27.

This lead-containing substance is not relevant for the exemptions of pack 27.

Entries 28 and 30

For details of the entry conditions see the entry for 28 and 30 under cadmium.

Lead and lead compounds are mentioned in the related appendices 1, 2, and 5, as well as in part 3 of CLP-Annex V with the above-mentioned classifications. Entry 72 defines the thresholds for these substances as 1 mg/kg.

The use of lead or lead compounds in exemptions to be reviewed in pack 27 do not imply the supply of such substances in any of the above-described forms to the general public. Lead or its compounds are used in articles, i.e. in electrical and electronic equipment.

Entry 63

Point 1 stipulates that lead and its compounds 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. Jewellery articles addressed in this context include, among others, bracelets, piercing jewellery, and wristwatches. According to point 4, this restriction of lead does, however, not apply to lead used in internal components of watch timepieces that are inaccessible to consumers. [10]

Point 7 restricts the use of lead in articles and accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children, which does, however, not apply to articles in the scope of Directive 2011/65/EU (RoHS Directive).

The restriction of lead use in wristwatches (point 1 of entry 63) that qualify as EEE, even if it is applicable, is not relevant for the exemptions at hand since the focus of the review is their use in EEE of categories 8, 9 and 11 only while wristwatches are EEE of cat. 4 (consumer equipment) or possibly cat. 3 (IT and telecommunication equipment).

Legally, point 7 is not relevant either because articles/EEE in the scope of the RoHS Directive are excluded. Other restrictions of lead and its compounds in entry 63, like for example, lead in gunshots, are not applicable to EEE and its components and materials.

Entry 72

Entry 72 lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It stipulates that the substances listed in column 1 of the table in Appendix 12 shall not be used in textiles, clothing and footwear. The table lists lead and its compounds mentioned in entries 28, 29, 30 and Appendices 1-6.

The use of lead and its compounds in the exemptions to be reviewed is not related to textiles, clothing and footwear. Entry 72 is, therefore, not relevant.

The use of lead within the scope of the requested exemption does not regard paints or jewellery nor components that could be expected to be placed in the mouth by children under normal or foreseeable use. Furthermore, this use of lead is not a supply of lead compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, the above entries of Annex XVII of the REACH Regulation would not apply.

[10] Cf. Conditions of restriction for entry 63, https://echa.europa.eu/documents/10162/64e0e958-99c2-e75e-4fa8-d2b71b18f0b4)

No other entries with relevance for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status of these annexes, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

4.3. Mercury

Annex IX

There are no entries for mercury or its compounds.

Annex XVII

Annex XVII of the REACH Regulation contains several entries restricting the use of mercury and of mercury compounds.

Entry 18

Entry 18 restricts placing on the market, or use, as substances or in mixtures mercury compounds where the substance are intended for certain uses, e.g. in treatment of industrial sewage or for the impregnation of heavy-duty industrial textiles and yarn.

Mercury in the applications in scope of the requested exemption is not used for any of the above applications, and the restrictions are therefore not applicable.

Entry 18a

Entry 18a restricts the use of mercury in:

- *fever thermometers;*
- *other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers);*
- *a number of specified measuring devices intended for industrial and professional uses, in particular barometers, hygrometers, manometers, sphygmomanometers[11], strain gauges to be used with plethysmographs[12], tensiometers, thermometers and other non-electrical thermometric applications, mercury pycnometers and mercury metering devices for determination of the softening point.*

In the exemptions that were reviewed in pack 27, mercury is neither used in fever thermometers or other measuring devices for sale to the general public nor in the above devices for industrial and professional uses.

[11] Device used to measure blood pressure.

[12] Device for measuring changes in volume within an organ.

Entry 23

Entry 23 restricts the use of cadmium in certain types of plastics (see respective paragraph for cadmium in this chapter). This includes the cadmium compound "cadmium mercury red".

This substance is not relevant for the exemptions of pack 27.

Entry 30

This entry refers to substances which are

- *classified as reproductive toxicants in Part 3 of Annex VI to Regulation (EC) No 1272/2008, and*
- *listed in Appendices 5 or 6. The placing on the market, or use of various substances as such, as constituents of other substances, or in mixtures, for supply to the general public is restricted.*

Mercury is mentioned in appendix 6, as well as in part 3 of CLP-Annex V with the above-mentioned classifications.

The use of mercury or mercury compounds in exemptions to be reviewed do not imply the supply of mercury or mercury compounds as substances or mixtures to the general public. Cadmium or its compounds are used in articles, i.e. in electrical and electronic equipment.

Entry 62

Entry 62 lists several phenylmercury compounds[13]*.*

Phenylmercury compounds are not relevant for any of the exemptions in the scope of this review.

4.4. DEHP

Annex XIV

DEHP has been included in the SVHC REACH candidate list for the reason of being toxic for reproduction in 2008 and has been added to Annex XIV in 2012. In July 2017, DEHP has been additionally recognized for endocrine disrupting properties. Thus, DEHP as substance cannot be placed on the Union market or used after the 21 February 2015 (sunset date), unless an authorisation is granted.

The above stipulation is, in principle, relevant for the renewal of exemption IV-46 (phthalate (DEHP) in plastic components in MRI detector coils). Since the PVC material for the cable strain reliefs is supplied from outside the EU, Annex XIV is not relevant because the stipulation does not apply to imported articles into the EU.

[13] ECHA, https://echa.europa.eu/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

Annex XVII

DEHP is listed on Annex XVII.

Entry 30

Entry 30 (for details see above entry 30 for mercury) is relevant. DEHP is listed in Appendix 6, and in part 3 of CLP-Annex V due to its properties as reproductive toxicant. DEHP shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public.

The use of DEHP in exemption IV-46 does not imply the supply of such substances in any of the above described forms to the general public. DEHP is used in articles, i.e. in electrical and electronic equipment.

Entry 51

Clauses 1 and 2 stipulate that DEHP shall not be used as substances or in mixtures, individually or in an combination with the other phthalates listed in entry 51 (equivalent to those restricted under RoHS, status May 2024), in concentrations equal or greater than 0.1 % by weight of the plasticised material, in toys and childcare articles.
Toys and childcare articles containing DEHP in a concentration greater than 0.1 % by weight of the plasticized material shall not be placed on the market.

The exemptions at hand are not used in toys or childcare EEE so that the above stipulations are not relevant.

Clause 3 stipulates that DEHP shall not be placed on the market after 7 July 2020 in articles, individually or in any combination of the other phthalates that are also restricted under RoHS (DBP, BBP, DiBP) in a concentration equal to or greater than 0,1 % by weight of the plasticised material in the article.

The restriction of clause 3 does, however, not apply to medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof, and it shall not apply to electrical and electronic equipment within the scope of Directive 2011/65/EU (RoHS Directive).

Thus, the restriction for lead and it compounds in clause 3 is not relevant for the exemptions to be reviewed.

In the consultants' understanding, the restrictions for substances under entry 30 of Annex XVII do not apply. The supply of DEHP in plastic strain reliefs is in the consultants' point of view not a supply of DEHP as a substance, mixture or constituent of other mixtures to the general public. DEHP is part of an article and as such, entry 30 of Annex XVII of the REACH Regulation would not apply.

No other entries, relevant for the use of DEHP in the requested exemption could be identified in Annex XIV and Annex XVII (status May 2020). Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could, therefore be granted if other criteria of Art. 5(1)(a) apply.

5. Exemption 6(a)-series of Annex III: Lead as alloying element in steel

The below Table 5-1 shows the wording, scope and expiry dates of the exemption.

Table 5-1: Current wording of the exemption 6(a)-series

No.	Exemption	Scope and dates of applicability
6(a)	Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight	Applies to categories 8, 9 and 11 and expires on - on 21 July 2021 other than category 8 in vitro diagnostic medical devices and for category 9 other than industrial monitoring and control instruments. - on 21 July 2023 category 8 in vitro diagnostic medical devices - on 21 July 2024 for cat. 9 industrial monitoring and control instruments and for cat. 11
6(a)(I)	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	Expires on 21 July 2021 for categories 1-7 and 10

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

RoHS Restriction of Hazardous Substances in Electrical and Electronic Equipment

SEA socio-economic analysis

TMC Test & Measurement Coalition

UP 6(a) Umbrella Project Working Group 6(a)

WEEE Waste from Electrical and Electronic Equipment

5.1. Background and technical information

On 20 January 2023, (TMC 2023a) and (EUROMOT 2023a) requested the renewal of exemption III-6(a), as displayed in the table below.

Table 5-2: Requested renewals of exemption III-6(a)

Applicant	*Exemption*	*Scope and dates of applicability*
(TMC 2023a),[(TMC 2023b)]	*Lead as an alloying element in steel for machining purposes [and in galvanised steel] containing up to 0,35 % lead by weight*	*Applies to category 9 industrial monitoring and control instruments and expires on 21 July 2031 (= 2024 + 7 years).*
(EUROMOT 2023a) [(EUROMOT 2024b)]	*Lead as an alloying element in steel for machining purposes [and in galvanised steel] containing up to 0,35 % lead by weight*	*Applies to category 11 and expires on 21 July 2029 (= 2024 + 5 years)*

In their renewal request, (EUROMOT 2023a) and (TMC 2023a) apply for the renewal of exemption III-6(a) without galvanised steel being incorporated into the wording. In the clarification questionnaire, (TMC 2023b) state that they request the renewal of exemption 6(a) with “galvanised steel” included in the wording. In a corrigendum to the clarification questionnaire, (EUROMOT 2024b, S. 49–65)clarify that their renewal request shall also include galvanised steel.

(EPPA 2023) submitted a socioeconomic analysis (SEA) along with the TMC renewal request. (NAM 2023) *contributed a support letter to the renewal request of (EUROMOT 2023a),* is included in the list below, along with the nine contributions that were received during the consultation period for the exemption.

Table 5-3: Stakeholder contributions

Contributors	*Contribution/request*
(EGMF 2024)	*Letter of support for renewal request submitted by (EUROMOT 2023a)*
(JCB 2023)	
(EMA 2023)	
(Cummins 2023)	
(EUROPGEN 2023)	
(Volvo Penta 2023)	

(NAM 2023)	*Letter of support for renewal request submitted by (EUROMOT 2023a)*
(MTE 2023)	*Letter of support for exemption renewal requests submitted by 'Umbrella Project' in 2020 for "lead exemptions" including cat. 8* medical technology
(UP 6 (a) 2023)	*Objection against the split of exemptions recommended by (Baron et al. 2022)* and *request for extension of exemption III-6(a) for all categories of EEE for the maximum validity period.*

5.1.1. History of the exemption

When Directive 2002/95/EC (RoHS 1) was published in 2003, exemption 6 exempted the use of lead in steel. Following a review in 2009, exemption 6 was split into three exemptions 6a, 6b and 6c in order to cover lead in steel, aluminium and copper alloys with a separate wording, respectively. Exemption 6(a) covered the use of lead as an alloying element in steel for machining purposes and the presence of lead in galvanised steel. The exemption was transferred to Annex III of the current RoHS Directive 2011/65/EU, with its expiry dated for 21 July 2016. Ex. 6(a) was reviewed in 2015/16 by (Gensch et al. 2016), resulting in the currently (status February 2024) still valid exemption displayed in Table 5-4. Exemptions 6(a) and 6(a)(I) were reviewed then by (Baron et al. 2022), resulting in the below recommendation, including also the EEE of cat. 9 IMCI and cat. 11.

Table 5-4: Renewal of the current exemption 6(a) and 6(a)(i)

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

Source: (Baron et al. 2022)

5.1.2. Focus of the review of this renewal request

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status as of January 2024). The COM has

requested the consultants to assess in this current review round whether there are any substantial reasons in line with Art. 5(1)(a) against the adoption of the above recommendation of (Baron et al. 2022) for EEE of categories 9 and 11.

A re-evaluation of the previous review by (Baron et al. 2022) is not intended. The consultants rely on the critical review conducted by (Baron et al. 2022) and on the resulting conclusions and recommendations unless the renewal request gives reasons to reassess the state of science and technology.

5.1.3. Summary of the requested exemption

(TMC 2023a) explain that lead as an alloying element in steel containing up to 0.35% lead by weight is intrinsic for machining purposes in niche applications and as such, is used in numerous product groupings and equipment types of category 9 industrial monitoring and control instruments (IMCI)*. Alternatives to lead for all type 6 exemptions are in development. However, the manufacturers of Test & Measurement Instruments are not component manufacturers and need to rely on component manufacturer supplies of parts for 75%+ of the components in their instruments. As and when such alternative parts become available, they will be designed into new equipment that is developed in a cycle of 7-10 years, depending on the type of Category 9 equipment concerned. The applicants, therefore, believe a technical solution will and possibly is already available, but it needs to be implemented for the specific usage, tried by the downstream user (e.g., producer, manufacturer) of the component, and then tested in the full individual piece of equipment.*

(TMC 2023a) conclude that in consideration of the specific characteristics of Category 9 equipment and its long life span and development cycles, they apply for a renewal of the exemption 6(a) for the maximum validity period to allow for this process to take place.

According to (EUROMOT 2023a),lead is used in steel alloys as a machining aid to allow deep drilling and/or high-speed operations and to aid hot workability in a number of different components in internal combustion engines, associated components and end-products.

(EUROMOT 2023a) explain that their products are commonly used in highly demanding conditions, including exposure to contaminants, high vibration, and high mechanical loads while being required to operate for extended periods and sometimes without the opportunity for servicing of parts. Many of the applications are critical, such as back-up generators or operate in highly dangerous environments such as mining and construction. As a consequence of this, design changes to all components need to be rigorously formally assessed, especially as alternative alloys are not always identical drop-in replacements to the lead-based alloys.

Therefore, EUROMOT members always need to carry out research and testing to determine whether each potentially suitable substitute is able to offer the required technical performance. If the properties of the alternative alloy are significantly different such that either the engine design needs to change, or this could potentially affect reliability or emissions, then it may be necessary to gain approval for the engines made with alternative alloy parts as required by engine emissions legislation.

Alternative alloy compositions to include bismuth, increased sulphur (with and without tellurium), tin (with low and high copper), phosphorus and calcium give inferior performance. Bismuth especially has additional concerns regarding its environmental impact, which is worse than lead, and its availability.

EUROMOT indicate that they are making initial progress on developing alternatives, but additional time is required to undertake the necessary assessments and testing. Timescales vary between manufacturers due to the number of affected parts and the technical requirements of those parts and range between 5 and 7 years.

5.1.4. Technical description of the exemption and use of the restricted substance

This section provides the basic knowledge that is required to follow the applicant's arguments. The technical background is described in more detail by (Baron et al. 2022) and by (TMC 2023a) and (EUROMOT 2023a).

TMC explain that industrial test and measurement instruments (category 9 – Industrial under the RoHS Directive) are very different from low-mix, high-volume consumer products which are frequently re-designed to follow consumer trends and are placed on the market for a limited duration. Industrial test and measurement are high mix, low volume producers, managing portfolios of thousands of highly complex instruments. Each instrument is intentionally designed for high reliability and serviceability to support long useful lifespans, and are made available on the market for at least a decade. These instruments are designed: exclusively for professional and industrial use; to meet high performance requirements in critical applications; and last up to 40 years. Redesign is not frequent and happens every seven years on average (as compared to every 1.5 years or less for consumer products). Once test and measurement instruments are placed on the market, they are typically accompanied with a long-term customer support arrangement to maintain reliability and calibration.

Product portfolios are widely diversified, with TMC members each having typically 2,000 to 3,000 products currently on the market. These are highly complex, sophisticated electronic instruments, each having many necessary options and accessories. Each instrument can have a minimum of 2,000 and up to 40,000 parts; requiring a vast supply chain involving tens of thousands of suppliers and hundreds of thousands of unique components.

The full list of product groupings and equipment types relevant to exemption 6(a) is provided by (TMC 2023a). Examples of TMC products include:

- *Oscilloscopes, Analyzers & Meters including for instance Spectrum Analyzers (Signal Analyzers), Bit Error Ratio Testers, Noise Figure Analyzers and Noise Sources, Materials Test Equipment, etc.*
- *Generators, Sources and Power: including for instance Signal Generators (Signal Sources), Pulse Generator Products, HEV/EV/Grid Emulators and Test Systems, Source Measure Units, Sourcemeter, Sensitive Meter/Source etc.*
- *Wireless: including for instance Wireless Network Emulators, Channel Emulation Solutions, 5G OTA Chambers, Wireless Analyzers, IoT Regulatory Compliance Solutions, etc.*
- *Modular Instruments: including for instance PXI Products, Data Acquisition – DAQ, USB Products, etc.*
- *Network Test, Security & Network Visability: including for instance Protocol and Load Test, Network Test Hardware, 5G NR Base Station Test, Network Security, Application and Threat Intelligence, Cloud Visibility, Industrial Communications Hardware, etc.*
- *Application-Specific Test Systems and Components*

- *Photonic Test & Measurement Products*
- *Laser Interferometers and Calibration Systems: including for instance Monolithic Laser Combiners & Precision Optics, etc.*
- *In-Circuit Test Systems*
- *Used Equipment*
- *Bioprocessing Equipment Automation: including for instance Large Chambers, Mixers for Processing Drug Intermediaries*
  Laboratory Products: including for instance Autoclave Sterilizers, Biological Safety Cabinets, Blood Culturing Devices, Electrophoresis, Refrigerators, Freezers, Water Purification
  Chemical Analysis: including for instance Handheld XRF Analyzers, Dosemetry Personnel Contamination Monitors, etc.
- *Genetic Sciences: Gold Standard Products for COVID-19, PCR Testing Modules etc.*
  Other: including for instance Test and Measurement Upgrades and Accessories, Semiconductor Characterization System, Chromatography, Mass Spectrometry, etc.

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(EUROMOT 2023a) application concerns internal combustion engines, associated components and end-products in which these are used, under category 11. EUROMOT products are commonly used in highly demanding conditions including exposure to contaminants, high vibration, and high mechanical loads, while being required to operate for extended periods of time and sometimes without the opportunity for servicing of parts. Many of the applications are critical, such as back-up generators or operate in highly dangerous environments such as mining and construction.

Examples of steel parts used by EUROMOT's members and reliant on this exemption include:

• *Air compressors*
• *Air intakes and exhausts*
• *Alternator parts*
• *Bolts, nuts, screws*
• *Brackets, mechanical assemblies (e.g., flanges, blocks, rocker arms, tensioners)*
• *Component housings and covers (e.g., oil or fuel filter, heater, flywheel)*
• *Connectors, unions, and inserts*
• *Gaskets (e.g., cylinder head)*
• *Hose assembly components*
• *Parts of fuel filters*
• *Pumps and hydraulic components (e.g., valves, injectors, tubes, pipes, pistons, springs, stems, stators, yokes, nipples, armatures)*
• *Shaft, gears and shaft intake assemblies*
• *Spacers and fixings (e.g., spacers, plugs, sleeves, bushes, locking pins)*
• *Turbochargers.*

5.1.5. Amount(s) of restricted substance(s) used under the exemption

Category 9 IMCI

According to the SEA of (EPPA 2023), TMC members stressed that up to 35 % lead amounts *are used in their homogenous materials. The applicant mentions that category 9 – Industrial equipment contributes a fraction of one percent of the total annual quantities of RoHS substances. TMC indicates that the amount of substance entering the EU market annually through application for which the exemption is requested is approximately 9.82 kg.* No information was provided on how this amount was calculated.

Category 11

According to (EUROMOT 2023a) in 2013, the import of steel products for machining *purposes amounted to approximately 73,000 tonnes. EUROMOT does not have more recent figures specific to machining, however, EUROFER data on EU consumption levels of steel indicates that this has risen by 8.9 % over the course of 2013 to 2022.*

Assuming that the lead content in steel for machining purposes is between 0.2 and 0.35 %, this means that the lead annually entering the EU market through the import of free-cutting steels can vary between 159 and 278 tonnes for all uses. These figures do not correspond solely to steel intended for EEE (which it was not possible to estimate) and encompass steel intended for other applications, such as automotive applications.

(EUROMOT 2023a) underline that they have data only regarding their members' products only. Based on members' uses, the amount of lead from both free-machining and galvanised steels is estimated to be 700 kg per annum. It should be noted that this estimate is not for all of Category 11, which is unable to be calculated in part due to its less precise scope compared to other RoHS Categories.

5.2. Justification of the requested exemption

According to (TMC 2023a), industrial test and measurement instruments under category 9 are high mix, low volume producers, managing portfolios of thousands of highly complex instruments, each of which is intentionally designed for high reliability for long useful lifespans and available on the market for at least a decade. Lead as an alloying element in steel containing up to 0.35% lead by weight is intrinsic for machining purposes in niche applications and as such used in numerous product groupings and equipment types of category 9 Industrial Test & Measurement instruments.

Such instruments are designed exclusively for professional and industrial use and last up to 40 years. Redesign happens every seven years on average. According to (TMC 2023a), alternatives to lead for all type 6 exemptions are under development and are possibly already available in some cases. But once such alternatives become available, they will need to be implemented for the specific usage, tried by downstream users (e.g., producer, manufacturer) of the component, and then tested in the full individual piece of equipment. This process will require a cycle of 7-10 years depending on the type of category 9 equipment concerned. For these reasons, (TMC 2023a) applies for an extension of the current exemption.

As regards category 11, according to the application and information provided by (EUROMOT 2023a), lead is used in steel alloys as a machining aid to allow deep drilling and/or high-speed operations to aid hot workability in a number of different components in internal combustion engines, associated components and end-products. According to (EUROMOT 2023a), research on substitutes is ongoing but a number of technical issues continue to be raised making the substitution not immediately be possible from a technical perspective. The applicant therefore argues that additional time is required to undertake the required assessments and testing. (EUROMOT 2023a) therefore requests an extension of the current exemption.

5.2.1. Substitution and elimination of the restricted substance

(TMC 2023a) maintain that currently there are still no substitutes of lead as alloying element in steel for machining purposes available and tested that could be used for at least some current applications under this category. Nonetheless, the applicant states that alternatives to lead for all type 6 exemptions are in development. (TMC 2023a) argue that an extension of the existing exemption is required as such technical solutions will need to be implemented for the specific usage, tried by the downstream user (e.g., producer, manufacturer) of the component, and then tested in the full individual piece of equipment. According to the applicant, the process required for re-designing of the test and measurement equipment could take five to seven years.

For what concerns category 11, (EUROMOT 2023a) state that it is known that lead-free machining alloys are marketed by alloy manufacturers and are being used. However, these alloys are not always drop-in replacements to the lead-based alloys used in internal combustion engines, associated components, and end-products in which these are used. Therefore, it is always necessary for EUROMOT's members to carry out research and testing to determine whether each potentially viable substitute is suitable. Also, they mention that in case the properties of the alternative alloy are significantly different such that either the engine design needs to change, or this could potentially affect reliability or emissions, which may require to gain approval for the engines made with alternative alloy parts according to the EU engine emissions legislation. The applicant states that tests on non-leaded alternative grades (including bismuth, increased sulphur - with and without tellurium, tin - with low and high copper, phosphorus and calcium) generally gave inferior performance. (EUROMOT 2023a) indicate that bismuth is best able to substitute lead, however, the hot workability of bismuth steels is reduced compared to leaded steels. According to the applicant, this means that it is not possible for a steel roller to produce a bar with the same machining properties and surface integrity as steel containing lead. Therefore, the expected energy cost associated with bismuth is higher as well as potentially higher error rates leading to increased waste.

They also make reference to a comparative study of the machinability of different free cutting steels to realise their real behaviour and potential as alternatives to conventional steels, whose results showed that the presence of lead extended the tool life at low and medium cutting speeds between two and four times depending on the free-machining steel. (EUROMOT 2023a) also mentions that satisfactory machining results were obtained using CMnCr steel alloyed with 0.08 wt. % Bi however no comparison with leaded alloys was provided.

(EUROMOT 2023a) request a five-years extension as they argue that at least 5 years are expected to be necessary as if the properties of the alternative alloy are significantly

different such that either the engine design needs to change, or this could potentially affect reliability or emissions, then it may be necessary to gain approval for the engines made with alternative alloy parts as required by the EU engine emissions legislation. (EUROMOT 2023b) affirms that the (Baron et al. 2022) proposal would be suitable for 6(a)(I) relating to machining purposes if the extension is granted for 5 years. (EUROMOT 2024b) add that the same applies to 6(a)(II) relating to hot dip galvanised steel.

5.2.2. Environmental, health, safety and socioeconomic impacts

According to (EPPA 2023), the environmental impact of industrial test and measurement products is negligible. The participating companies have reported that changes in releases to the environment of lead will be unlikely during equipment production or use phases of the concerned products over the next seven years as a consequence of the revocation of the RoHS exemption. During equipment production, any discarded material is properly recycled. At component manufacturers, waste is controlled. Under normal conditions of equipment use, the lead content associated with the application of Annex III, exemption 6(a) is encapsulated within the equipment enclosure and will neither be touched nor released to the environment. As this equipment is sold B2B for professional/industrial use only, equipment that finally reaches end-of-life will be appropriately processed by professional recyclers who are obligated to have suitable controls to avoid any environmental releases and are notified of the presence of the substance under the producers' obligation to provide a SCIP notification.

As a result of the participating companies' relatively low consumption of parts, in comparison to the product Categories 1-7 and 10, renewing this exemption for Category 9 will have a minimal impact on the environment. (EPPA 2023) explain that Category 9 Industrial equipment's contribution to the waste electrical and electronic equipment is very limited (equivalent to 0.2% by weight of EU WEEE). Also, EPPA indicate that these test and measurement equipment enter typically the waste stream many decades after it is placed on the EU market. (EPPA 2023) explain that at this stage of the availability of alternatives, there is no material gain for the environment in restricting the alternative compared to the huge costs involved in gradual substitution of existing equipment.

According to (EUROMOT 2023a), bismuth raises concerns regarding its environmental impact, which is regarded as being worse than lead. Also, concerns are linked to its availability as this is a critical raw material existing in limited supply, mainly mined in China (approx. 80%) and imported in the EU. The applicant also suggests that expected energy cost associated with bismuth is higher as well as potentially higher error rates leading to increased waste. (EUROMOT 2023a) also recall that the previous Umbrella Project (UP) exemption request pointed out a number of benefits of using lead in free-machining steel, including: the addition of lead into low carbon free cutting steels enhances machinability and can increase the production rate of a component by up to 40% depending upon part and machining process design; and a potential reduction in energy usage of approximately 27% when machining parts using leaded versus non-leaded steel. As supporting evidence, (EUROMOT 2023a) cite the partial LCA previously provided by the Umbrella Project which they still considered valid although it did not cover end of life aspects.

As regards environmental and health impacts, (EUROMOT 2023a) argue that lead-free machining alloy alternatives also have larger negative impact on health compared to current lead-based alloys.

(TMC 2023b) state that its members have difficulty in understanding how the rewording and relisting and/or splits recommended by the consultants will lead to greater protection of human health and the environment compared to the wording in its current form.

In their SEA, (EPPA 2023) mention that the total impact of a non-renewal is monetized in the range of 2.1 billion EUR and 2.9 billion EUR (conservative estimates in net losses), consisting of economic impacts (EBIT loss) on test and measurement industrial type products' manufacturers; substitution costs for test and measurement industrial type products' manufacturers; and social impacts (i.e., unemployment in the EU-27).

Also, (TMC 2023b) emphasise the importance of retaining the initial wording and numbering as published in the original RoHS annexes. They argue that amending the scope of the exemption by changing the application or substance restriction value has a significant administrative burden to industry and negatively impacts the compliance.

(EUROMOT 2023a) state that should the exemption not be renewed, engine and end-product manufacturers would be forced to stop selling non-ROHS compliant products. They believe that the non-renewal of the extension could affect many types of end-users: they indicate that some industries, such as the ones in the construction sector, may not be able to operate because of the non-renewal of the extension as some essential equipment may not available. In case supply of emergency generators is affected, hospitals, for example, could suffer power cuts which may affect the health of patients.

Both applicants argue that the non-renewal of the extension would ultimately lead to job losses resulting from reduction in sales over the years.

5.2.3. Roadmap towards substitution or elimination of the restricted substance

As regards category 9 IMCI, (TMC 2023a) recognize that alternatives to lead for all 6(b) type exemptions are in development. As and when they become available, they will need to be designed for the specific usage, tried by downstream user (e.g., producer, manufacturer) of the component, and then tested in the full individual piece of equipment. (TMC 2023b) claim that as a result the substitution process to take a minimum of 5 to 7 years.

As regards category 11, (EUROMOT 2023a) have indicated that they are making initial progress on developing alternatives, but additional time is required to undertake the required assessments and testing. These timescales vary between manufacturers due to the number of affected parts and the technical requirements of those parts and ranges between 5 and 7 years.

5.3. Critical review

5.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds (cf. section 4.2 on page 51). None of these entries are, however, relevant for the use of lead in the scope of the exemption 6(a)-series in EEE of cat. 9 IMCI and 11.

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

5.3.2. Substitution and elimination of the restricted substance

Following the approach to assess whether the recommendation of (Baron et al. 2022) can be adopted to cat. 9 IMCI and cat. 11 in the light of applicants' arguments presented by (TMC 2023a) and (EUROMOT 2023a), it is worthwhile realizing the reasoning of (Baron et al. 2022) for their recommendation.

(Baron et al. 2022) concluded from the information made available during their review that substitutes are still under development, or design adjustments are necessary and/or the availability of substitutes is not sufficient to allow a quick transition of the whole EEE sector. For this reasons, (Baron et al. 2022) state that revoking the exemption would not be pragmatic as it would de facto require a transition in a very short time and is likely to result in withdraw of product.

(Baron et al. 2022) thus propose a short-termed exemption, which in their view would 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 communications. (Baron et al. 2022) conclude that in case the industry fails to provide sufficient and relevant data in the next assessment, it would be recommended to withdraw the exemption, possibly allowing a longer 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.

Based on the information provided through the two applications, possible alternatives are either still under development, or - when already available - they still require research, development and testing before they are ready to be used.

(TMC 2023a) explain that alternatives to lead for all 6(a) series exemptions are under development, but do not provide information on the actual status of development of such alternatives*.*

(EPPA 2023) mention they are not aware of specific alloys able to substitute all parts. According to the applicant "A single assessment of the performance of the alternatives is not possible because of the ubiquity of the alternative use. Each use must be considered in and of itself to validate if an alternative would work as well as or better than the component made currently using the exemption."

No additional information is offered as to concrete activities aimed at developing or testing such alternatives. The explanations and argumentation provided by the (TMC 2023a) are generic, and do not detail any information for specific applications.

(TMC 2023b) argue that lead as an alloying element in steel containing up to 0.35% lead by weight is intrinsic for machining purposes in niche applications and as such used in numerous product groupings and equipment types of category 9.

(EUROMOT 2023a) point out that the main supposed alternatives to lead are bismuth, increased sulphur (with and without tellurium), tin (with low and high copper), phosphorus and calcium.

(EUROMOT 2023a) explain that such alternative alloy compositions when tested gave inferior performance compared to lead. (EUROMOT 2023a) indicate bismuth as the best alternative solution, referring to test and research carried out by the Umbrella Project (UP) (2022), which concluded "that leaded steels showed the best performance in tests at lower cutting speeds, with high-speed steel tools and in deep hole drilling. Non-leaded alternative grades generally gave inferior performance However, EUROMOT point out that the hot workability of bismuth steels is reduced compared to leaded steels. They mention that the expected energy cost associated with bismuth is higher as well as potentially higher error rates leading to increased waste. (EUROMOT 2023a) refer also to other more recent studies which shows that research on substitutes is ongoing.

(EUROMOT 2023a) concludes that it is known that lead-free machining alloys are marketed by alloy manufacturers and are being used. However, these alloys are not always drop-in replacements to the lead-based alloys. Therefore, it is always necessary for EUROMOT's members to carry out research and testing to determine whether each potentially viable substitute is suitable.

The applicants do not provide specific information regards the application of lead-free steels for specific applications with specific requirements for potential lead-free steels. The situation reflects the consideration by (Baron et al. 2022) 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*."

5.3.3. Environmental, health, safety and socioeconomic impacts

(EPPA 2023) foresee severe socio-economic, health and safety consequences if the exemption is not renewed for cat. 9 IMCI.

As the consultants do not recommend revoking the exemption, or restricting its scope so that cat. 9 IMCI would be excluded, these consequences will not arise unless the COM decides otherwise.

(EUROMOT 2023a) *reference the LCA submitted by the Umbrella Project during the review of the exemption by* (Baron et al. 2022) *pointing out that lead-containing machining alloys have a higher environmental impact than lead-free machining alloys.* (Baron et al. 2022), however, rejected this LCA in the 2021/2022 review stating that 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 their view.

(EUROMOT 2023a) also foresee negative socio-economic, health and safety consequences. In case of non renewal of this exemption, engine and end-product manufacturers will be forced to stop selling products that do not comply with RoHS, with general severe impacts that "could affect many types of end-users" which the applicant is not in the position to detail "as is not known which products would be affected". Also, (EUROMOT 2023a) lament that "manufacturers of affected products would also be impacted with loss of jobs and "possibly some also by loss of competitiveness". Also, *(EUROMOT 2023a) states that should the exemption not be renewed, engine and end-product manufacturers would be forced to stop selling non-ROHS compliant products.*

EUROMOT did not provide quantitative impacts of possible socio-economic impact as they argue that, at this stage, it is not known which products would be affected.

5.3.4. Contributions to the stakeholder consultation

While the other stakeholder submitted letters in support of applicants' renewal requests, (UP 6 (a) 2023) (Umbrella Project Working Group 6(a) additionally contributed specific arguments for the renewal of the exemption which are discussed below.

(UP 6 (a) 2023) indicate that the use/presence of lead in galvanised steel is not addressed the renewal applications made by either EUROMOT or TMC. They strongly disagree that "no additional time is to be permitted for exemption 6(a)(II) so that it can expire in 2026 for cat. 11" and they understand that this was not the intention of these Pack 27 renewal applications. (UP 6 (a) 2023) underline that the technical situation for lead in galvanized steel is largely unchanged from the situation reviewed by (Baron 2022a) and it would be the intention of the Umbrella Project to seek to further renew this Exemption 6(a)(II) dependent on the timing of the Commission response to the current application. That application would likely include all categories, including 9 and 11. In fact, Category 11 is the most relevant for the exemption 6(a)(II).

The above comment refers to the renewal requests of EUROMOT et al. and TMC for exemption 6(a) which did not include galvanised steel. Both applicants amended their renewal requests to include galvanised steel (cf. Table 5-4 Renewal of the current exemption 6(a) and 6(a)(I) on page 59).

(UP 6 (a) 2023) propose that all EEE Categories and subcategories covered under Ex. 6(a) (all Cat. 8, Cat. 9 and Cat 11 EEE Categories and subcategories under scope of Ex. 6(a) would be merged into the current Ex. 6(a)-I in the future (which would then be valid for All EEE Categories and subcategories 1 - 11), with the following proposed wording for All EEE

Categories and subcategories 1 - 11: "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". The validity of this exemption should be extended for all categories of EEE for the maximum validity periods.

They consider that (Baron et al. 2022) proposal to split the exemption 6a into 6(a)-I and 6(a)-II would generate administrative burden with no benefit for the environment and human health. They underline that the reason for their proposal is mainly related to the substitution issue on which UP are still working and need additional time to conduct and finalise research.

UP is invited to submit the above proposal for the next review of the exemption 6(a)-series. The consultants' mandate for this review of the exemptions is focused to assess whether the proposal of (Baron et al. 2022) can be adopted for cat. 9 IMCI and for cat. 11.

(UP 6 (a) 2023) indicate that they are aware of lead-free substitutes being used in EEE of cat. 11 and in general. Not only for substitutes used in cat. 11, but used in general, they do not have enough information so far for instance on 11SMn30-EM + C as a possible alternative, so they cannot conclude if it can be used for all specific applications. Between different other alternatives, they mention that bismuth has been able to substitute for lead under certain conditions, although the reduced hot ductility and the increased cost of Bi addition may make it uneconomic, particularly for large scale applications. (UP 6 (a) 2023) also mention a study of 2005 that shows that 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. (UP 6 (a) 2023) also reference life cycle assessments which in their view show that the use of lead is environmentally preferable compared to lead substitutes.

UP 6(a) submitted the above information already to the previous review of the exemption where its was discussed by (Baron et al. 2022) who still recommended to renew the 6(a)-series exemptions as displayed in Table 5-4 on page 59. The consultants therefore see the above comments to be considered in that recommendation.

5.3.5. Summary and conclusions

Article 5(1)(a) ROHS 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.

Following their mandate for this exemption, the consultants assessed whether the result of the previous review of this exemption by can be adopted for cat. 9 industrial monitoring and control instruments (IMCI) and cat. 11 in the light of the applications at hand. (TMC 2023a) and (EUROMOT 2023a) request the renewal of exemption 6(a) for the maximum validity periods of 7 and 5 years, respectively.

(TMC 2023b) argue that no lead-free alternatives are currently available, and once they will be available, five to seven years will be required for their qualification to ensure their testing and reliable functioning in cat. 9 IMCI.

(EUROMOT 2023a) claim that tests on non-leaded alternative grades of lead-free steels for machining purposes (including bismuth, and others) generally gave inferior performance, and hot workability of bismuth steels is reduced compared to leaded steels.

Both applicants' arguments are general rather than providing application-specific information as to the status of lead-free steel alloys in different fields of applications in cat. 9 IMCI and cat. 11. In the evaluation by (Baron et al. 2022), the applicants presented similarly general and unspecific arguments as to the scientific and technical status concerning the practicability of lead substitution or elimination. This situation caused (Baron et al. 2022) to recommend the renewal of the exemption only for a short period for all categories of EEE in order to point out to the industry that the information has to be updated and that support in phasing out the exemption is expected. The parallel review for all categories would, in their view, avoid future co-existence of several sub-items with slightly different scopes and align the expiry dates, and motivate producers of EEE to provide information for the specification and possibly restriction of the exemption scope.

(Baron et al. 2022) recommended the expiry of exemption 6(a) and integrating cat. 9 IMCI and cat. 11 into the renewed exemptions 6(a)(I) and 6(a)(II). In the light of the above, the applicants were asked whether they would agree to follow this recommendation.

(EUROMOT 2023b) agree with (Baron et al. 2022) proposal under the condition that the expiration dates of both exemptions are extended for 5 years, as they state that EUROMOT's members need to carry out research and testing to determine whether each potentially viable substitute is suitable.

(TMC 2023b) do not agree with the proposal of (Baron et al. 2022) and insisted on the renewal of the exemption in its current wording and numbering as published in the RoHS annexes until 21 July 2031. (TMC 2023b) underline that amending the scope of the exemption by changing the application or substance restriction value has a significant administrative burden to industry and negatively impacts the compliance.

Overall, the consultants could not identify technical aspects suggesting that the approach proposed by (Baron et al. 2022) could not be followed for cat. 9 IMCI and cat. 11. On this ground, it can be concluded that substitution and elimination of lead are currently still scientifically and technically impracticable so that the renewal of the exemptions for cat.9 IMCI and cat.11 can be justified by Art. 5(1)(a).

5.4. Recommendation

The consultants conclude from the available information that the approach proposed by (Baron et al. 2022) can be adopted for cat. 9 IMCI and cat. 11. If the COM decides to follow the proposed approach, the consultants recommend the below wording and expiry dates.

No.	Exemption	Scope and dates of applicability
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	Applies to categories 8, 9 and 11. Expires on 21 July 2023 for category 8 in vitro diagnostic medical devices. Expires on 21 July 2024 for cat. 9 industrial monitoring and control instruments and for cat. 11
6(a)(I)	Lead as an alloying element in steel for machining purposes containing up to 0,35 % lead by weight	Applies to - categories 1-7 and 10. - from [expiry date of exemption 6(a) + 1 day] on to categories 9 industrial monitoring and control instruments, and to category 11 Expires on 21 July 2024 for categories 1 to 11.
6(a)(II)	Lead in batch hot dip galvanised steel components containing up to 0,2 % lead by weight	Applies to - categories 1-7 and 10. - from [expiry date of exemption 6(a) + 1 day] on to categories 9 industrial monitoring and control instruments, and to category 11 Expires on 21 July 2026 for categories 1 to 11.

This transfer of cat. 9 IMCI and cat. 11 from exemption 6(a) formally can be understood as a rejection of the applicants' renewal request for exemption 6(a) with the consequence that the exemption expires for cat. 9 IMCI and cat. 11. If the COM follows this interpretation, a transition period is to be granted according to Art. 5(6). The consultants recommend 12 months of transition to allow for administrative adaptations since no actual scope restriction is linked to this shift.

The COM should leave sufficient time for the preparation and timely submission of renewal requests between the official publication of their decision as to the renewal of the exemptions and their expiry.

The adverse socioeconomic impacts assessed by EPPA will not arise until 2026 since the consultants do not recommend revoking the exemption. TMC will, however, have to bear the cost for preparing and processing a renewal request prior to 2031, which they requested as expiry date in their current renewal request.

5.4.1. Applicants' feedback on the recommendation

(TMC 2024) do not agree with the recommendation reiterating that they applied for the renewal of exemption III-6(a) in its current wording for the maximum validity period of 7 years. (EUROMOT 2024b) underline that their preferred option for renewal would be the expiry date in 2029.

The consultants are confident that they considered all relevant arguments made available by applicants and stakeholders during the review, and that the arguments have been

evaluated taking into account the requirements of Art. 5(1)(a) and the mandate commissioned by the COM for the review of this exemption.

5.5. References

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6. Exemption 6(b)-series of Annex III: Lead in aluminium alloys

The below Table 6-1 shows the wording, scope and expiry dates of the exemption.

Table 6-1: Current wording of the exemption 6(b)-series

No.	Exemption	Scope and dates of applicability
III-6(b)	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight	Applies to categories 8, 9 and 11, and expires on - 21 July 2021 for cat. 8 other than in-vitro diagnostic medical devices, and cat. 9 other than industrial monitoring and control instruments - 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
III-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 on 21 July 2021 for categories 1-7 and 10
III-6(b)-II	Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight	Expires on 18 May 2021 for categories 1-7 and 10

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
RoHS 1	Directive 2002/95/EC

6.1. Background and technical information

On 20 January 2023, (TMC 2023a) submitted a request for renewal of exemption III-6(b) for EEE of category 9 industrial monitoring and control instruments (IMCI) in its current wording for the maximum validity period.

Table 6-2: Exemption renewals requested by TMC

No.	*Requested exemption*	*Requested scope and dates of applicability*
III-6(b)	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight	*Applies to category 9 monitoring and control instruments and expires on 21 July 2031*

On 20 January 2023, (EUROMOT 2023a) submitted a request for the renewal of exemption III-6(b) and III-6(b)(I) for category 11. On the same day, (EUROMOT 2023b) submitted another request for the renewal of exemptions III-6(b) and III-6(b)(II) for EEE category 11. The below table reflects EUROMOT's exemption requests.

Table 6-3: Exemption renewals requested by EUROMOT

No.	*Requested exemption*	*Requested scope and dates of applicability*
III-6(b)	*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 on 21 July 2029 (= 2024 + 5 years) for cat. 11*
III-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*	*Applies to category 11 from 22 July 2024 on and expires on 21 July 2029 (= 2024 + 5 years)*
III-6(b)(II)	*Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight*	*Applies to cat. 11 from 22 July 2024 on and expires on 21 July 2029 (= 2024 + 5 years)*

(EPPA 2023) submitted a socioeconomic impact assessment (SEA) along with their renewal request. (NAM 2023) submitted a letter of support along with the EUROMOT renewal request. Their contribution was added to the below table which summarises the contributions submitted during the consultation period.

Table 6-4: Stakeholders' contributions

Contributors	*Contribution/request*
(Copreci S Coop 2023)	Letter of support for renewal requests submitted by (EUROMOT 2023a) and (EUROMOT 2023b)
(NAM 2023)	
(JCB Power System 2023)	
(Deutz AG 2023)	
(The Truck and Engine Manufacturers Association (EMA) 2023)	
(Volvo Penta 2023)	
(EuropeGen 2023)	
(Cummins 2023)	
(EGMF 2024)	
(APPLiA Italia 2023)	Express their support to the agreement of (EUROMOT 2023c) that exemption 6(b)(IV) proposed as renewal of exemption 6(b)(II) (cf. Table 6-5) is applicable to cat. 11 provided it will remain valid until 2029. Both stakeholders request this expiry date of exemption 6(b)(IV) to be applied to EEE of categories 1 and 2 as well.
(Afecor 2023)	

6.1.1. History of the exemption

The predecessor exemption of the current 6(b) series exemptions was already listed on the Annex of (European Union 13.02.2003) when it was published in 2003:

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.

According to (Baron et al. 2022a), following an assessment in 2009, exemption 6 was split into three exemptions 6a, 6b and 6c in order to cover the use of lead in steel, aluminium and copper alloys with a separate wording respectively. Exemption 6(b) was reformulated again after its last review by (Gensch et al. 2006), which resulted in the current architecture and wordings of the exemption 6(b) series.

The exemption was reviewed by (Baron et al. 2022a) for all categories of EEE including cat. 9 industrial monitoring and control instruments (IMCI) even though the exemption would have expired on 21 July 2024 only. (Baron et al. 2022a) recommended the architecture and wordings for the exemption 6(b) series as displayed in the below table.

Table 6-5: Renewal of current exemption 6(b) series recommended by (Baron et al. 2022a)

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

Source: (Baron et al. 2022a)

6.1.2. Focus of the review of this renewal request

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation. The COM required to assess in this current review round whether there are any substantial reasons in line with Art. 5(1)(a) against the adoption of the above recommendation for EEE of categories 8, 9 and 11.

Unless the review shows that the applicants' arguments justify a different approach, the consultants would therefore prefer recommending the wordings of III-6(b)(III) and III-6(b)(IV). The expiry dates may be adapted to the specific situation of cat. 9 IMCI and cat. 11

in the scope of the renewal requests where the expiry dates and the underlying approaches proposed by the previous reviewers may not be applicable.

6.1.3. Summary of the requested exemption

TMC (cat. 9 IMCI)

In (TMC 2023a) it is reported that: *Lead as an alloying element in aluminium containing up to 0.4% lead by weight is intrinsic for machining purposes in niche applications. Aluminium alloys (containing lead) are used to make a very wide range of categories 9 industrial EEE products, parts, and product components. As further outlined in [TMC] submission, alternatives to lead for all type 6 exemptions are in development. However, the manufacturers of Test & Measurement Instruments are not component manufacturers and need to rely on component manufacturer supplies of parts for 75%+ of the components in their instruments. As and when such alternative parts become available, they will be designed into new equipment that is developed in a cycle of 7-10 years depending on the type of Category 9 equipment concerned. The applicants therefore believe a technical solution will and possibly is already available, but it needs to be implemented for the specific usage, tried by the downstream user (e.g., producer, manufacturer) of the component, and then tested in the full individual piece of equipment. Given the specific characteristics of Category 9 equipment and its long-life span and development cycles, the Test & Measurement Coalition applies for a renewal of the exemption 6(b) for the maximum validity period to allow for this process to take place.*

According to the socio-economic analysis conducted by TMC, *the total impact of non-renewal of this exemption is monetized in the range of 2 billion EUR and 2.8 billion EUR (conservative lower bound estimate).*

EUROMOT (cat 11)

According to (EUROMOT 2023a): *Lead is present as an impurity in aluminium up to 0.4% by weight whose removal or dilution would have a significant negative environmental and health impact. Although there is the trend of reducing lead content in some alloy specifications, some specifications still permit >0.3% lead which are utilised in EUROMOT members parts. Parts with up to 0.4% lead are still used by EUROMOT members as they produce special types of engines some of which are sold annually in only small numbers, as few as one or two per year. Stocks of parts for these special types of engines may last for up to seven years before they are consumed, and new batches of parts are obtained. Some of the parts currently in stock contain between 0.3% and 0.4% lead and so manufacturers need this exemption to allow up to 0.4% lead until these parts are used in finished products that are placed on the market. Without the continuation of the exemption these parts will become waste and have to be disposed of and replaced which has a considerable environmental impact.*

In addition, (EUROMOT 2023b) provides the following summary of the requested exemption: Lead is added to aluminium components used in internal combustion engines, associated components and end-products in which these are used mostly to achieve superior machinability by aiding chip fracturing and improved surface finish. Lead also aids in anodisation and extrusion performance, electrical conductivity, corrosion resistance and other mechanical properties. Leads inclusion in aluminium allows the manufacture of lightweight, intricately shaped parts which is especially important for the many very small and light weight parts used in engines. Although there are lead-free alternatives, they are

not always identical drop-in replacements to the lead-based alloys. Therefore it is always necessary for EUROMOT's members to carry out research and testing to determine whether each potentially suitable substitute offer the necessary technical performance. Material testing and development activities take many years to complete and so far is incomplete. The time required by manufacturer varies from five to eight years.

Bismuth is commonly used as an alternative to lead, however it has significantly more negative impact than lead. EUROMOT members also have machined parts which are kept in stock, but not yet placed on the market which without the exemption will become waste and have to be disposed of and replaced.

6.1.4. Technical description of the exemption and use of the restricted substance

The technical background is described in more detail by (Baron et al. 2022b)

6.1.5. Amount(s) of restricted substance(s) used under the exemption

TMC (cat. 9 IMCI)

According to (TMC 2023b): *the surveyed companies stressed that the content of substance in homogeneous material is highly variable. Based on literature review, contacts in electrical switching devices typically contain less than 0.4% lead in the homogeneous material. Overall, through application for which the exemption is requested (cat 9 IMCI), approximately 1.80 kg of Pb enters the EEA market every year.*

EUROMOT (cat. 11)

In (EUROMOT 2023a) and (EUROMOT 2023b), two EUROMOT members provided data for III-6(b)-I and III-6(b)II, relevant to cat 11, as detailed below.

Manufacturer A: Figures for 6b (not differentiated for 6bI and 6bII).

Total of lead in aluminium parts containing >0.1% lead in one typical engine: 233 grams.

Based on the 20131 EUROMOT 68,000 engines are in scope of RoHS sold in the EU and EUROMOT stated in its 2017 lead in sensor request that this figure was unchanged. As such there is 15.84 tonnes placed on the EU + UK market annually. The UK is 7.42% of the EU sales quantity according to Power Systems Research with 2021 information. As such this manufacturer estimates the amount of lead placed on the EU market annually is 14.67 tonnes from both 6bI and 6bII.

Manufacturer B: Provided information for genset engines in range 250 – 550kVA.

This manufacturer estimated that for 6(b)-I they place 60kg of lead annually on the market combined EU and UK market. Based on their estimated market share of 30%, the amount of lead placed on the market by all manufactures would be 200kg.

250 – 550kVA range accounts for 6% of total gensets, therefore using EUROMOTs estimates for EU (excluding the UK) market (also considering Power Systems Research with 2021 information that the UK accounts for 7.42% of EU sales). As such, based on this manufacturers estimation the annual amount placed on the EU market for 6(b)-I is 3.08 tonnes.

This manufacturer estimates for 6(b)-II they place 150 kg of lead annually on the EU and UK market. Following the same methodology as outlined above, this would result in 500kg of lead placed on the EU and UK market for genset engines in range 250 – 500kVA. Therefore, the total amount of lead placed on the EU market for all manufacturers is 7.71 tonnes for exemption 6b-II.

As such the combined value for 6bI + 6bII total is 10.8 tonnes

6.2. Justification of the requested exemption

6.2.1. Substitution and elimination of the restricted substance

TMC (cat. 9 IMCI)

According to (TMC 2023a), *alternative to lead for all types of 6(x) exemptions, including 6(b), are in development. While the applicant needs to rely on component manufacturer supplies of parts for 75%+ of the components of their instruments, they believe it is likely that component manufacturers will gradually make available workable alternatives to the lead containing parts currently on the market. And if such parts become available, they will be designed into new equipment that is developed in a cycle of 7-10 years depending on the type of Cat. 9 equipment involved*.

The applicants therefore believe a technical solution will and possibly is already available, but it needs to be implemented for the specific usage, tried by the downstream user (e.g., producer, manufacturer) of the component, and then tested in the full individual piece of equipment. Given the specific characteristics of Category 9 equipment and its long-life span and development cycles, the Test & Measurement Coalition applies for a renewal of the exemption 6(b) for the maximum validity period to allow for this process to take place.

EUROMOT (cat. 11)

According to (EUROMOT 2023a), three options are considered as possible alterative applications or alternatives for use of RoHS substances: *1) Lead removal from aluminium alloy; 2) use of primary metal to dilute lead concentration; 3) achieving a lower lead content in refined scrap metal.*

Moreover, in (EUROMOT 2023b) it states that *it is always necessary for EUROMOT's members to carry out research and testing to determine whether each potentially suitable substitute is suitable […] Many lead-free substitute alloys contain tin, but alloys containing tin often cannot be used in engines because tin is known to cause cracking in machined parts when subjected to stress and high temperature, both of which can be common in engines. The most commonly used machining aid apart from tin is bismuth, although it is very different from lead […] The LCA provided by the Umbrella project to support renewal of exemption 6(b) does show that bismuth has significantly more negative impacts then lead.*

6.2.2. Environmental, health, safety and socio-economic impacts

TMC (cat. 9 IMCI)

(TMC 2023b) aims at demonstrating that the non-renewal of the exemption would have disproportionate negative impacts on society when compared with the risk to human health, animal health or the environment.

The total monetized impact of non-renewal is estimated in the range of 2 billion EUR and 2.8 billion EUR – the analysis includes confidential data with regard to detailed costs related to test and measurement of industrial product type manufacturers; substitution costs; social impact deriving from unemployment; also mentioning that this is a conservative estimate.

In terms of business and market impacts, a non-renewal would constraint most of the companies currently supplying RoHS-based test and measurement industrial products to cease production and business activities of all products that include lead.

EUROMOT (cat. 11)

Also (EUROMOT 2023b) elaborated on the possible impacts of the non-renewal of the exemption. *The use of substitutes, such as bismuth, as also assessed in the LCA provided by the Umbrella project to support renewal of exemption 6(b), has significantly more negative impacts than lead and EUROMOT requests that this is taken into account.*

Another environmental issue that specifically affects EUROMOT's members is that they manufacture many special types of engines some of which are sold annually in only small numbers, as few as one or two per year. However, the machined parts that are used to make these are made in moderately large numbers either by the engine manufacturers or by their suppliers and then kept in stock until needed. Stocks of parts for these special types of engines may last for up to seven years before they are consumed, and new batches of parts are obtained. This exemption will be needed to allow those parts that have already been made to be used in finished products that are placed on the market, otherwise, they will become waste and have to be disposed of and replaced.

Another argument is that: *if this exemption is not renewed, engine and end-product manufacturers will be forced to stop selling products that do not comply with RoHS. At this stage, it is not known which products will be affected but this is likely to affect many types of end-users. For example, construction and other industries may not be able to operate if essential equipment is not available. If emergency generators are affected, this may affect, for example, hospitals who use these when there are power cuts. Unavailability will either pose a safety risk during essential surgical operations and will pose a risk to patient's survival or these operations and also other medical procedures (such as MRI examinations and monitoring patients in intensive care) may not be possible if emergency generators are not available.*

(EUROMOT 2023a) also makes reference to environmental and health impact related to the use of primary instead of secondary aluminium. If the secondary alloys cannot be used due to lead restriction, then primary metal will be needed to dilute the lead content. But use of primary aluminium foresees 18 times more energy and its associated impacts on global warming, hazardous substance emissions etc. Considering all lifecycle phases, reuse of secondary aluminium will have the least impact on health and the environment.

6.2.3. Roadmap towards substitution or elimination of the restricted substance

TMC (cat. 9 IMCI)

(TMC 2023a) refer that the companies have indicated that there are currently no suitable alternatives that meet the performance expectations of their customers. However, it is foreseeable that such alternatives will be made available in the coming years but the implementation for the different uses will be very gradual and implementation is not likely to be linear. Members of the Test & Measurement Coalition have pointed out that they principally rely on their component suppliers to find alternatives since most of the exemptions used in those components are not produced by the supplier but are bought off-the-shelf from their suppliers. As such, this part of the supply chain are slower and more inconsistently able to adapt. Assuring full adaption in the supply chain and validating the alternatives in the final product application can and often does require up to 4 years.

If a new substance-free part is available from a supplier, this part must be qualified for use by the Category 9 manufacturer by performing a variety of additional tasks. Due to the complexity and diversity of the applications, this must be done individually by each company for each product group. This process diverts resources from other projects and increases the cost to ensure continued availability of these products. This validation and testing process varies according to part complexity; which can be categorised as low, medium, and high:

- *Low complexity parts are the off-the-shelf components or hardware parts that do not have a substantial performance impact. Replacement can be done based on supplier information, assuming a form/fit/function compliance, with standard manufacturing, testing, and validation processes. Based on process timescales reported by a TMC coalition company, the average time that it can take for these parts to be replaced ranges from 3 to 6 months.*
- *Medium complexity parts are more complex sub-assembly electronic parts, such as small motors, which need additional validation for their performance. These parts are often commercial assemblies that are generally available to the electronic industry and are utilised by the TMC companies. Replacement of these assemblies, like-for-like, requires testing and validation prior to integration into the manufacturing process. The average time to find an alternative for medium complexity parts for production is reported to range from 6 to 12 months.*
- *High Complexity parts are the complex sub-assemblies or parts that have a significant impact on performance of the company's products or play a critical role in overall safety of the products. These parts need to go through extensive validation for performance and/or compliances for varying regulations before the appropriate files can be updated and the proper competent authorities or regulatory bodies can be notified prior to purchase of parts for validation. The average time that it would take to find an alternative for high complexity parts for production is up to 1 year for additional testing. Where the exemption directly impacts the performance of that component (e.g., a centrifuge rotor) the evaluation of the replacement could take from 3 to 5 years.*

What makes substituting exemption 6(b) challenging is the ubiquity of the application of the exemption. Below it is reported a graphic summarizing the substitution milestones:

Figure 6-1: Roll out of compliant equipment

Source : (TMC 2023a)

According to (TMC 2023a), the conclusion on the suitability and availability of alternatives is that whilst substitution is possible, it will require time. Time that is likely to exceed the redesign cycle of equipment which as of today are already being developed without use of the exemption. There is therefore a continued need for a 7-year additional exemption for Category 9 to allow the phasing out of the older equipment for newly designed ones which are lead-free.

<u>EUROMOT (cat. 11)</u>

In their application for exemption III-6(b)(I), (EUROMOT 2023a) refers that once manufacturers have identified parts that use alloys with 0.3% – 0.4% lead, they will need to carry out the following work:

Determine whether the alloy currently used can be sourced with <0.3% lead and whether this will affect essential performance requirements. This may be possible by either sourcing the component from a different supplier, or by the current supplier selecting batches of scrap metal with lower lead content after chemical analysis. The latter option may not always be possible as suppliers may not be willing to do this if most of their production is for products excluded from the RoHS Directive.

If it is not possible to guarantee that the currently used alloy will always contain <0.3% lead, if the alloy specification does not limit lead to this value or below. As all alloys have slightly different performance and properties, assessment and testing of prototypes will be required. The timescale will vary depending on how significant the changes and the types of engine and the end-uses are. This will involve some or all of the following:

- *Selection of alloys based on published properties*
- *Production of prototype parts and laboratory testing to determine suitability*
- *Re-tooling if required, selection and approval of new suppliers, etc.*
- *Construction of engines using prototype parts and bench testing to determine reliability*

- *Field trials in end-use equipment*
- *If substitute alloys require significant changes, such as re-design, then approvals under the NRMM Emissions legislation will be required. This will take as long as it takes for a new engine design.*

The timescales for these stages vary between 18 months and eight years depending on the type of component.

- *Timescales for above:*
  - *Without NRMM Emissions Regulation re-approval up to seven years*
  - *With approvals eight years. This may be longer as approvals will be required globally as usually each design of engine is sold world-wide, not only in the EU.*
  - *As a minimum, to consume existing stocks of components, an additional 7 years is required from the date when substitutes with verified reliability are available.*
  - *In addition, in its application for exemption 6(b)-II, EUROMOT refers that the following will be required before lead-free substitute parts can be used in end-equipment. This work is required before modified engines can be sold in the EU and in the UK. It may also be necessary for much lengthier trials to be carried out to comply with emissions legislation. The current situation is that each EUROMOT member may use up to several hundred of machined aluminium parts. Research will be needed with each part to:*

1. Confirm which parts are currently made using a lead-based alloy.

2. Identify one or more lead-free substitute alloys that have comparable properties and performance and appear to meet any essential technical requirements. Any heat treatment requirements would also need to be investigated at this stage. These requirements will depend on the specific applications of the component and where the end-products are used. Any one part is likely to be used in several end-products and be used under a variety of environmental conditions.

3. Make prototype parts and assess for quality, dimensional accuracy, surface finish, strength, corrosion resistance and any other property that is essential for the parts made using this alloy. Specific heat treatments may also need to be investigated to identify suitable processes.

4. Reliability testing. These are in-house tests carried out to ensure that parts are suitable and meet manufacturer's specifications.

5. If a change to the alloy is not trivial (e.g. if the properties are different or a design change is needed), it is likely that manufacturers will need to build prototype engines using new parts and test these. This is because they have found previously that laboratory testing does not always identify long term field failure issues, which are identified only when tested in real engines.

6. If necessary, testing of modified engines to comply with the NRMM Emissions Regulations

7. Request re-approvals if necessary. Changing some components such as throttle and control units will require re-certification as these are essential components for granting of emissions certificates.

The time required for all of the above for each manufacturer will depend on how many lead-based alloy parts are identified, how successful is the work to identify suitable substitutes and if re-certification are needed.

The predicted timescales for these activities to be fully completed are between 5-8 years, depending on the types of component each manufacturer uses and the changes and testing that are required for each component.

6.3. Critical review

6.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds (cf. section 4.2 on page 51). None of these entries are, however, relevant for the use of lead in the scope of the exemption 6(b)-series in EEE of cat. 9 IMCI and 11.

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

6.3.2. Substitution and elimination of the restricted substance

Both applicants apply for the renewal of exemption 6(b), and EUROMOT additionally for the renewal of exemptions 6(b)(I) and 6(b)(II). Following their mandate, the consultants assessed whether the recommendations for the renewal of exemptions 6(b), 6(b)(I) and 6(b)(II) as exemptions 6(b)(III) and 6(b)(IV) recommended by (Baron et al. 2022a) (cf. Table 6-5 on page 78) can be adopted for cat. 9 IMCI and cat. 11 in the light of their renewal requests.

Renewal of exemption 6(b) and 6(b)(II) as exemption 6(b)(IV)[14]

TMC (cat. 9 IMCI)

(TMC 2023c) do not agree to adopt the recommendation of (Baron et al. 2022a) to cat. 9 IMCI.

They stated that *lead as an alloying element in aluminium containing up to 0.4% lead by weight is intrinsic for machining purposes in niche applications. Aluminium alloys (containing lead) are used to make a very wide range of category 9 IMCI, parts, and components.* In the context of adopting the recommended renewed exemption 6(b)(IV) for cat. 9 IMCI, TMC (2023c) stated that *"[…] alternatives to lead for all type 6 exemptions are in development [...] As and when such alternative parts become available, they will be designed into new equipment that is developed in a cycle of 7-10 years depending on the type of category 9 equipment concerned. The applicants therefore believe a technical solution will be forthcoming and is possibly already available in some cases, but it needs to be implemented for the specific usage, tried by downstream user (e.g., producer, manufacturer) of the component, and then tested in the full individual piece of equipment".*

However, (Baron et al. 2022a) refer in the context of exemption III-6(b)(IV) 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.*

Moreover, the 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. 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".

On this basis, TMC was asked to provide examples of specific cases where lead-free aluminium alloys are readily available but are not applicable for cat 9 IMCI. However, no specific examples were provided. *(TMC 2024) reiterated that the reliability of substitution has not been ensured for all parts made of this material.*

It can therefore be concluded that TMC does not know of any specific cases where substitutes would not be available. The consultants also asked to further explain why, considering that substitutes were already present on the market when the last review was carried out in 2016, still seven to ten years are required to design alternatives into new equipment around eight years later, and why this process was not started earlier already.

(TMC 2024) mentioned that detailed examples are listed in their SEA, associated with the scale of the equipment portfolios, active life of equipment, and detailed breakdowns of the steps required to assure the reliability of substitution in cat 9 IMCI.

By double checking (TMC 2023b), the consultants found out rather general descriptions, mentioning that each TMC member typically has between 2-3,000 products available on the

[14] The adoption of 6(b)(IV) for cat. 9 IMCI and cat. 11 implies that the wording would be adapted to allow the integration of these two categories of EEE into the exemption scope.

market – which are highly complex, sophisticated electronic instruments (e.g. signal generators, power analysers, oscilloscopes, spectrum analysers etc.) and each instrument can have up to 40,000 parts. However, we could not find technical specification on the reasons why the revising of the portfolio products have not started already – at least for some of them. The lack of examples makes it difficult to assess the reasons why alternatives have not been integrated yet, considering that substitutes were already present on the market during the last review. The consultants can, however, follow that the redesign and partially requalification of cat. 9 IMCI is required to ensure the reliability of the substitutes.

EUROMOT (cat. 11)

(EUROMOT 2023c) agree that their cat. 11 EEE would be covered by exemption 6(b)(IV) recommended by (Baron et al. 2022a) provided that the exemption remains valid until 31 July 2029 to have 5 more years for essential testing as outlined in their renewal request.

Regarding exemption renewal request for III-6(b)(II), recommended to be renewed as 6(b)(IV), (Baron et al. 2022a) *understand[…] that there are lead-free alternatives on the market that are reliable according to aluminium producers. […]. While the aluminium manufacturing industry stated that they would be immediately able to supply any quantity needed of lead-free alloys, some other stakeholders such as (Mondragón Componentes S. Coop. 2021) mention that for "very long delivery dates, for example for alloy 2077 and […] for "Ø10.5mm aluminium coil" there is no lead-free alternative on the market.*

As specified by (EUROMOT 2024), *even though their members are developing their new applications to be in compliance with lower threshold of lead in this exemption, legacy applications still require validation to ensure that lower limits are suitable. EUROMOT's members cannot use parts made using different alloys until prototypes have been made, assessed, and tested to ensure that the properties and performance meet the specific requirements. So while priority is given to develop new products, higher lead content is still required according to EUROMOT for legacy applications.*

As a technical constraint, (EUROMOT 2024) put forward that lead-free aluminium containing tin or bismuth cannot be used in EUROMOT members' products (engines). *Tin is known to cause cracking in machined parts when subjected to stress and high temperature, both of which can be common in engines, and from the technical standpoint bismuth offers very different properties to lead. .*

This statement seems implausible as a technical argument against the use of lead-free aluminium alloys in EEE of cat. 11. The automotive industry as a user of engines agreed to the expiry of the corresponding ELV exemption 2(c)(i) in the review by (Deubzer et al. 2021), acknowledging that lead-free alloys are available that can be used.

(EUROMOT 2024) put forward that their applications might differ from the automotive sector, as light duty vehicles are in scope of ELV while heavy-duty vehicles might be in scope of RoHS. If the automotive industry is able to use a lead-free alloy it is a good indication that it may be suitable, but it could not be implemented without the relevant testing being undertaken.

The applicant already conceded that exemption III-6(b)(IV) can be adopted for cat. 11 if more time is granted for redesign, testing and qualification. From the above, it can be concluded that substitution of lead is scientifically and technically practicable for cat. 9 IMCI and cat. 11. The limitation is only time-related, i.e. to ensure the reliability of the substitutes,

a redesign of the equipment or parts thereof is required including testing and, at least in some cases, requalification.

(Baron et al. 2022a) recommended the expiry of exemption III-6(b)(IV) in 2024, based on the fact that Al alloys suppliers have developed alternatives with performance comparable to most uses of leaded-alloys. It is conceivable that manufacturers of EEE should also be able to phase-in such alternatives. Where this is not the case, given the expiry dates in the short term, applications for renewal would have already started/been submitted.

With substitution of lead being scientifically and technically practicable in the consultants' point of view, the two renewal requests represent a case where the applicants claim that the phase-in of lead-free aluminium alloys is not feasible until the expiry of the recommended exemption 6(b)(IV) on 21 July 2024.

The arguments of TMC can be followed that EEE of cat. 9 IMCI can be complex devices with long model lives, which is reflected in the maximum validity period for exemptions of seven instead of only five years. Long model lives are also plausible for most cat. 11 equipment of EUROMOT members. Redesign and, where obligatory, recertification of these products take time.

(EUROMOT 2024) demand that, since supply chains are to a large extent shared with automotive (light duty vehicles in scope of ELV and heavy-duty vehicles excluded from both ELV and RoHS), any exemption expiry dates imposed on industry's use of lead in aluminium alloys used in engines will be technically impractical if these are not the same dates as for the corresponding ELV exemptions.

ELV exemption 2(c)(i) corresponding to the recommended renewed exemption 6(b)(IV) expires on 31 December 2027. In the related review resulting in the current wording and expiry date of exemption 2(c)(i), (Deubzer et al. 2021) *found that the last lead-free alloys which are relevant to avoid lead in aluminium completely have become available in 2019 and 2020.* Taking 2020 as reference point, an expiry of exemption 6(b)(IV) would result in a seven year period to implement lead-free alloys in cat. 9 IMCI and cat. 11, which corresponds to the seven to ten years of time TMC claim to be required for phase-in when lead-free alloys are available. For cat. 11, the expiry date would be aligned with the ELV exemption as requested by EUROMOT. The consultants therefore recommend adopting the recommended exemption 6(b)(IV) with an expiry date for cat. 9 IMCI and cat. 11 not exceeding 31 December 2027.

Renewal of exemptions 6(b) and 6(b)(I) as exemption 6(b)(III)

The adoption of the recommended exemption 6(b)(III) would result in a reduced lead-content in casting aluminium alloys, down from 0.4 % to 0.3 % after 21 July 2024. The review was therefore focused on whether this is feasible for cat. 9 IMCI and cat. 11 technically, and in the foreseen timeframe.

(EUROMOT 2023c) reject adopting the renewed exemption 6(b)(III) recommended by (Baron et al. 2022a), stating that *exemption 6(b)(I) permitting lead up to 0.4% is still required, rather than 6(b)(III) permitting 0.3%.*

EUROMOT (cat. 11)

(EUROMOT 2023a) has been using casting alloys according to EN 1706 AC 46500, which is normally used for high pressure diecasting as it can be used to make thin-walled components with complex geometries. This alloy was specified by EU standard EN 1706 until its revision in 2020 with up to 0.35% lead for this alloy, but the concentration was reduced to 0.29% by the 2020 revision.

The applicant was therefore requested to clarify how EUROMOT members comply with the new standard stipulating a maximum of 0.29 % of lead, if it takes five years and more to qualify and test such parts until they can be used in their products.

(EUROMOT 2024a) *confirm that parts made to EN 1706 before the standard was changed in 2020 contain up to 0.35% lead. Changes to this standard has changed several other casting alloys by lowering the maximum lead content. Components which (EUROMOT 2023c) used to manufacture for their devices prior to the change in the specification of the standard, have been pre-bought to support long term manufacture and therefore are stock parts with the original lead concentration. Without an exemption these parts would just become waste as they would not be able to be used in equipment placed on the market in the coming years.*

With this regard, the consultants asked why EUROMOT pre-buy these parts on stock, for a period of time that makes it an obstacle against a change in aluminium content. The consultants assume that pre-buys are made instead of redesigning parts to facilitate the use of aluminium alloys with lower lead contents according to the new standard.

(EUROMOT 2024b) replied that their "[…] *members are system manufactures and not alloy manufacturers and as such rely on their supply chain to provide those components. EUROMOT members have no control over the chemical composition of alloys and have to rely on their suppliers to implement the changes. Alloy suppliers in some instances are tier 4 or 5 in the EUROMOT members products supply chain which makes control on the composition of the alloy even more challenging. Moreover, although suppliers might be aware of new restriction of concentration of lead in aluminium alloys and have acted accordingly, the components with the reduced concentration of lead might not have reached system manufacturers yet".*

The consultants asked whether EUROMOT could provide an estimate of how long manufacturers need to terminate the stocks of aluminium parts still containing between 0.3 % and 0.4 % of lead. *As a minimum, to consume existing stocks of components, an additional 7 years is required from the date when substitutes with verified reliability are available,* according to (EUROMOT 2024b).

If any changes to EUROMOT products are significant, such as having to use a totally different type of alloy, the temper needs to be changed (as this can affect corrosion resistance), the casting method or the shape or design of the part is changed, then more comprehensive testing will be needed and it may be necessary to gain re-approvals for the engine under the EU Non-Road Mobile Machinery (NRMM) Emissions Regulation (Regulation (EU) 2016/1628).

The consultants wondered why a change in a material composition should require a re-approval under an emissions regulation. (EUROMOT 2024b) *explained that the use of aluminium alloys in EUROMOT applications is implemented in relative moving parts, and the change in alloy composition would have different friction coefficient, which is directly linked to emissions and therefore would require the above-mentioned approval under the*

NRMM Emission Regulation. Also, where a change in the design of the system is implemented, this would also trigger the requirement for requalification under the same Regulation.

In addition, for the parts which require qualification to permit the reduction in lead content, this needs to be scheduled into the testing of each manufacturer. Priority is given to new products to be qualified and therefore this creates a longer timeframe for legacy products to be transitioned to lower lead content. As the EUROMOT requirements are highly specific and demanding, and only a finite number of test rigs are available, and a limited number of qualifications can be performed at a given time making the validating of systems time extensive. The testing required for the qualification of EUROMOT applications can take up to several years to accurately simulate the long operating timeframes. If an appropriate timeframe is not granted, then the qualification activities to ensure that the reduced lead content is technically suitable would not be able to occur. As such, this would result in the unavailability of equipment for the EU market.

The consultants conclude that, like in the case of lead-free alloys for machining purposes, redesign of devices is required to ensure the reliability of substitutes which requires time beyond the expiry dates suggested by (Baron et al. 2022).

TMC (cat. 9 IMCI)

The main technical reason put forward by (TMC 2023b), as for recommended ex 6(b)(IV), is that l*ead as an alloying element in aluminium containing up to 0.4% lead by weight is intrinsic for machining purposes in niche applications. Aluminium alloys (containing lead) are used to make a very wide range of category 9 IMCI, parts, and components.*

(TMC 2024a) also mention: *"[…] while new product introductions have adopted lead-free or lower lead concentration aluminium alloys as materials for the production of new parts, this does not address all of the unique parts in TMC mature portfolio, which rely on the current wording of exemption 6(b) for conformity with the RoHS Directive.*

When asked why TMC did not participate in the previous review of the exemption III-6(b) series by (Baron et al. 2022), as result of which the reduction of the lead level down to 0.3 % was recommended, they made reference to their contribution to the previous consultation, where they mentioned a detailed rationale why the renewal application for III-6(b) was considered premature for cat 9 IMCI.[15] The COM had, however, already rejected this argument in the review of exemptions by (Deubzer et al. 2022) so that the exemptions were reviewed for all categories of EEE for which the renewal was requested.

Overall, the information provided by both applicants suggest that in the end, in line with the findings of (Baron et al. 2022), substitution and elimination of lead in cast aluminium alloys are scientifically and technically practicable in cat. 9 IMCI and EEE of cat. 11. The reliability of the substitutes needs, however, to be ensured, which is achieved with redesign and, where required, the requalification of EEE. The renewal of the exemption would therefore be in line with the requirements of Art. 5(1)(a). Since the redesign of cat. 9 IMCI and cat. 11 EEE can be assumed to enable both the use of lead-free machining alloys as well as the use of aluminium alloys with 0.3 % of lead, the expiry dates of the renewed exemptions should be aligned.

[15] https://rohs.exemptions.oeko.info/exemption-consultations/2020-consultation-2/aiii-ex-6b/6b-i

6.3.3. Environmental, health, safety and socio-economic impacts

(EUROMOT 2023a) and (EUROMOT 2023b) claim that exemption 6(b) is needed to avoid that several parts in stock will become waste and will have to be disposed of and replaced. (For further details, see paragraph 6.2.2) They also specified a period of 7 years to consume all the stocks which, according to the consultant, could to some extent justify the need of the exemption renewal.

Another issue brought up by (EUROMOT 2023a) is that *the most commonly used machining aid apart from tin is bismuth […] The LCA provided by the Umbrella project to support renewal of exemption 6(b) does show that bismuth has significantly more negative impacts then lead.*

However, it was already concluded by (Baron et al. 2022a) that the 3rd criterion of Article 5(1)(a) is not fulfilled and cannot follow the argumentation of the Umbrella Project 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. (EUROMOT 2024) further on point out that bismuth is being listed as a critical raw material, of which availability is scarce and of higher impact to source from the environmental impact standpoint.

Bismuth actually has been listed as critical raw material[16] in 2020 already at the time of the review of the exemption 6 series by (Baron et al. 2022a). The criteria to qualify a material as "critical" are its economic importance and the supply risk, not the environmental impacts, and bismuth is to a large degree mined together with lead. In the light of Art. 5(1)(a), the listing of a material as a critical material does not justify recommending the exemption to be granted unless the availability of this material would be severely reduced. In the consultants' understanding of the current situation, this is not the case with bismuth and its criticality/scarcity is at maximum, if at all, reflected in its price. The consideration of legal or strategic conflicts with other EU policies are beyond the consultants' mandate and will be addressed by the COM if deemed appropriate in the decision whether the exemption is granted.

TMC foresee substantial socio-economic impacts if exemption 6(b), including 6(b)(I), is not renewed. The consultants cannot exclude that at least some of these impacts would actually arise if the COM does not renew the exemption.

6.3.4. Stakeholder contributions

While the other stakeholder submitted letters in support of applicants' renewal requests (cf. Table 6-4), two of them specifically expressed their support to the agreement of (EUROMOT 2023c) that exemption 6(b)(IV) proposed as renewal of exemption 6(b)(II) (cf. Table 6-5) is applicable to cat. 11 provided it will remain valid until 2029.

[16] See https://single-market-economy.ec.europa.eu/sectors/raw-materials/areas-specific-interest/critical-raw-materials_e

(Afecor 2023) and (APPLiA Italia 2023) request exemption 6(b)(IV) to remain valid until 2029 (for 5 more years beyond the recommended expiry in 2024), also for EEE of categories 1 and 2. They justify their request with delays due to unexpected global events (Covid, Ukraine war etc.) so that they cannot substitute the aluminium alloys with 0.4 % by alloys with 0.3 % lead until 31 December 2024.The above requests are beyond the consultants' mandate and thus out of scope of this current review. The consultants therefore did not follow up on these requests but recommend the stakeholders to bring their above issues to the COM's attention.

6.3.5. Summary and 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.*

(EUROMOT 2023b; TMC 2023a) applied for the renewal of exemption 6(b), and exemption 6(b)(I) and 6(b)(II) (EUROMOT only). (Baron et al. 2022) recommended the renewal of exemption 6(b) that covers both cast aluminium alloys as well as alloys for machining purposes, as exemptions 6(b)(III) (cast aluminium alloys) and 6(b)(IV) (aluminium alloys for machining) for cat. cat. 9 IMCI and cat. 11.

The consultants in 2022 proposed the same for current exemptions 6(b)(I) (cast aluminium alloys) and 6(b)(II) (alloys for machining), i.e. their renewals as exemptions 6(b)(III) and 6(b)(IV) (cf. Table 6-5). Following their mandate, the current consultants assessed in their review whether these recommendations can be adopted for cat. 9 IMCI and cat. 11.

Renewal of exemption 6(b) and 6(b)(II) as exemption 6(b)(IV)

(EUROMOT 2023b; TMC 2023a) agree that EEE of cat. 11 would be covered by exemption 6(b)(IV) as recommended by (Baron et al. 2022), but 5 years until 2029 are still necessary to undertake necessary development and testing. They raise doubts as to whether lead-free aluminium alloys can actually be used in engines and other components of their members' products. The applicant can, however, not substantiate this claim considering that the automotive industry agreed to the expiry of the corresponding ELV exemption 2(c)(i) on 31 December 2027, the more as they argue that they share part of their supply chain with the automotive sector. For the same reason, they also mention aligning the expiry date of the renewed exemption 6(b)(IV) with the expiry date 31 December 2027 of the corresponding exemption 2(c)(i) in (Directive 2000/53/EC 21.10.2000).

TMC explain that new product introductions have adopted lead-free aluminium alloys as materials for the production of new parts but that this does not address all of the unique parts in the TMC mature portfolio, which rely on the current wording of exemption 6(b). As and when lead-free alternatives to lead-containing aluminium alloys become available, they will be designed into new equipment that is developed in a cycle of 7-10 years depending on the type of cat. 9 IMCI equipment concerned.

The consultants take from the submitted information for cat. 9 IMCI and for cat. 11 and in line with the findings of (Baron et al. 2022), that substitution of lead in machining aluminium alloys is scientifically and technically practicable. The reliability of substitutes needs, however, to be ensured via redesign and, at least in some cases, requalification. Lead-free aluminium alloys for machining purposes have been available since 2020 latest. Taking 2020 as reference point, EUROMOT members and cat. 9 IMCI producers had four years time already to implement the use of lead-free alloys in their EEE. Seeing the technical specificities of cat. 9 IMCI and cat. 11, it can be followed that this process requires time to ensure the reliability of the substitutes so that renewing the exemption for the use of lead in machining alloys would be in line with Art. 5(1)(a).

As to the expiry date of the exemption for cat. 9 IMCI and cat. 11, the COM requires the consideration of the expiry dates recommended by (Baron et al. 2022) in the previous review, in this case the expiry of the recommended exemption 6(b)(III) on 21 July 2026 which is the only expiry date recommended while the other exemptions were recommended for expiry.

Renewal of exemptions 6(b) and 6(b)(I) as exemption 6(b)(III)

EUROMOT reject the adoption of the renewed exemption 6(b)(III) recommended by (Baron et al. 2022a) stating that exemption III-6(b)(I) permitting up to 0.4 % of lead in aluminium cast alloys is still required for cat. 11 EEE, instead 0.3 % permitted in 6(b)(III).

EUROMOT reason with the revision of standard EN1706 AC 46500 in 2020 lowering the lead content in Al from 0.35 % to 0.29 %, which caused their members to pre-buy and manufacture components prior to the change which would become waste without an exemption renewal. They also argue that a change in the material composition of cat. 11 EEE would require a re-approval under the NRMM emission regulation, which would take time and could result in the unavailability of equipment for the EU market. EUROMOT claim seven additional years to be needed to consume the pre-bought parts – from the date when substitutes with verified reliability are available.

Like in the case of lead-alloys for machining, TMC explain that new product introductions have adopted lower lead concentration aluminium alloys as materials for the production of new parts. However, this does not address all of the unique parts in the TMC mature portfolio, which rely on the current wording of exemption 6(b) for conformity with the (Directive 2011/65/EU 2011).

The information and arguments provided by both applicants suggest that in the end, in line with the findings of (Baron et al. 2022), substitution and elimination of lead in cast aluminium alloys are scientifically and technically practicable in cat. 9 IMCI and EEE of cat. 11. The reliability of the substitutes needs, however, to be ensured, which is achieved with a

redesign and, where required, the requalification of EEE, which is plausible to require more time for EEE of cat. 9 IMCI and cat. 11 than for other categories of EEE.

Like for the aluminium alloys for machining purposes, the consultants recommend 21 July 2026 as expiry date.

6.4. Recommendation

The information provided by the applicants suggests that for cat. 9 IMCI as well as for EEE of cat. 11, substitution of lead in aluminium alloys is scientifically and technically practicable, which is in line with the conclusions of (Baron et al. 2022). The reliability of substitutes needs, however, to be ensured, which requires time for redesign, requalification and in some cases for recertification. A renewal of the exemptions would thus be justifiable by Art. 5(1)(a).

The consultants recommend adopting the recommendation of (Baron et al. 2022) which implies the expiry of exemption 6(b) and the transfer of cat. 9 IMCI and cat. 11 to other exemptions of the 6(b)-series. The exemption architecture recommended by (Baron et al. 2022) is recommended to be modified to allow the integration of cat. 9 IMCI and cat. 11 without complicating the complexity of the 6(b)-series exemptions.

No.	Recommended Exemption	Recommended scope and dates of applicability
6(b)	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight	Applies to categories 8, 9 and 11. Expires on - 21 July 2021 for cat. 8 other than in-vitro diagnostic medical devices, and cat. 9 other than industrial monitoring and control instruments - 21 July 2023 for category 8 in-vitro diagnostic medical devices - **[date of official publication of the COM decision + 12 months] for categories 9 industrial monitoring and control instruments, and 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	Applies to - categories 1 to 7 and 10 - **from [date of official publication of the COM decision + 12 months + 1 day] on to categories 9 industrial monitoring and control instruments, and 11** Expires on - [date of official publication of COM decision + 12 months] for categories 1 to 7 and 10 - **21 July 2026 for categories 9 industrial monitoring and control instruments, and 11**

6(b)(II)	Lead as an alloying element in aluminium for machining purposes with a lead content up to 0,4 % by weight	Applies to - categories 1 to 7 and 10 - **from [date of official publication of the COM decision + 12 months+ 1 day] on to categories 9 industrial monitoring and control instruments, and 11** Expires on - **21 July 2026 for gas valves in category 1 large household appliances, and for categories 9 industrial monitoring and control instruments, and 11** - [date of official publication of the COM decision + 18 months] for other uses of lead in category 1, and for categories 2 to 7 and 10
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	Applies from [date of official publication of COM decision + 12 months + 1 day] on to categories 1 to 8, 9 other than industrial monitoring and control instruments, and 10 Expires on 21 July 2026 for categories 1 to 8, category 9 other than monitoring and control instruments, and 10

As to the expiry date of the exemption for cat. 9 IMCI and cat. 11, the COM requires the consideration of the expiry dates recommended by (Baron et al. 2022) in the previous review, in this case the expiry of the recommended exemption 6(b)(III) on 21 July 2026 which is the only expiry date recommended while the other exemptions were recommended for expiry.

The COM should ensure to allow sufficient time for preparation and timely submission of renewal requests between the official publication of the decision concerning the renewal of the above exemptions and their expiry dates.

The adverse socioeconomic impacts assessed by EPPA will not arise until 2026 since the consultants do not recommend revoking the exemption. TMC will, however, have to bear the cost for preparing and processing a renewal request prior to 2031, which they requested as expiry date in their current renewal request.

Applicants' feedback on the recommendations

(EUROMOT 2024c) recognise that the alignment of the expiration dates for all categories of EEE would be beneficial from an administrative viewpoint. They criticise the short validity period and that the expiry date is not aligned with the corresponding exemption in Directive 2000/53/EC (ELV Directive) in December 2027.

(TMC 2024b) highlight *that the RoHS legal text requires that decisions on granting exemptions have to take into account the socioeconomic impact of substitution which they deem to be disregarded with the alignment of the expiry date for all categories of EEE.*

Furthermore, this approach goes against the logic of having different validity periods. This approach would not take the specificities of the cat. 9 into account.

The consultants are confident that they considered all relevant arguments made available by applicants and stakeholders during the review, and that the arguments have been evaluated taking into account the requirements of Art. 5(1)(a) and the mandate commissioned by the COM for the review of this exemption.

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7. Exemption 7(a) of Annex III: Lead in high melting temperature type solders

The below Table 7-1 shows the wording, scope and expiry dates of the exemption.

Table 7-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
III-7(a)	*Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)*	*Applies to categories 1 to 11 (except applications covered by point 24 of this Annex)* *Expires on* - *21 July 2021 for categories 1 to 7, 8 medical devices other than in vitro diagnostic medical devices, 9 monitoring and control instruments other than industrial monitoring and control instruments, and 10* - *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*

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instruments (sub-group of category 9)
HMP(S)	High melting point (solders), i.e. solder with 85 % of lead and more
LHMPS	Lead-containing high melting point solder, i.e. solder with 85 % of lead and more
NRMM	Non-road mobile machinery
Pb	Lead [chem.]

UP Umbrella Project

7.1. Background and technical information

The below Table 7-2 shows the requested exemption renewals that were submitted 18 months prior to the expiries of exemption III-7(a) for category (cat.) 9 industrial monitoring and control instruments (IMCI) and for cat. 11. Requested wordings deviating from the current wording are underlined.

Table 7-2: Requested renewals of exemption III-7(a)

Applicants	*Requested Exemption*	*Requested Scope and dates of applicability*
(EUROMOT et al. 2023a)	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more of lead) <u>used in engines, engine components and ancillary components and in end-products in which they are used</u>	Applies to category 11 Expires on 21 July 2029 (= 2024 + 5 years) for cat. 11
(TMC 2023a)	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)	Applies to category 9 industrial monitoring and control instruments Expires on 21 July 2031 (= 2024 + 7 years)

The below Table 7-3 lists stakeholder contributions that were submitted with the renewal requests or during the stakeholder consultation for exemption 7(a).

Table 7-3: Stakeholder contributions

Contributors	*Contribution/request*
(DEUTZ 2023)	Letter of support for renewal request submitted by (EUROMOT et al. 2023a)
(EGMF 2024)	
(EMA 2023)	
(EUROPGEN 2023)	
(JCB 2023)	
(Volvo Penta 2023)	
(KEMI 2023)	Support for new wording of exemption 7(a) to specify applications for which exemption can be used, for example as suggested by (Baron et al. 2022) to stop products with more than 85 % lead that should not benefit from the exemption.

MTE	Letter of support for exemption renewal requests submitted by 'Umbrella Project' in 2020 for "lead exemptions" including cat. 8 medical technology
(NAM 2023)	Letter of support for renewal request submitted by (EUROMOT et al. 2023a)
(SRT 2023)	Structured scope recommended by (Baron et al. 2022) (cf. Table 7-4) probably too narrow but no specific cases known.
(UP 7(a)2023)	Objection against subdivision of exemption scope recommended by (Baron et al. 2022) and concerns about consequences, e.g. that not lead applications are not covered where elimination or substitution of lead are still scientifically and technically unpracticable.

7.1.1. History of the exemption

The exemption was listed with the current wording already on the Annex of (European Union 13.02.2003) (RoHS 1) when it was officially published in 2003. In 2008/2009, the exemption was reviewed for the first time, by (Gensch et al. 2009). The reviewers found that the exemption was still required. However, they raised concerns that exemption 7(a) is material-specific, while most other RoHS exemptions are application-specific. LHMPS can therefore be used in each application as long as it contains at least 85 % of lead, even if lead-free alternatives are available. The Commission (COM) renewed the exemption, and it was reviewed again by (Gensch et al. 2016) who concluded that elimination or substitution of lead are scientifically and technically not yet practicable. The consultants undertook a first attempt to structure the scope towards application-specific uses of lead-containing high melting point solders which was placed on the annex of the review report as an interim step towards further elaboration and refinement. The COM renewed the exemption as recommended by the consultants with the same wording. The exemption was reviewed by (Baron et al. 2022), again with the result that its renewal was recommended, however with a different, application-oriented wording which is reflected in the below table.

Table 7-4: Renewal of exemption III-7(a) recommended by (Baron et al. 2022)

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:* *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*	Applies to all categories except applications covered by point 24 of this Annex, expires on 21 July 2026.

Source: (Baron et al. 2022)

7.1.2. Focus of the review of this renewal request

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status March 2024). The applicants therefore applied for the renewal of the current exemption III-7(a) for cat. 8, cat. 9 IMCI and cat. 11 which are earmarked for expiry on 21 July 2023 and 2024 respectively in the currently valid exemption III-7(c)(I). The exemption thus became due for review.

In the light of this situation, the COM tasked the consultants to assess in their review of the exemption renewal requests at hand whether and how far the recommendation of (Baron et al. 2022) can be adopted to EEE of categories 8, 9 IMCI and 11 in the light of the information provided by the applicants and stakeholders. A re-evaluation of the previous review by (Baron et al. 2022) is not intended. The consultants will rely on the critical review conducted by the previous consultants and on the resulting conclusions and recommendation unless the renewal request or stakeholder contributions give reasons to reassess the status of science and technology.

7.1.3. Summary of the requested exemption

(EUROMOT et al. 2023a)

High temperature melting point (HMP) solders containing lead are used to electrically and physically join two elements in internal combustion engines, associated components and end-products in which they are used. Lead provides essential characteristics such as high melting point, strong heat conduction, high electrical conductivity, high ductility corrosion resistance and high reliability. Components using HMP solder are subject to aggressive environments, vibration and temperatures. Alternative technologies with similar ductility and strength as lead alloys and that can survive a standard reflow process (or several) on PCB with either leaded or unleaded solder are as yet unavailable for the intended uses EUROMOT members require them for.

Due to the operational environment and an expected service for up to and beyond 20 years, material testing and development activities necessarily take many years to complete to ensure long term reliability. Conversion to lead-free processes cannot begin until alternatives are developed and perfected by solder manufacturers. Testing then needs to be undertaken by each engine manufacturer to ensure the testing reflects the demands of their application and the tolerances that are inherently in-built into each system. The reliability of the system then needs to be proven to understand if the alternative is able to offer the required technical characteristics. As such the qualification timeframe is estimated to be 5 - 7 years (without NRMM Emissions Regulation re-approval) and 6 - 8 years (with NRMM Emissions Regulation approvals) from the date a promising alternative is identified.

EUROMOT recognises that there is the recommendation to limit the exemption scope to sub-divided scope listing out specific uses. EUROMOT members, as end equipment suppliers does not have the necessary technical information to be able to determine if all of the HMP solder uses are listed. However, EUROMOT members are of the opinion that this scope is too restrictive and will likely preclude to necessary technical use of HMP solders in applications not listed. In the meantime it is essential that the original scope of the exemption remain valid for EUROMOT members uses such that there is sufficient time to allow for these activities to be undertaken.

(TMC 2023a)

Lead is a significant ingredient of the solder alloys used to electrically or physically join two elements. High Melting Point (HMP) solders are used for a wide variety of applications. Based on the application type, a lead amount of >85% is required to achieve the necessary melting temperature and to obtain other material properties.

As further outlined in this submission, there is no single substitute available that would be suitable for all the applications identified and match the technical performance of lead. Currently, substitutes for even the major uses have rarely been found. Evaluating alternatives for each of the niche uses would take an enormous amount of time and resources, with little probability of success. The Test & Measurement Coalition therefore applies for the renewal of exemption 7(a) for the maximum renewal period.

A thorough Socio-Economic Analysis was conducted in addition to the technical assessment and attached to this submission, further illustrating the negative socio-economic impacts a non-renewal of exemption 7(a) would have at this stage. Overall, the analysis concludes that the total impact of non-renewal of this exemption is monetized in the range of 2.9 billion EUR and 4.1 billion EUR (conservative lower bound estimate).

7.1.4. Technical description of the exemption and use of the restricted substance

The technical background of this exemption is described in detail in the previous review reports of (Gensch et al. 2009, 2016) and (Baron et al. 2022). Specifically for their renewal requests, the applicants provide the below information.

(EUROMOT et al. 2023a)

EUROMOT members manufacture engines used in a wide variety of end-applications including heavy goods vehicles, excavators, emergency generators, compressors, pumps, and tools (portable and stationary). The majority of these engines have end-uses that are excluded from the scope of RoHS as they are forms of transport or non-road mobile machinery as defined by the RoHS Directive. As a result, only a small proportion of engines and their solders that are used by EUROMOT members need to comply with RoHS17.

EUROMOT's members use commercially available electronic components but select those that are specified for use at higher temperatures where these are necessary. High melting point solders are used in these components only if standard eutectic solders cannot be used because of the temperatures that are experienced. Lead is used as the majority constituent in High Melting Point (HMP) solder alloys to make electrical connections. Based on the type of application, a lead level >85 % is necessary to achieve the required melting temperature and other material properties.

The following is an illustrative list of uses of exemption 7a obtained from EUROMOT members and from other sources of information:

[17] *These engines are not used in road vehicles in scope of the EU End of Life Vehicle (ELV) Directive;* remark adopted from EUROMOT et al. 2023a.

- Solders used to attach components, sensor, etc to wiring looms, etc.
- Internal solder bonds in sensors that operate at high temperatures (>180ºC in exhausts)
- Solders used to lead wire for ignition coil, motor etc.
- First and second level soldering inside components where these bonds must not melt when components are solder reflow bonded to circuit boards
- Voltage transient suppressors
- Field effect transistors
- Switching ICs and many other types of integrated circuit including voltage regulators and current monitors, used as die attach (a wide range of die size may require HMP solder especially if the components are used in engines
- Engine Control Units (ECUs) which can operate at temperatures of 150 ºC
- Bridge rectifiers
- Various types of diodes
- High power transistors
- Ball grid arrays (BGAs) with lead HMP solder balls
- Thermistors
- Fuses, solder used for hermetic sealing and for electrical connections
- High power resistors and other passive components such as relays, inductors, potentiometers, sensors, transformers, oscillators, capacitors, etc. Note that most standard passive components do not use HMP solder, but some of these that need to be used in high temperature environments may require lead HMP solder to be used, e.g. for internal bonding or as a hermetic seal.
- MOSFET (Metal Oxide Semiconductor Field Effect Transistor), as die attach
- Crystal components for internal bonding and as hermetic sealing
- Internal solder bonds in components that use high temperature over-moulding (this is for superior sealing from moisture and environmental pollutants)
- Sensors and actuators

These electronic components of the engines in scope of RoHS can experience severe operating conditions of temperature, vibration and corrosion and must be reliable for at least several decades, although service conditions and lifetime are end-product dependent.

(EUROMOT et al. 2023a) provide more information as to specific components applying lead-containing high melting point solders (LHMPS), and on assessment of potential substitutes versus LHMPS that highlight the superior properties of LHMPS. More details are available in the exemption renewal request of (EUROMOT et al. 2023a) and in former review reports (cf. (Gensch et al. 2009, 2016; Baron et al. 2022).

(TMC 2023a)

Cat. 9 IMCI are very different from low-mix, high-volume consumer products which are frequently re-designed to follow consumer trends and are placed on the market for a limited duration. Industrial test and measurement instruments are high mix, low volume producers, managing portfolios of thousands of highly complex. Each instrument is intentionally designed for high reliability and serviceability to support long useful lifespans, and are made available on the market for at least a decade. These instruments are designed: exclusively for professional and industrial use; to meet high performance requirements in critical applications; and last up to 40 years. Redesign is not frequent and happens every seven years on average (as compared to every 1.5 years or less for consumer products). Once test and measurement instruments are placed onto the market, they are typically accompanied with a long-term customer support arrangement to maintain reliability and calibration.

Product portfolios are widely diversified, with T&M Coalition members each having typically 2,000 to 3,000 products currently made available on the market. These are highly complex, sophisticated electronic instruments such as signal generators, power analysers, oscilloscopes, spectrum analysers, digital multi-meters, electron microscopes, chemical and biological analysers, complex chromatography systems and their detectors, each having many necessary options and accessories. The Annex of this SEA contains further details concerning the product groupings and equipment types of the participating companies. Each instrument can have between 2,000 and 40,000 parts; requiring a vast supply chain involving tens of thousands of suppliers and hundreds of thousands of components.

Considering the EU added-value, test and measurement equipment is manufactured and sold in relatively small volumes (per instrument design) and placed on the global market. There is an added value in community level action, which guarantees more coherent and consistent rules across Europe. But with the expansion of RoHS-like requirements beyond the EU, this creates a risk of discrepancies in RoHS-like national laws adopted in third countries.

The professional test and measurement products provide the tools for engineers to develop new solutions and businesses to bring them to market. These instruments are used in Research, Quality Control and Testing laboratories (including field testing) in Universities, Manufacturing and clinical facilities and by Governmental Agencies for conformance verification and environmental testing. They are essential to the good functioning of electronic communications networks, heavy industrial processes such as steel manufacturing, the testing of vehicles for compliance with emissions standards, and the monitoring of complex and critical systems. The nature of the tests and measurements made by industrial equipment necessitates that the equipment itself is highly complex; with upwards of 40,000 components necessary to produce a single instrument. Even a relatively simple hand-held instrument incorporates significantly more components than a typical consumer product.

Historically, between 25 % to 35 % of the components used in cat. 9 IMCI are custom designed. The features of the T&M Coalition's equipment necessitate the development and production of unique components that are not commercially made available on the open market and are typically made by sole, boutique suppliers. These components have their own development lifecycle and take years to bring into production. When these suppliers

are unable to deliver compliant parts that meet current RoHS regulations, the product would be stopped from being sold into the EU.

The below table lists some of the components and devices for which exemption III-7(a) is relevant.

Table 7-5: Examples of components and cat. 9 IMCI relying on exemption 7(a)

Product Grouping	Equipment Types
Oscilloscopes, Analyzers & Meters	Oscilloscopes
	Spectrum Analyzers (Signal Analyzers)
	Network Analyzers
	Logic Analyzers
	Protocol Analyzers and Exercisers
	Bit Error Ratio Testers
	Noise Figure Analyzers and Noise Sources
	High-Speed Digitizers and Multichannel DAQ Solutions
	AC Power Analyzers
	DC Power Analyser's
	Materials Test Equipment
	Device Current Waveform Analyzers
	Parameter and Device Analyzers, Curve Tracers
	(Digital) Multimeters
	Phase Noise Measurement
	Power Meters and Power Sensors
	Counters
	LCR Meters and Impedance Measurement Products
	Picoammeters & Electrometers
	Oscilloscope Upgrades and Accessories
Generators, Sources and Power	Signal Generators (Signal Sources)
	Waveform and Function Generators
	Arbitrary Waveform Generators
	Pulse Generator Products
	HEV/EV/Grid Emulators and Test Systems
	DC Power Supplies
	Source Measure Units
	DC Electronic Load
	AC Power Sources
	Sourcemeter
	Sensitive Meter/Source
Wireless	Wireless Network Emulators
	Channel Emulation Solutions
	Nemo Wireless Network Solutions
	5G OTA Chambers
	Wireless Analyzers
	IoT Regulatory Compliance Solutions
Modular Instruments	PXI Products
	AXIe Products
	Data Acquisition – DAQ
	USB Products
	VXI Products
	Reference Solutions

Source: (TMC 2023a)

(TMC 2023a) provide a more comprehensive list in their renewal request.

The use of lead in high melting temperature type solders provide superior properties and reliability compared to lead-free alternatives. Some of these properties and reasons for these required characteristics include:

- high melting point (>260°C) that is higher than standard eutectic solders. This prevents melting during secondary installations and the deterioration of the functionality of electrical parts;
- thermal conductivity ensures the reliability of electronic components due to heat dissipation;
- ductility is essential to join materials that have different coefficients of thermal expansion together in order to guarantee mechanical reliability;
- electrical conductivity is essential for electrical functionality;
- electrical resistivity;
- corrosion resistivity ensures reliability;
- resistance to thermal oxidation;
- appropriate oxidation nature prevents oxidation at the secondary mounting and guarantees reliability;
- wettability;
- manufacturability;
- reliability in a harsh environment.

Lead, as stated in the application of the RoHS Umbrella Industry from January 2020, is the only known element which satisfies all these properties. It is the combination of physical and chemical properties of the leaded alloys that is important. It is therefore not possible to pick a single property as a criterion of distinction under RoHS.

7.1.5. Amount(s) of restricted substance(s) used under the exemption

(TMC 2023a) state that the quantity of lead utilized in their homogeneous materials can contain between 85 % and 95 % of lead by weight. Based on TMC members' data, they indicate approximately 25.5 kg of lead entering the EU market annually through applications for which the exemption is requested.

(EUROMOT et al. 2023a) that the amount of lead varies significantly between the various types of cat. 11 equipment and that they are therefore unable to be quantify it.

7.2. Justification of the requested exemption

7.2.1. Substitution and elimination of the restricted substance

(EUROMOT et al. 2023a)

Since RoHS was first proposed, research has also been carried out to identify substitutes for LHMP solders but with only limited success. The main candidates at present are:

- Alternative solders
- Conducting adhesives
- Metal Sintering
- Transient Liquid Phase Sintering (TLPS)
- Brazing or welding – due to the much higher temperature required (>400°C for brazing and several thousand degrees for welding, these are not suitable for use in engines or for all of their components. One manufacturer has substituted lead solder by welding in an application where the high temperature does not damage other parts or materials and reliability was proven to be at least as good as the solder.
- Other innovative bonding method

(EUROMOT et al. 2023a) describe the drawbacks of these methods in their renewal request. More details are available the previous review reports ((Gensch et al. 2016; Baron et al. 2022) and in the exemption renewal request of (EUROMOT et al. 2023a).

(EUROMOT et al. 2023a) summarise that all of these potential substitutes have inferior reliability and / or performance and so are unsuitable for use in EUROMOT members' engine systems. EUROMOT's members do not make electronic components and so rely on the supply chain, which has the expertise, to carry out this research. Only when suitable substitute components and bonding materials are developed and proven to be reliable will EUROMOT's members be able to test these in their engine systems which will require additional time.

(TMC 2023a)

To TMC's the best knowledge, there remains no single substitute available that would be suitable to all the applications identified. Currently, substitutes for even the major uses have rarely been found. Evaluating alternatives for each of the niche uses would take an enormous amount of time and resources, with little probability of success.

HMP solders are used for a wide variety of applications. There are potential substitutes for several applications; however, when the chemical and physical properties of substitutes are compared with HMP solder bonds, it becomes clear why these ***substitutes are not broadly suitable****.*

Alternatives must melt above the temperature for Pb-free solder reflow. Potential alternatives, and the main reason why these are not suitable for substitution, are listed here:

- **Standard lead-free solders** have a lower melting point than HMP lead solders but are also used for reflow soldering of PCBs. These would melt during reflow and therefore cause bond failure when used for sealing components and for making bonds inside components or in modules.
- **Welding and brazing** are alternative bonding methods but require much higher temperatures. Brazing alloys typically melt at >400°C and welds are formed at >1,000°C. The silicon chip and the polymers used in electronic components will be destroyed at these temperatures.
- **Crimp connections** are often used in electrical equipment but suffer from a multitude of disadvantages. They cannot be used for sealing and their size precludes them from use inside small electronic components. Their main limitation is unreliability; repeated temperature cycles and vibrations cause very small movements between crimp and terminal that expose the underlying base metals that re-oxidise after their natural air-formed oxide is disrupted. The increase in the oxide amount can increase contact resistance to a value where the equipment no longer functions. The increased resistance in power circuits, for example, will cause heating that can ultimately lead to fires.

The following alternatives are also deemed unsuitable for substitution and replacement:

- **Mixed alloy pastes** that combine when melted to a new high temperature alloy. These are new to the market. Manufacturability and reliability of the resultant high temperature alloys has not been fully tested. These pastes could, in due time, achieve 70 % efficacy.
- **Gold-tin braze** requires a particularly high melting temperature that can damage the components. This alternative has a limited 10 % efficacy.
- **Sintered silver** is currently being tested but has not yet proven to be manufacturable and reliable. This alternative has a limited efficacy at 30 %.

These alternatives are, for the reasons listed above, not suitable for substitution or replacement. They do not fulfil the same functions and do not have the same unique combinations of advantageous characteristics as lead.

7.2.2. Environmental, health and safety impacts

(EUROMOT et al. 2023a) state that some applications utilising this exemption are safety relevant and may cause accidents in case of failure.

(TMC 2023a) claim that cat. 9 IMCI contribute only 0.2 % by weight to the Waste Electrical and Electronic Equipment stream. Consequently, the environmental impact of cat. 9 IMCI is negligible. Nevertheless, test and measurement equipment does enter the waste stream, typically many decades after it is placed on the EU market.

7.2.3. Socioeconomic impacts

(EUROMOT et al. 2023a) forecast that, if this exemption is not renewed, engine and end-product manufacturers will be forced to stop selling products that do not comply with RoHS. At this stage, it is not known which products would be affected, but could affect many types

of end-users in the EU and the UK. For example, construction and other industries may not be able to operate if essential equipment is not available. If supply of emergency generators is affected, this may affect, for example, hospitals who use these during power cuts. There would be a risk to patients' survival during operations or other medical procedures (such as MRI examinations and monitoring patients in intensive care) may not be possible if emergency generators are not available. Manufacturers of affected engines and their end-products would also be negatively affected causing loss of competitiveness, potentially leading to loss of jobs.

(TMC 2023a) conclude from the main findings of the SEA prepared by (EPPA 2023) that the total impact of a non-renewal is monetized in the range of 2.9 billion EUR and 4.1 billion EUR (conservative estimates in net losses; potential gains for suppliers of other components have been already taken into account), consisting of: economic impacts (EBIT loss) on test and measurement industrial type products' manufacturers; substitution costs; social impacts (i.e., unemployment in the EU-27). More details are available in the SEA provided by (EPPA 2023).

7.2.4. Roadmap towards substitution or elimination of the restricted substance

(EUROMOT et al. 2023a)

(EUROMOT et al. 2023a) state that they and their suppliers have been monitoring research so that, if an apparently suitable substitute is discovered, this could be evaluated and tested for reliability in engines. Careful scrutiny will be needed by manufacturers of engines and their components to maintain the required high quality in the production process and high reliability of products to avoid failures of equipment with engines and this will continue to be the case. Therefore, the adoption of any new technology will take many years.

If a promising lead-free bonding process is developed, then this must next be tested under realistic engine conditions by EUROMOT's members. The timescale will vary depending on how significant the changes, the types of engine and their end-uses. This will involve some or all of the following:

- Production of prototype parts/ circuits and laboratory testing to determine suitability and reliability. This would include accelerated environmental testing such as thermal cycling, vibration, high humidity, corrosion tests, functional testing of circuits, etc. However, if there are many components to assess, this could take longer due to limitations in the availability of suitable trained engineers.
- Construction of engines using the lead-free replacement HMP material and bench testing to determine reliability. This is the only reliable way of assessing new bonding methods.
- Field trials in end-use equipment. This is important because it is not possible to reliably reproduce field conditions in laboratory testing environments.
- If use of substitute bonding material requires significant changes, such as re-design of circuits or of the engine, then approvals under the NRMM Emissions legislation will be required.
- Installation and evaluation of new production processes able to use new materials.

- Timescales for above depending on the type of component, engine and the end-uses:
    - Without NRMM Emissions Regulation re-approval 5 - 7 years
    - With NRMM Emissions Regulation approvals at least 6 - 8 years

In addition to the above timescale, as a minimum, to consume existing stocks of components, 7 years are required from confirmation that a substitute exists and is reliable.

(TMC 2023a)

As to their past compliance efforts, (TMC 2023a) report that some combinations of substitutes will meet some criteria, but the significance of lead in HMP solders is its unique ability to satisfy a unique combination of essential properties. It is therefore not possible to pick a single property as a criterion of distinction under RoHS. Substitution is therefore not possible due to the numerous properties required from substitutes. Alternative technologies that match the ductility and strength of lead whilst retaining reliability during one or several reflow processes (melting of solder), which would otherwise weaken the bond, are not yet available.

The unavailability of alternatives for replacement and substitution asserted above echoes the findings of the previous review of exemption 7(a) by (Baron et al. 2022). The information made available accordingly suggests that the substitution and elimination of lead in high melting temperature type solders is still technically and scientifically impracticable. The granting of exemption 7(a) should therefore be justified by Art. 5(1).

As to their future compliance activities, (TMC 2023a) pointed out that that they principally rely on their component suppliers to find alternatives to the use of restricted substances since most of the components utilizing exemption 7(a) incorporated into cat. 9 IMCI are COTS[18] parts. Therefore, meeting with suppliers to understand their (potential) alternatives, getting samples, measuring, and testing are part of the typical process to evaluate the suitability of potential alternatives. The process would then be followed by the validation of the potential suitable alternatives.

The companies reported that the validation period alone would take a minimum of 6 months and up to a year after the delivery of suitable alternatives per product. It is significant to note that this validation period would only apply if the component were a fit, form, and function drop-in replacement. If any design changes to the exemption-free part of the product would be required to accommodate for the alternative, a validation period would be required for each redesigned product that used to utilize the component that relied on the exemption. Moreover, the validation would lead to the organizations incurring additional expenses. These include labour costs and costs arising from potential product resubmission requirements for testing to various notified bodies to ensure that substitution does not create any electrical and functional safety concerns.

If a new substance free part is available, this part must be qualified for use by performing a variety of tasks, as described above. Due to the complexity and diversity of the applications, this must be done individually by each company for each product group. This process would

[18] Commercial off-the-shelf

divert resources from other projects and increase the cost to ensure continued availability of these products. This validation and testing process varies according to part complexity and impact upon the final product design; which can be categorised as low, medium, and high:

- **Low complexity** parts are the off-the-shelf components or hardware parts that do not have a substantial performance impact. Replacement can be done based on supplier information, assuming a form/fit/function compliance, with standard manufacturing, testing, and validation processes. Based on process timescales reported by a T&M coalition company, the average time that it can take for these parts to be replaced ranges from **3 to 6 months**.
- **Medium complexity** parts are more complex sub-assembly electronic parts, such as small motors, which need additional validation for their performance. These parts are often commercial assemblies that are generally available to the electronic industry, and are utilised by the Test & Measurement coalition companies. Replacement of these assemblies, like-for-like, requires testing and validation prior to being integrated into the manufacturing process. The average time to find an alternative for medium complexity parts for production is reported to range from **6 to 12 months**.
- **High Complexity** parts are the complex sub-assemblies or parts that have a significant impact on performance of the company's products or play a critical role in overall safety of the products. These parts need to go through extensive validation for performance and/or compliances for varying regulations before the appropriate files can be updated and the proper competent authorities or regulatory bodies can be notified prior to purchase of parts for validation. The average time that it would take to find an alternative for high complexity parts for production is up to 1 year for additional testing. Where the exemption directly impacts the performance of that component (e.g., a centrifuge rotor) the evaluation of the replacement could take from **3 to 5 years**.

7.3. Critical review

7.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds (cf. section 4.2 on page 51). None of these entries are, however, relevant for the use of lead in the scope of exemption 7(a) in EEE of cat. 9 IMCI and 11.

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

7.3.2. Substitution and elimination of the restricted substance

(EUROMOT et al. 2023a)

EEE of cat. 11 was not included in any of the renewal requests reviewed by (Baron et al. 2022). Nevertheless, (Baron et al. 2022) recommend the expiry of the renewed exemptions 7(a)(I to VII) for all categories on 21 July 2026. EUROMOT were asked whether the recommended exemptions 7(a)(I to VII) could be adopted for cat. 11.

(EUROMOT et al. 2023b) replied that the original scope of 7(a), rather than the proposed 7(a)(I to VII) is required for internal combustion engines, associated components, and end-products in which these are used. The proposed scope of the renewed exemption 7(a) is too restrictive and will likely preclude to necessary technical use of high melting point solders in applications not listed. EUROMOT members are not able to determine if all lead-high melting point solders are captured by the proposed 7(a)(I to VII) as they use a wide variety of electronic components utilising exemption 7(a), but electronics suppliers do not provide information as to whether this is covered by 7(a)(I to VII). As such, it is essential that sufficient time is required where the 7(a) scope remains valid for EUROMOT members, so the qualification of lead-free alternatives is able to be undertaken. Due to the impacts to reliability and the consideration that EUROMOT member products have a lifetime of up to 20 years, 5 - 7 years (without NRMM Emissions Regulation re-approval) and 6 - 8 years (with NRMM Emissions Regulation approvals) is required to undertake the relevant testing. With the testing starting from the date a promising alternative is identified. Without the continued provision of 7(a) engine and end-product manufacturers will be forced to stop selling products that do not comply with RoHS.

It is, on the one hand, plausible that users of electrical and electronic components do not know in which exact application under exemption 7(a) lead is used. Producers and suppliers of these components do not provide additional information besides the fact that the component contains lead as authorised by exemption 7(a). Producers of electrical and electronic components provide information to their customers confirming the RoHS-compliance of their products even though they are not legally obliged, since the RoHS Directive does not apply to their products, but to the end-products. On the other hand, producers of EEE could include into their requested supplier declarations information as to the specific use of LHMPS. Since such more detailed supplier declarations might cause additional administrative expenses, suppliers may not be willing to provide such information, or they only do this for key customers that purchase large volumes of components. Ultimately, EEE producers' access to such information cannot necessarily be expected. As a consequence, in the consultants' view, producers of EEE should include the expertise of component manufacturers to be in the position to answer technical questions related to exemption 7(a). The Umbrella Project Technical Working Group 7(a) – which includes manufacturers of electrical and electronic components – show with some examples that the current wordings of the recommended exemptions 7(a)(I to VII) do not include all uses of lead in the scope of the current exemption 7(a) for which substitution or elimination of lead

are scientifically and technically still impracticable (cf. section “Stakeholder contribution of the Umbrella Project” on page 119).

With view to the adoption of the recommended exemptions 7(a)(I to VII), and given the relevance of the current exemption 7(a) across almost all electrical and electronic components, producers of cat. 11 EEE actually face the risk that uses of lead remain out of scope for which its substitution or elimination are scientifically and technically not yet practicable.

(EUROMOT et al. 2023a) want to avoid this risk by extending the scope of the exemption in its wording by adding to the current wording of exemption 7(a) that the LHMPS can be *“used in engines, engine components and ancillary components and in end-products”* of cat. 11 (cf. Table 7-2 on page 101). This addition neither fits the architecture of the current exemption 7(a) if it shall remain applicable for other categories of EEE as well, nor the intention of the recommended exemptions 7(a)(I to VII), which attempt specifying and structuring the exemption scope by specific technical application criteria instead of renewing the exemption with the current material-specific exemption scope.

(TMC 2023a)

(TMC 2023a) request the renewal of exemption 7(a) with the current wording for seven years. Cat. 9 IMCI was included in the review of exemption 7(a) by (Baron et al. 2022) since its renewal was requested by applicants including the Umbrella Project at that time.

Upon request, (TMC 2023b) state that they do not agree to adopt the recommended exemptions 7(a)(I to VII) to cat. 9 IMCI. Lead is a significant ingredient of the solder alloys used to electrically or physically join two elements. High Melting Point (HMP) solders are used for a wide variety of applications. Based on the application type, a lead amount of >85% is required to achieve the necessary melting temperature and to obtain other material properties. T*here is no single substitute available that would be suitable for all the applications identified and match the technical performance of lead. Currently, substitutes for even the major uses have rarely been found. Evaluating alternatives for each of the niche uses would take an enormous amount of time and resources, with little probability of success. The Test & Measurement Coalition therefore applies for the renewal of exemption 7(a) for the* ***maximum*** *renewal period.*

As regards the proposed splitting of exemption III-7(a), (TMC 2023b) would like to emphasise the importance of retaining the initial wording and numbering as published in the original RoHS annexes. Amending the scope of the exemption by changing the application or substance restriction value has a significant administrative burden to industry and negatively impacts the compliance. This includes:

- The data management and ERP Solution re-engineering to segregate existing supplier declarations from those of the new (re-worded) exemption takes time as well as 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.

It needs to be kept in mind that industrial monitoring and control instrument manufacturers have to manage suppliers’ declarations for hundreds of thousands of items. Additionally, after reviewing the current state of the evolution of technology for the cat. 9 industrial

measurement and control instruments, TMC members have difficulty in understanding how the rewording and relisting and/or splits recommended by the consultants will lead to greater protection of human health and the environment compared to the wording in its current form. The recommended rewording/split would only lead to significant unnecessary burden for stakeholders without commensurate benefits.

As noted, the European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendations, and so the global electronics supply chain is not able to provide any information regarding these revised exemption definition proposals. Expiring exemption 7(a) in the proposed timeline of July 2024 would necessitate a complete market withdrawal triggering the financial impacts as outlined in the SEA prepared by (EPPA 2023).

(TMC 2023b) therefore do not agree with the consultants' proposed wording and splitting as outlined in the above table and reiterate the renewal request as outlined in renewal application documents.

The applicants' above-answer addresses non-technical aspects why the recommended renewed exemptions cannot be adopted for cat. 9 IMCI, and they argue with the seemingly imminent expiry of the exemption. In the consultants' understanding, (Baron et al. 2022) targeted structuring the scope but not excluding uses of lead for which its substitution and elimination is scientifically and technically not yet practicable. Additionally, (Baron et al. 2022) do not recommend the expiry of their recommended exemptions 7(a)(I to VI) in 2024, but in 2026, including cat. 9 IMCI, and the COM can be assumed to leave sufficient time for requesting renewals of the exemption. In the consultants' view, TMC's above arguments are thus not relevant for the technical assessment.

Technically, the applicants' statement concerning the impracticability of lead substitution and elimination is, however, in line with the findings of (Baron et al. 2022). Like producers of cat. 11 EEE (see previous section), producers of cat. 9 IMCI face the risk that not all uses of LHMPS are covered for which elimination or substitution are scientifically or technically not yet practicable.

Stakeholder contribution of (KEMI 2023)

The stakeholder contributions and the core of the information they provided is listed in Table 7-3 on page 101. The information provided by (KEMI 2023), the Swedish Chemicals Agency, is more detailed and could not be fully reflected in that table. *(KEMI 2023) state that they have many years of experience as a market surveillance authority to conduct enforcement activities on the RoHS Directive and especially on exemption 7a.*

(KEMI 2023) report their observations from these many years: „With the current wording of exemption 7(a), we cannot stop products with more than 85 % lead from being placed on the market even though it is obvious that there is no need for high melting temperature type solders. The products that we have this problem with are typically cheap non-complex products with a short lifespan. Only in 2023 we have analysed seven products that contain more than 85 % lead in solders and to our knowledge should not benefit from this exemption.

We support a new wording of the exemption which specifies in what applications the exemption can be used. With such a wording of the exemption, for example the suggestion by the consultant, the enforcement authorities will be able to stop products

with more than 85 % lead that should not benefit from the exemption, from being placed on the market. Another solution or addition to a specified exemption could be to require that the exemption is justified in the technical documentation if applied."

The consultants requested KEMI to provide details on the seven cases in 2023 where they considered the LHMPS to be misuses, but they could not make more information publicly available for legal reasons.

Stakeholder contribution of the Umbrella Project

(UP 7(a) 2023) (Umbrella Project Technical Working Group 7(a) highlight that several applications might exist that are not covered by the consultants´ (i.e. (Baron et al. 2022) *recommended new wording for exemption 7 (d). (UP 7 (a) 2024a) provide the below examples which they claim to be by no means exhaustive:*

1) Zener diodes (which do not "block" voltages and do not always have steady state or transient/impulse currents > 0,1 A) some with die edge sizes smaller than 0.3 mm; *(related to 7(a)(I)*
2) Transient voltage suppressors, some with die edge sizes smaller than 0.3 mm x 0.3 mm. Some are manufactured specifically for the protection of USB and HDMI interfaces and are therefore below the 0,1A/10V thresholds proposed by Baron et al. (2022). (Related to 7(a)(I)
3) Integrated Circuits, such as voltage regulators and references and current monitors
4) Self-protected MOSFETs
5) Clip bonded diodes and other products with currents ≤ 1 A & ≤ 200 V
6) SMD and axial diodes and bridge rectifier < 1 A and < 200 V;
7) SMD and axial diodes < 0.3 mm;
8) Products with life time expectation above 2000 h of product use
9) Products where operating conditions exceed 60 °C.
10) Some crystals parts use LHTMPS internally to solder the crystal element to the package, this is not die attach.

The consultants derive from the above examples that the recommended exemptions 7(a)(I to VII) seem not to cover all uses of lead that are in the scope of the current exemption 7(a) assuming that substitution and elimination of lead are scientifically and technically not yet practicable for the above examples. Following their mandate for this review, the consultants did not conduct a detailed assessment on this aspect. Given, on the one hand, the broad use of exemption 7(a) in electrical and electronic components and the exemplary character of the above list, and on the other hand the use of multiple such components in EEE of all categories, it can be assumed that cat. 9 IMCI and 11 would be affected if the recommended exemptions 7(a)(I to VII) do not cover all applications of lead.

(UP 7(a)2023) also would like to clarify that there is no agreement to any sub divisions of the exemption wording and the exemption wording should stay as it is currently published. They assume that any split will enact legislation, which will not be implementable and will cause increased administrative burden only. In view of the implementation of the

harmonized standard [19] EN IEC 63000, (UP 7(a)2023) 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.

(UP 7(a)2023) have also identified that this approach will result in a ***single component claiming multiple exemptions due to the possible use of lead-containing high melting point solders in different roles within the component.*** *The implications cannot be assessed for the time being and it should be avoided that there is an interruption in availability of electronics in the EU market and competitiveness is damaged. As there is an end-of-life product stream for electrical and electronic products in place, they suggest conducting representative material analysis every 5 years. (UP 7(a)2023) are confident that these procedures will testify that intentional lead uses are on very low levels and continuously decreasing.*

In the case at hand, it is expectable that any change of the so far completely undefined scope of exemption 7(a) will result in additional administrative and compliance burdens. Producers of EEE check, however, compliance on the component level, not on the exemption level, i.e. they ask for supplier declarations for specific components. Even if one component uses different exemptions, there will be only one such declaration. Additional effort will, however, occur in the supply chain to prepare such declarations.

As to the implications which the Umbrella Project (UP 7(a)2023) could not yet assess, the question arises why they have not yet assessed them in the last years since the publication of the report prepared by (Baron et al. 2022). A first attempt to structure the 7(a) scope was started during the review by (Gensch et al. 2016) already – against the opposition of applicants and stakeholders - but was only added as an Annex to the report. There would have been sufficient time and reason for the Umbrella Project to have had such assessments performed for the review of (Baron et al. 2022), and for this current review. The same holds true for the UP's proposal to conduct representative material analyses of waste EEE. The UP could have had such an assessment conducted in the past years if they are confident that the result will testify the low levels of intentional lead use and its continuous decrease.

It needs to be added in this context, however, that Art. 5(1)(a), as interpreted in the past more than 15 years of exemption review practice, demands exemption scopes that are as broad as necessary and as narrow as possible. Exemption reviews can thus not rely on evidence that a wide and unstructured scope of an exemption is not abused, and that producers of EEE invest time and efforts in further reducing the use of restricted substances as alternative to define the scope accordingly.

Applicants in past reviews have followed the approach of a 1:1 substitution, i.e. they claimed that the lead-containing high melting point solder (LHMPS) in the scope of exemption 7(a) must be replaceable in all its manifold uses by one lead-free solution. The applicants otherwise considered substitution and elimination of lead to be scientifically and technically impracticable. In past reviews, it was observed that applicants and stakeholders highlighted the activities of the DA5 consortium[20] investigating lead-free die-attach substitutes for more

[19] Harmonized Standard to Demonstrate RoHS Compliance

[20] DA = Die Attach; the „5" stands for the number of semiconductor manufacturers that established the working group.

than 10 years. They claimed that once the DA5 identified a viable lead-free solution, it would be adopted for all the other current uses of LHMPS. In the consultants' view, it is not self-evident that this approach is viable. The DA5 research, inter alia, bonding techniques which do not imply the use of solder, and it is not clear how, if successful for die attach, such a solution could be used in all other applications of LHMPS.

Gensch et al. (2016) had criticised this approach and demanded diversified, application-specific research and development efforts for the time of the next review of this exemption. The Umbrella Project was therefore requested to provide evidence of their research and development efforts related to the above examples which they see not covered by the recommended exemptions 7(a)(I to VII).

(UP 7 (a) 2024a) report material suppliers to be working on alternatives for LHMPS to address the requirements of industry. High temperature adhesives and Transient Phase Liquid Sinter materials are showing particular promise for the future, but there is nothing now that meets all the technical requirements that LHMPS meets. Until the materials are available, development of the products to use them will remain restricted. Once materials become available, there will obviously be a timescale for product qualification and approval within application. Substitution still seems to be several years in the future. While industry continues its efforts to phase out lead wherever possible, there are many applications where this is not possible and therefore, they ask to grant the exemption as applied for and suggest a follow up review not before five years.

As the requested evidence for their application-specific efforts to find lead-free solutions for their above 10 examples, (UP 7 (a) 2024a) submitted the DA5 customer presentation[21] describing the efforts of this group to identify lead-free solutions for die attach, which can be interpreted as confirming the observations of past reviews described above.

Overall, it seems that the exemptions 7(a)(1 to VII) recommended by (Baron et al. 2022) in their current wording do not cover all applications of lead which have been practiced under the current exemption 7(a). Granting the exemptions 7(a)(I to VII) with their wordings could therefore exclude from the exemption scope uses of lead for which its elimination or substitution are scientifically and technically not yet practicable.

UP criticise the approach of (Baron et al. 2022), but just request the perpetuation of the current situation with the purely material-specific scope which, in the consultants' view, does neither promote application-specific research and development nor a clear demarcation of areas where substitution and elimination of lead may already be feasible. UP Technical Working Group 7(a) do not commit themselves to participate in a constructive dialogue and cooperation with all stakeholders to find a perhaps viable, if not perfect, solution. This is different for exemption 7(c)(I) where the respective UP Working Group (UP 7(a)2024) committed themselves to preparing a proposal for the next review as a base for further discussions instead of insisting on their objections.

In the light of the feedback from applicants and stakeholders, the consultants nevertheless recommend the same proceeding like for exemption 7(c)(I), i.e. renewing the current exemption 7(a) and amend the current approach and wordings in the next review of the

[21] Cf. Infineon, https://www.infineon.com/dgdl/DA5+Customer+Presentation+23112023.pdf?fileId=5546d4616102d26701610905cfde0005

exemption taking up critical points raised in this and the previous review. The objective could be to arrive at a viable wording as a start for further refinements in later reviews. Better solutions will be feasible with constructive participation from industry to pool the expertise of all stakeholders.

7.3.3. Environmental, health, safety and socio-economic impacts

(EUROMOT et al. 2023a) are concerned about adverse safety and health impacts if they cannot produce emergency systems such as power generators for hospitals. The consultants agree that such negative impacts could arise given the broad use of exemption 7(a) in all categories of EEE.

(TMC 2023a) claim that cat. 9 IMCI contribute only 0.2 % by weight to the Waste Electrical and Electronic Equipment stream. Consequently, the environmental impact of cat. 9 IMCI is negligible.

The current RoHS Directive does not define any thresholds for use of restricted substances or contributions to the overall waste generation for which Art. 5(1)(a) would justify granting an exemption if these thresholds are not exceeded.

As to the socioeconomic impacts, the consultants cannot exclude that adverse impacts described by TMC (cf. section 7.2.3 on page 112 and (EPPA 2023) arise if the renewal of the exemption 7(a) is not granted for cat. 9 IMCI.

(TMC 2023b) point out that it needs to be kept in mind that industrial monitoring and control instrument manufacturers have to manage suppliers' declarations for hundreds of thousands of items. TMC members have difficulty in understanding how the rewording and relisting and/or splits recommended by the consultants (Baron et al. 2022) will lead to greater protection of human health and the environment compared to the wording in its current form. The recommended rewording/split would only lead to significant unnecessary burden for stakeholders without commensurate benefits.

In the consultants' view, this administrative aspect is part of the compliance obligations of all manufacturers of all categories of EEE. Even though it should be kept in mind that changes of exemption wordings and exemption scopes may cause temporary administrative burdens for affected manufacturers, Articles 4 and 5(1)(a) require priority of substitution and elimination of use of restricted substances, and well-defined exemption scopes are a pre-condition for this. The attempt of (Baron et al. 2022) to structure the exemption scope is motivated by this priority. It is at the discretion of the COM to decide whether specific cases would justify different priorities, e.g. administrative or other socio-economic impacts.

7.3.4. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria[22] is fulfilled:

[22] Differently from Art. 5(1)(a) in the RoHS Directive, the criteria are numbered so that they can be addressed in the below text.

1. *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;*
2. *the reliability of substitutes is not ensured;*
3. *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.*

EUROMOT (cat. 11) and TMC (cat. 9 IMCI) applied for the renewal of exemption III-7(a) for the maximum validity period claiming that substitution or elimination of lead is scientifically and technically not yet practicable for the applications of lead in the scope of this exemption.

These statements are in line with the conclusions of (Baron et al. 2022). Cat. 9 IMCI was included in the recent review of exemption 7(a) by (Baron et al. 2022), while cat. 11 was not. Exemption 7(a) is, however, of central importance for electrical and electronic components that are used in all categories of EEE so that the impracticability of lead substitution or elimination in lead-containing high melting point solders (LHPMS) can be considered to apply to all categories.

The applicants objected adopting the recommended exemptions 7(a)(I to VII) as renewal of exemption 7(a) to cat. 9 IMCI and cat. 11. EUROMOT see the risk that not all uses of LHMPS may be covered by these exemptions, and (UP 7(a)2024) (Umbrella Project Technical Working Group 7(a) contribute examples which they consider not to be covered. Granting these exemptions as proposed would thus actually result in a high risk that uses of LHMPS are not covered where elimination or substitution of lead are scientifically and technically not yet practicable. (UP 7(a)2023; UP 7 (a) 2024a) also object structuring the exemption scope as proposed by (Baron et al. 2022) stating that, besides not all applications of LHMPS being covered, this structure would result in too many sub-clauses and would not be practicable. Differently from the Umbrella Project Working Group 7(c)(I) ((UP 7(a)2024) in the context of the renewal of exemption 7(c)(I), there is, however, neither any commitment to provide a concept for a better approach nor for a constructive cooperation to arrive at a better solution.

Considering the overall situation, the consultants recommend renewing exemption 7(a) and aspire an amendment of the approach and the wordings of the exemptions recommended by (Baron et al. 2022), taking into account the critical points raised by stakeholders. This could be more successful than the previous recommendation from 2022 if industry supports these efforts so that all the expertise required for a solid approach and wording would be accessible. Possibly, ideas can be adopted from the concept which the UP Technical Working Group 7(c)(I) provided, if this concept turns out to be a good approach. In case the industry will, like in previous reviews of exemption 7(a), not cooperate to move the currently purely material-specific exemption 7(a) towards an application-specific one, a viable approach and wording may still be achievable. KEMI do not only support structuring the scope of exemption 7(a) but also propose that "*Another solution or addition to a specified exemption could be to require that the exemption is justified in the technical documentation if applied".* This approach may be complemented with the requirement to declare the specific uses of LHMPS in components. The viability of this proposal could be evaluated in the next review.

7.4. Recommendation

Substitution and elimination of lead in lead-containing high melting point solder (LHMPS) are scientifically and technically not yet practicable in EEE of cat. 9 IMCI and cat. 11. Renewing exemption 7(a) would therefore be in line with the requirements of Art. 5(1)(a).

The information provided by the applicants and stakeholders suggests that the recommended renewal of exemption 7(a) as exemptions 7(a)(I to VII) as proposed by (Baron et al. 2022) would not yet cover all uses of lead in cat.9 IMCI and cat.11 for which its substitution or elimination are scientifically and technically not yet practicable.

The consultants therefore recommend renewing exemption 7(a) with its current wording for cat. 9 and cat. 11 but with the expiry dates proposed by (Baron et al. 2022). This would enable an early review of the exemption for cat. 9 IMCI and cat. 11 with the other categories of EEE which should enable a defined scope for all categories of EEE.

Adding to this, both applicants highlight that they depend on their suppliers to provide them with RoHS-compliant materials and components but do not have such suppliers in their consortia that requested the renewal of the exemption. A joint next review of the exemption with other consortia representing material and component manufacturers as well is therefore considered to be a precondition to further develop the exemption from the current purely material- to a more application-specific scope.

No.	Exemption	Scope and dates of applicability
III-7(a)	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)	Applies to categories 9 IMCI and 11 (except applications covered by point 24 of this Annex) Expires on 21 July 2026 for category 9 industrial monitoring and control instruments, and for category 11

The consultants further recommend that the COM ensures sufficient time between the official publication of the decision and the expiry date of the exemption to allow for the preparation and timely submission of renewal requests.

This offers a chance that all relevant stakeholder groups can be involved to either elaborate a different approach. There is, however, currently no commitment from UP or other stakeholders to support or cooperate in this effort, differently from exemption 7(c)(I), where the respective Umbrella Project Working Group 7(c)(I) committed itself to provide a concept. Possibly, the approach and concept, if expedient to structure the scope, could give guidance for an approach for exemption 7(a) as well. Alternatively, as a fallback option, the current proposal of (Baron et al. 2022) could be amended despite the Umbrella Project's (Working Group 7(a) reservations, taking into account stakeholder inputs of this review related to yet uncovered applications.[23] To ensure that all applications of lead in the scope of the renewed exemption 7(a) are covered, a salvatory clause could be added that would cover all applications that are not yet specifically defined in the scope. This approach would require producers to specifically declare the use of lead in the specific applications at least. For the applications of lead under the salvatory clause, the practicability of the approach proposed

[23] Cf. section "Stakeholder contribution of the Umbrella Project".

by KEMI could be assessed *to require that the exemption is justified in the technical documentation if applied*, and to declare the specific uses of LHMPS.

Applicants' and stakeholders' feedback on the recommendation

(EUROMOT et al. 2024) support the exemption wording and recognise that the alignment of the expiration dates for all categories of EEE would be beneficial from an administrative viewpoint. EUROMOT members criticise, however, that this alignment does not fully consider the technical evidence submitted which outlines the need for the maximum validity period of the exemption.

(TMC 2024) support the wording of the exemption but contest the expiry on 21 July 2026 since they submitted a full application dossier requesting the renewal of exemption 7(a) for cat. 9 IMCI in its current wording for a maximum validity period of 7 years.

(UP 7(a) 2024c) regret that they can't offer an exemption wording proposal for the moment. To agree on such a proposal more time is needed for discussion and alignment within the Umbrella Project working group 7(a).

(SRT 2024) state that renewing exemption 7(a) with its current wording for cat. 9 and cat. 11 but with the 2026 expiry date proposed by Baron et al. seems feasible keeping in mind that a new request is possible.

The consultants are confident that they considered all relevant arguments made available by applicants and stakeholders during the review, and that the arguments have been evaluated taking into account the requirements of Art. 5(1)(a) and the mandate commissioned by the COM for the review of this exemption.

7.5. References

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8. Exemption 7(c)(I) of Annex III: Lead in glass and ceramic

The below Table 8-1 shows the wording, scope and expiry dates of the exemption.

Table 8-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
III-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	Applies to categories 1 to 11 (except applications covered under point 34) and expires on - 21 July 2021 for categories 1-7 and 10, and for category 8 other than in vitro diagnostic medical devices and cat. 9 other than industrial monitoring and control instruments - 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

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

Ω	Ohm, unit of electrical resistance
Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instruments (sub-group of category 9)
IVD	In vitro diagnostic medical devices (sub-group of category 8)
UP	Umbrella Project

8.1. Background and technical information

The below Table 8-2 shows the requested exemption renewals that were submitted 18 months prior to the expiries of exemption III-7(c)(I) for category (cat.) 8 in vitro diagnostic medical devices (IVD) in January 2022, and in January 2023 for cat. 9 industrial monitoring and control instruments (IMCI) and for cat. 11. Requested wordings deviating from the current wording are underlined.

Table 8-2: Requested renewals of exemption III-7(c)(I)

Applicants	Requested Exemption	Requested Scope and dates of applicability
(EUROMOT et al. 2023a)	*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 <u>used in engines, engine components and ancillary components and in end-products</u>*	*Applies to category 11.* *Expires on 21 July 2029 (= 2024 + 5 years) for cat. 11*
(TMC 2023a)	*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*	*Applies to cat. 9 industrial monitoring and control instruments* *Expires on 21 July 2031 (= 2024 + 7 years) for cat. 9 industrial monitoring and control instruments*
(Werfen 2023)	*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, <u>which are used in in vitro diagnostic medical devices for the analysis of whole blood</u>*	*Applies to category 8 in vitro diagnostic medical devices (IVD)* *Expires on 21 July 2028 (= 2023 + 5 years)*

The stakeholders listed in the below Table 8-3 contributed to the stakeholder consultation for exemption 7(c)(I).

Table 8-3: Contributions to the stakeholder consultation

Contributors	Contribution/request
(DEUTZ 2023)	*Letter of support for EUROMOT request*
(JCB 2023)	
(Volvo Penta 2023)	

(MTE 2023)	*Letter of support for exemption renewal requests submitted by 'Umbrella Project' in 2020 for exemption 7(c)(I) including cat. 8 medical technology*
(Pari Pharma 2023)	*Inclusion of "vibrating membrane nebulizers in active medical devices for inhalation therapy" in addition to IVD for the analysis of blood (cf. application of (Werfen 2023) in Table 7-2)*
(SRT 2023b)	*Resistivity limits of 7(c)(V)(4) recommended by (Baron et al. 2022) (cf. Table 7-4) too narrow*
(UP 7(c) (I) 2023)	*Renewed exemptions 7(c)(IV to VI) recommended by (Baron et al. 2022) do not cover all uses of lead for all cat. of EEE*

8.1.1. History of the exemption

When (European Union 13.02.2003) (RoHS 1) was published in 2003, the use of lead in glass and ceramics was covered by two different exemptions with a different wording:

Exemption 5 allowed the use of lead in glass:

- "Lead in glass of cathode ray tubes, electronic components and fluorescent tubes"

Exemption 7d covered the use of lead in ceramics of electronic components:

- "Lead in electronic ceramic parts (e.g. piezoelectronic devices)"

In 2007, the Commission received an application for exemption of "Lead in cermet-based trimmer potentiometer elements". The applicant requested this exemption claiming that exemptions 5 and 7(d) did not cover the use of lead in these cermet-based trimmer potentiometers. The applicants said that this resistive layer in the cermet-based trimmer potentiometer is a homogeneous material, as it can be mechanically separated from the ceramic base. This homogeneous material, the thick-film layer containing the lead, is in itself neither a glass nor a ceramic material. The exemption request was reviewed (Gensch et al. 2007) and the Commission granted the exemption as exemption 34 in the annex of RoHS 1.

Exemption 11 of Annex II in Directive 2000/53/EC (ELV Directive), the equivalent to the current exemption 7c(I) of RoHS Annex III, was reviewed in 2007/2008 by (Lohse et al. 2008). The stakeholders decided that the wording in the ELV Directive covers applications like lead in cermet-based trimmer potentiometers. To avoid uncertainty whether and how far similar uses of lead, like in the cermet-based trimmer potentiometers, are exempted, it was decided in the review of RoHS exemption 7d in 2008/2009 by (Gensch et al. 2009) to adopt the wording of the ELV exemption with slight modifications for RoHS exemption 7d and merge it with exemption 5 to form the current exemption III-7c-I.

Exemption 7c-I was transferred from the annex of RoHS 1 into annex III of RoHS 2 without changes. The wording of the exemption remained unchanged after the next review by (Gensch et al. 2016). The last review of the exemption was performed by (Baron et al. 2022), resulting in the proposal to renew exemption 7(c)(I) as exemptions 7(c)(V) and 7(c)(VI) as shown in the below table.

Table 8-4: Renewal of current exemption 7(c)(I) recommended by (Baron et al. 2022)

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

Source: (Baron et al. 2022) ***Exemption III-34*

8.1.2. Focus of the review of this renewal request

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status March 2024). The applicants therefore applied for the renewal of the current exemption III-7(c)(I) for cat. 8, cat. 9 IMCI and cat. 11 which are earmarked for expiry on 21 July 2023 and 2024 respectively in the currently valid exemption III-7(c)(I). The exemption thus became due for review.

In the light of this situation, the COM tasked the consultants to assess in their review of the exemption renewal requests at hand whether and how far the recommendation of (Baron et al. 2022) can be adopted to EEE of categories 8, 9 IMCI and 11 in the light of the

information provided by the applicants and stakeholders. A re-evaluation of the previous review by (Baron et al. 2022) is not intended. The consultants will rely on the critical review conducted by the previous consultants and on the resulting conclusions and recommendation unless the renewal request or stakeholder contributions give reasons to reassess the status of science and technology.

8.1.3. Summary of the requested exemption

(EUROMOT et al. 2023a)

Lead in glass and ceramic materials are widely used in all types of Electrical and Electronic Equipment, including in EUROMOT member applications. Lead is used for its unique properties including high precision sensors, hermetic sealing properties and material stability in a wide range of conditions.

EUROMOT applications have to withstand temperature cycling in the range of -40°C to +150°C, harsh environmental conditions with high humidity and exhaustion fumes in addition to mechanical strain due to the high vibrations. Those operation conditions require the high reliability that is characteristic of the of leaded glass and ceramic materials such as low-melting point, excellent wettability with different materials, weather and corrosion resistance, low susceptibility to dielectric breakdown under high electric loads and high mechanical strength and crack resistance. Those properties make leaded glasses and ceramics components reliable over a life cycle of over 10 years.

Industry has investigated the substitution of lead in glass, ceramic and matrix compounds for the last 20 years with the aim of the developing reliable technical solutions on an industrial scale. Despite this extensive research, substitution technology has not been found up to the present day for many critical applications and there are no prospects of finding substitutes with comparable characteristics of performances and reliability in the near future. Once a viable alternative has been developed, EUROMOT members will need to undertake systems level testing, reliability assessments and approvals for some component changes.

EUROMOT recognises that there is the recommendation to change the current wording of the exemption and sub-divide the scope listing into specific uses. EUROMOT members, as end equipment suppliers does not have the necessary technical information to be able to determine if all of the uses of lead in a glass or ceramic are listed. However, EUROMOT members have engaged extensively with their supply chain and, although information is scarce it has been made apparent that lead-free alternatives for EUROMOT applications are not available from the manufacturers and therefore a timeline for assessing the transition to a lead-free alternative is difficult to predict. Moreover, EUROMOT members are of the opinion that the proposed scope is too restrictive and will likely prevent the use of lead in a glass or ceramic in applications that are not listed and this would prevent engines and the corresponding end-products from being sold in the EU. In the meantime, it is essential that the original scope of the exemption remain valid for EUROMOT members uses such that there is sufficient time to allow for these activities to be undertaken.

(TMC 2023a)

Exemption 7(c)-I is the most frequently used exemption in T&M electronic products; most electronic products contain this exemption because of the broad range of applications.

There is no single substitute available that would be suitable to all the applications identified. TMC therefore apply for a renewal of exemption 7(c)-I for the maximum validity period.

A thorough Socio-Economic Analysis was conducted in addition to the technical assessment and attached to this submission, further illustrating the negative socio-economic impacts a non-renewal of exemption 7(c)-I would have at this stage. Overall, the analysis concludes that the total impact of non-renewal of this exemption is monetized in the range of 3.1 billion EUR and 4.3 billion EUR (conservative lower bound estimate).

(Werfen 2023)

(Werfen 2023) manufacture equipment which analyses critical care analytes in whole blood, used in hospitals and laboratories in all world markets. Werfen manufacture the suite of GEM Premier diagnostic medical analysers for the entire EU Market. These instruments are used to measure the blood of patients and provide clinicians with accurate measurements of specific analytes vital to medical diagnosis and patient treatment. The reported analytes include, among others, pH, pCO2, pO2, Na+, K+, Ca++, Cl-, glucose, lactate and haematocrit.

Based on the GEM Premier 5000 Werfen is currently in the process of developing an instrument incorporating a piezoceramic material. The RoHS-regulated substance, Lead, is a constituent material in the Piezoceramic material of the disposable cartridge to be used with the GEM Premier 5000 MARS analyser. The Piezoceramic material is a vital component in the cartridges of the GEM Premier 5000 MARS used for measuring and reporting concentrations of critical care analytes in blood (pO2, pCO2, pH, Na+, K+, Ca++, Cl-, glucose, lactate and haematocrit). Lead is part of the Piezoceramic material of the piezoelectric transducer used to create acoustic power in a microfluidic detection flow chamber to separate plasma from whole blood patient samples by acoustofluidic separation. The purity and viability of the separated blood constituents is critical for diagnostic accuracy and for the therapeutic efficacy as well.

Any change in the Piezoceramic material can directly impact analytical performance characteristics and thereby impede the intended function of the GEM Premier 5000 MARS analyser. For the GEM Premier 5000 MARS analyser to provide patient blood data with uncompromised reliability and accuracy, continued use of Lead in the Piezoceramic material of the GEM Premier 5000 MARS analyser is required while the search continues for alternative substances.

The core obligation for their product in terms of meeting current EU requirements for diagnostic medical analysers is limiting the use of alternative lead-free PZT material. Currently there is no lead-free material on the market meeting our product requirements with equivalent performance. Despite the achieved improvement in piezoelectric properties, there are problems in the synthesis, processing and poling of the sintered ceramics.

For the reasons outlined above the substitution of Lead in the Piezoceramic material cannot be completed before the date of applicability of the restriction on use of Lead according to the RoHS Directive.

8.1.4. Technical description of the exemption and use of the restricted substance

The technical background of this exemption is described in detail in the previous review reports of (Gensch et al. 2009, 2016) and (Baron et al. 2022). Specifically for their renewal requests, the applicants provide the below information.

(EUROMOT et al. 2023a)

EUROMOT members manufacture engines used in a wide variety of end-applications including heavy goods vehicles, excavators, emergency generators, compressors, pumps, and tools (portable and stationary. Only a small proportion of engines and their glass or ceramic materials that are used by EUROMOT members need to comply with RoHS.

Lead is used in a wide variety of Electric and Electronic Components that are incorporated into Electrical and Electronic Equipment (EEE). EUROMOT members use similar components to the wider electrical industry sector which is described in the Umbrella Project in its exemption 7(c)-I renewal request and its answers to clarification questions[24].

In addition to the general use of 7(c)-I components, there are also engine-specific components such as sensors and actuators which rely upon 7(c)-I. The following is an illustrative list of uses of components and their end uses utilising exemption 7(c)-I obtained from EUROMOT members and other sources of information.

[24] 4 https://rohs.exemptions.oeko.info/exemption-consultations/2020-consultation-2/aiii-ex-7c-i; source as referenced by EUROMOT et al. 2023a.

Table 8-5: Uses of exemption III-7(c)(I) in components and EEE of EUROMOT members

Indicative components used:

- Actuators,
- Dielectric converter,
- Diodes,
- Glass electrical contact, and
- Integrated Component (IC).

Equipment uses:

- Actuation module
- After-treatment control unit
- Alternating current generator
- Antenna Printed Circuit Board (PCB) components
- Belt drive
- Carburettor
- Charging device
- Common rail fuel injection systems
- Control unit or supply modules for Diesel Exhaustion Fluid
- Control unit components
- Differential pressure or vacuum switch
- Engine control unit
- Emissions device
- Electrical throttle
- Engine control components
- Fuel pump control components
- Fuel shut off valve
- Fuel filter assembly
- Ignition coil
- Motor power distribution unit
- Negative Temperature Coefficient Surface (NTC) Thermistors Regulator rectifier
- Oil mist separator
- Resistors, including metal film resistors and electrodes
- Sensors: such as pressure, differential pressure, level, temperature, temperature manifold absolute pressure, air, oil, NO_x and CO
- Positive Temperature Coefficient (PTC) thermistors
- Transient voltage suppressor
- Throttle actuators
- Turbocharger

Source: (EUROMOT et al. 2023a)

Piezoelectric materials are used due to their accuracy and sensitivity, in components such as actuators, resistors and IC's. In addition, lead containing piezoelectric materials have a high Curie temperature (Tc) and depolarisation stability of material properties under changing temperature conditions. This is particularly important due to the operating temperatures of engines in which components can reach +150°C or higher in some applications. Piezoelectric materials are used in general applications, such as actuators for high precision positioning of tools with an accuracy in the order of micrometres (µm). Another indicative use is as heat-sensitive sensors whose resistance increases with temperature, and can be used in almost all areas where a digital temperature measurement is required, for example in motor protection.

Lead is also used in sealing and bonding glass, in applications such as a glaze overlay on chip components, to prevent corrosion of internal parts. Leaded glass is also used as an

hermetically sealing material for diodes, IC's and other components. The glass is characterised by particular resistance to high humidity environments and operating/storage temperatures varying between -55°C to +175°C. Moreover, it provides mechanical protection of components surfaces, electrical insulation, including dielectric breakdown resistance.

EUROMOT's members use many 100s and probably 1000s of components that rely on this exemption. The manufacturer of each component specifies the function and characteristics of each component and everyone will be different. EUROMOT members needs these components such that their engines operate correctly and meet emissions limits required by EU legislation. If there are significant changes in a component's characteristics (for example, if an IC is replaced by one with a different design), it may not be possible to supply these engines in the EU until re-design, testing and recertification are completed, which will take many years. In addition for EUROMOT's members, the components need to operate under harsh environmental conditions and all components must operate as specified for many decades.

EUROMOT recognises that from the Umbrella project there is the proposal to limit the exemption scope to sub-divided scope listing out specific uses. EUROMOT members, as end equipment suppliers, have not been able to obtain the necessary technical information from suppliers to be able to determine if all of the lead in a glass or ceramic uses are listed. However, EUROMOT members are of the opinion that this scope would be too restrictive and will likely exclude some essential technical use of lead in a glass or ceramic in applications that are not listed. Engagement with EUROMOT members supply chain is on-going to identify if any specific uses are not included. In the meantime, it is essential that the original scope of this exemption remain valid such that there is sufficient time to allow for these activities to be undertaken.

(TMC 2023a)

Cat. 9 IMCI are very different from low-mix, high-volume consumer products which are frequently re-designed to follow consumer trends and are placed on the market for a limited duration. Industrial test and measurement instruments are high mix, low volume producers, managing portfolios of thousands of highly complex. Each instrument is intentionally designed for high reliability and serviceability to support long useful lifespans, and are made available on the market for at least a decade. These instruments are designed: exclusively for professional and industrial use; to meet high performance requirements in critical applications; and last up to 40 years. Redesign is not frequent and happens every seven years on average (as compared to every 1.5 years or less for consumer products). Once test and measurement instruments are placed onto the market, they are typically accompanied with a long-term customer support arrangement to maintain reliability and calibration.

Product portfolios are widely diversified, with T&M Coalition members each having typically 2,000 to 3,000 products currently made available on the market. These are highly complex, sophisticated electronic instruments such as signal generators, power analysers, oscilloscopes, spectrum analysers, digital multi-meters, electron microscopes, chemical and biological analysers, complex chromatography systems and their detectors, each having many necessary options and accessories. The Annex of this SEA contains further details concerning the product groupings and equipment types of the participating

companies. Each instrument can have between 2,000 and 40,000 parts; requiring a vast supply chain involving tens of thousands of suppliers and hundreds of thousands of items.

Considering the EU added-value, test and measurement equipment is manufactured and sold in relatively small volumes (per instrument design) and placed on the global market. There is an added value in community level action, which guarantees more coherent and consistent rules across Europe. But with the expansion of RoHS-like requirements beyond the EU, this creates a risk of discrepancies in RoHS-like national laws adopted in third countries.

The professional test and measurement products provide the tools for engineers to develop new solutions and businesses to bring them to market. These instruments are used in Research, Quality Control and Testing laboratories (including field testing) in Universities, Manufacturing and clinical facilities and by Governmental Agencies for conformance verification and environmental testing. They are essential to the good functioning of electronic communications networks, heavy industrial processes such as steel manufacturing, the testing of vehicles for compliance with emissions standards, and the monitoring of complex and critical systems. The nature of the tests and measurements made by industrial equipment necessitates that the equipment itself is highly complex; with upwards of 40,000 components necessary to produce a single instrument. Even a relatively simple hand-held instrument incorporates significantly more components that a typical consumer product.

Historically, between 25 - 35% of the components used in cat. 9 IMCI are custom designed. The features of the T&M Coalition's equipment necessitate the development and production of unique components that are not commercially made available on the open market and are typically made by sole, boutique suppliers. These components have their own development lifecycle and take years to bring into production. When these suppliers are unable to deliver compliant parts that meet current RoHS regulations, the product would be stopped from being sold into the EU.

Exemption 7(c)-I is the most frequently used exemption in cat. 9 IMCI. Most electronic products contain this exemption because of the broad range of applications. These include, but are not limited to, the following:

- Resistor networks
- Diodes
- DC-DC converters
- Microwave and mm Wave frequency custom components
- Thermistors
- Thyristors
- Relays
- Crystal oscillators
- Bandpass filters
- Amplifiers
- Couplers

- High frequency RF filters

(TMC 2023a) provide a more comprehensive list of the relevant product groupings and equipment types relevant to exemption 7(c)-I in their renewal request.

(Werfen 2023)

The technical background is described in the applicant's summary.

As to the particular function of lead, the applicant says that the metal is a constituent of the Piezoceramic material used in the disposable cartridge in the form of Lead zirconate titanate (PZT) used as piezoelectric transducer due to superior performance referring to high Q-value and more. As noted the piezoelectric transducer used to create acoustic power in a microfluidic detection flow chamber to separate plasma from whole blood patient samples by acoustofluidic separation.

Acoustofluidic separation is based on the interaction of acoustic waves with fluids and inclusions within the fluids. One convenient way to generate acoustic waves is to use transducers made of piezoelectric materials. Piezoelectric materials can generate electrical polarization under an applied mechanical stress or, vice versa, mechanical deformation arise from electrical polarization.

There are various types of piezoelectric transducers based on their material properties, configurations, and actuation modes. Some materials like quartz show natural piezoelectric properties due to its crystal structure yielding a net electrical dipole, while others like lead zirconate titanate can be made piezoelectric by applying an external electric polarization. Depending on the material and orientation, the vibration mode can be different. The most common vibration modes used in piezoelectric transducers are thickness expansion mode. When an alternating current (AC) signal is applied to the planer electrodes of a transducer, piezoelectric materials vibrate at the frequency of the AC signal. In both the thickness expansion and thickness shear modes, the whole body of the piezoelectric material vibrates, producing waves that are usually referred as "bulk acoustic waves" (BAW).

Based on the combined action of ultrasound waves and the flow of carrier fluids, acoustofluidics has emerged as a useful tool for manipulation of biofluids and biological suspensions in microfluidic devices. These devices exploit standing acoustic pressure waves that through the purely mechanical parameters, such as compressibility, density and size, induce fluid- and particle-specific forces leading to acoustophoresis this phenomenon is the basis of the development of gentle and robust methods for concentrating, trapping, washing, aligning and separating cells [2]. To be used for manipulation purposes, the acoustic pressure wave inside the microchannel must exhibit well defined pressure nodes and intense pressure fields, that effectively attract or repel particles.

For these reasons, acoustofluidic devices operate at acoustic resonance frequencies. Because the speed of sound in water is around 1500 m/s, and the typical characteristic dimensions of acoustofluidic microchannels range in 200 − 500 μm, it is seen that ultrasound frequencies of about 1.5 − 2.5 MHz are ideally suited for creating effect.

The effectiveness of the device in focusing microparticles is quantified by two mechanical indicators: the average direction of the pressure gradient and the amount of acoustic energy localized in the microchannel. Further, we derive the relations between the Lagrangian, the Hamiltonian and three electrical indicators: the resonance Q-value, the impedance and the electric power (Bruus et al.). The acoustic standing wave formed by the channel walls

continuously translated blood cells from their original medium to clean plasma solution with virtually no mixing of the fluids.

As mentioned above, any change in the Piezoceramic material can directly impact analytical performance characteristics of this system. This is critical because the quality management system, which ensures high quality and accurate blood measurements in the GEM Premier 5000 MARS system, is designed around the analytical performance of the Piezoceramic material containing Lead.

The following advantages of the GEM Premier 5000 MARS as compared to other existing technologies on the market today are directly related to the material and require extensive validation for an alternative substance:

The GEM Premier 5000 MARS analyser utilizes the renowned Intelligent Quality Management (iQM™) System which automatically detects, corrects, and documents all errors, and confirms resolution ensuring patient safety and the highest quality of test results. iQM continuously monitors on-board Process Control Solutions (PCS), reducing the time to error detection to minutes instead of the hours required by traditional manual or Automated Quality Control (AQC) that normally are run every 8 hours, as regulated by CLIA in the United States and by applicable national legislation in EU Member States.

iQM eliminates manual intervention to correct sensor errors, such as removal of blood clots from the system, thereby significantly reducing time needed for the testing process and enhancing ease of use. The reduced testing time will, in critical situations, significantly improve patient safety by producing rapid and correct results that reduce the need for user interpretation of results or repeat testing.

iQM results in a longer usable lifetime of the disposable cartridge, compared to other analysers based on AQC technology. The iQM system conducts quality control as an integrated part of the testing process, whereas AQC counts quality control samples as separate tests thus reducing available number of patient blood samples during cartridge life.

The GEM Premier 5000 MARS analyser offers a single, disposable measurement cartridge which can be stored up to 6 months at room temperature. Other competing technologies utilize multiple cartridges to perform the same functions, some of which require refrigerated storage. This place an additional burden on the customer of stocking multiple consumable cartridges and providing refrigerated storage at point-of-care testing locations, where space is often limited.

Transducers produced for the GEM Premier 5000 MARS analyser are tested at the factory to ensure highest levels of quality to the customer. The combination of the iQM System, single measurement cartridge design, and rigorous testing procedure for the transducer ensures that the GEM Premier 5000 MARS analyser provides the best possible results in all relevant use scenarios. This combination curtails the need for users to perform correctional analytical actions, enabling Healthcare staff to better focus on critical patient care tasks. These advantages are directly linked to the performance of the transducers a critical component of the measurement system.

8.1.5. Annual amount(s) of restricted substance(s) used under the exemption

(EUROMOT et al. 2023a) use up to 93 % by weight of lead in the homogeneous material. As to the total amount of lead used they provide data based on estimates of two manufacturers. Manufacturer A estimated that the total quantity of lead in parts using exemption 7(c)(I) is 11.5 kg, based on their estimated use and market share. Manufacturer B estimated 1.5 kg based on their estimated use and market share. As such the quantity of lead used in engines in scope of RoHS for exemption 7(c)(I) is expected to be between 1.5 kg and 11.5 kg per year in the EU (excluding the UK). It should be noted that this is not reflective of all Category 11 uses which is not able to be calculated by EUROMOT.

Given the limitations of the applicants' above estimates, the actual amount of lead used in cat. 11 under exemption 7(c)(I) can be assumed to be higher.

(TMC 2023a) state that their members emphasized that the quantity of lead utilized in their homogeneous materials varies based on the application. Therefore, companies indicated that the homogeneous materials can contain between 3 % and 93 % lead by weight. As to the total amount of lead placed on the EU market under exemption 7(c)(I), they indicate 8.2 kg based on their members' data.

Since not all producers of cat. 9 IMCI are members of TMC, the actual amount of lead can be assumed to be higher.

(Werfen 2023) estimate the respective amount of lead used only in their products with 0.1 kg to 5 kg per year.

8.2. Justification of the requested exemption

8.2.1. Substitution and Elimination of the restricted substance

(EUROMOT et al. 2023a)

EUROMOT's members do not make electronic components and rely on their supply chain, which has the necessary expertise, to carry out research into lead-free alternatives. As such, the following is a summary of published literature on research on possible lead-free components. Additional work by EUROMOT's members' suppliers may have been carried out but as this is confidential it has not been divulged to EUROMOT's members. Only when suitable substitute components and bonding materials are developed and proven to be reliable by these suppliers will EUROMOT's members be able to start the systems level qualification and recertification activities which will require additional time.

Since RoHS was first proposed, a huge effort has been made to develop alternative lead-free glass and ceramic materials but with only limited success. The main candidates at present are:

1. *Lead-free piezoelectric ceramics,*
2. *Lead-free PTC thermistors,*
3. *Low melting point glasses,*
4. *Lead-free glass alternatives.*

(EUROMOT et al. 2023a) describe the drawbacks of these materials in their renewal request. Since the information is from public sources and not specific for the applications of EUROMOT's members, and is at least in parts discussed in the previous review reports, they are not listed here in more detail.

(TMC 2023a)

To TMC's the best knowledge, there remains no single substitute available that would be suitable to all the applications identified. Currently, substitutes for even the major uses have rarely been found. Evaluating alternatives for each of the niche uses would take an enormous amount of time and resources, with little probability of success.

The overall lack of a suitable alternative for lead as used in exemption 7(c)-I has also been echoed in the application submissions of other businesses relying on this particular RoHS exemption. Industry as a whole has been involved in finding substitutes for lead in glass, ceramic, or glass or ceramic matrix compounds for more than two decades.[25] Despite these tremendous efforts, a substitute for lead that is broadly applicable to the numerous applications has not been found.

For instance, low melting point (LMP) glass solders have been attempted with multiple substances with no success: They either melt at too high of a temperature (120-160 °C higher); do not perform functionally (do not wet, do not seal); or are more toxic than Pb (such as beryllium oxide BeO, uranium dioxide UO_2) – or a combination of these.

Additionally, lead-free resistor element materials have poorer reliability than Pb-containing materials due to low moisture resistance during load heating and low mechanical strength during overload heating. Resistance values are not stable, changing gradually over time or sometimes with sharp changes. For the accuracy and long life required by cat. 9 IMCI, substitutes with these technical inadequacies are not acceptable.

(Werfen 2023)

(Werfen 2023) have been working to replace Lead in the Piezoceramic material in close cooperation with commercial suppliers of Piezoceramic materials, academic institutions and private consultants to identify alternatives for Lead. This work is not yet complete, and Werfen is submitting this application for an exemption to allow additional time to complete this work while at the same time assuring uninterrupted supply to the EU healthcare sector of equipment critical to providing optimum care of critically ill patients.

A key finding of the work completed until now was that replacement of Lead in the Piezoceramic material resulted in deterioration in analytical performance of the GEM Premier analyser. We therefore conclude that presence of Lead in the Piezoceramic material is aiding performance, and published product claims were based on this optimum performance.

[25] A comprehensive overview of industry's efforts in this regard is outlined in the exemption renewal dossier of the Umbrella Project, which is downloadable from the Commission's webpage. Available at: https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive_en 11; source as referenced by TMC 2023a.

At present, the evaluation continues for an alternative, RoHS compliant material which will restore functions to their original level of performance, consistent with product claims, EN ISO 13485:2012 (EN ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes), EU Directive 98/79/EC on in vitro diagnostic medical devices, and the European In Vitro Diagnostic Regulation IVDR 2017/746 which is currently in progress. In vitro diagnostic medical devices mandate that a manufacturer must demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. The legal obligation for the manufacturer to meet applicable requirements of the current EU requirements includes performance in terms of analytical sensitivity, analytical specificity, accuracy, repeatability, reproducibility, and limits of detection stated by the manufacturer. The Manufacturer needs to document compliance with the above requirements of the EU by updating the Technical File as appropriate.

Due to the aforementioned issues, the investigated alternatives are not technically practicable or viable alternatives at this time, as they affect the accuracy and reproducibility of test results carried out with the alternatives, thereby preventing the analyser from performing its intended function within established product claims. There is no lead-free ferroelectric ceramics product on the market yet with high piezoelectric properties needed for their application. Despite the achieved improvement in piezoelectric properties, there are problems in the synthesis, processing and poling of the sintered ceramics. Lead free piezo ceramics are available on the market today, (i.e., by one of the market leaders and key suppliers, PI Ceramics, but they, suffer from their low Q-value (a Q-value[26] of >>1 is needed for the application used in the MARS product).

Although the search for practical and viable alternatives is on-going, Werfen must continue to manufacture the current cartridge using Lead until a new, non-Lead material is successfully identified, with performance equivalent to currently manufactured product.

Based on their evaluations (Werfen 2023) conclude that this application for an exemption falls within all three categories as established in Article 5(1)(a) with respect to the possibility to substitute the use of Lead in the Piezoceramic material:

1. *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,*
2. *The reliability of the substances investigated for substitution is not ensured.*
3. *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.*

Continued use of Lead in the Piezoceramic material of the GEM Premier cartridge is required while the search evaluation of substances continues for an alternative material with performance characteristics equivalent to the currently manufactured product. The alternative must not interfere with measurement of any analyte on the system over the

[26] A parameter indicating the efficiency in vibrating, and inversely its damping or internal losses. For power applications, the higher the Q-value, the better the device. The Q_m value is approximately the number of times the device oscillates at no-load condition after excitation ceases. Source: ATCP Physical Engineering, https://www.atcp-ndt.com/en/support/faq_trz/413-what-is-the-mechanical-quality-factor-qm-and-what-is-it-for.html (modified)

claimed product shelf-life (up to 6 months at room temperature) and use-life (up to 31 days in the analyser).

Stakeholder contributions

Exemption clause 7(c)(V)(4) recommended by (Baron et al. 2022) (cf. Table 7-4 on page 103) sets resistivity limits between 1 Ohm/square and 1 Megaohm/square to qualify for the use of lead in “resistance materials”.

(SRT 2023a, 2023b) state that lead-free pastes with resistivities of 100 MΩ/square and more are not available on the market, and that their availability is not foreseeable. They also state that they successfully produced several lead-free resistors from pastes with resistivities of 1 Ω/square, 10 kΩ/square and 10 MΩ/square. They still need, however, to test their life time, and whether they are trimmable. “Trimming” is a process to define the exact resistance of the resistor produced from the resistivity paste.

(Pari Pharma 2023) manufacture medical devices for the treatment of a broad range of respiratory diseases. Their "eFlow" devices are used in several clinical studies and are part of commercial drug- and device-combination products. Therefore, they are also part of medicinal product approvals and many patients profit from using their devices.

Their eFlow Technology is based on vibrating membrane technology. They are using a piezo element made of PZT to operate the membrane which falls under the RoHS exemption III-7c(I) (Pari Pharma 2023) and their suppliers have been working on substituting PZT for several years. However, due to the high performance and safety requirements of their devices, they have not yet succeeded in replacing the material. PZT is essential for their application and we will not be able to replace the material by July 21, 2026. They therefore request that the scope under III-7(c)(VI) be expanded to include the use of “Category 8 vibrating membrane nebulizers in active medical devices for inhalation therapy” in addition to the scope expansion "IVD for the analysis of blood" proposed by (Werfen 2023).

8.2.2. Environmental, health and safety impacts

(EUROMOT et al. 2023a) reference the Life Cycle Assessment (LCA) of lead-free piezoelectrics submitted by the Umbrella Project to the last review of exemption 7(c)(I) by (Baron et al. 2022) where the lead-free alternatives assessed have a greater total negative environmental impact.

(TMC 2023a) claim that cat. 9 IMCI contribute only 0.2 % by weight to the Waste Electrical and Electronic Equipment stream. Consequently, the environmental impact of cat. 9 IMCI is negligible. Nevertheless, test and measurement equipment does enter the waste stream, typically many decades after it is placed on the EU market.

(Werfen 2023) had a life cycle assessment (LCA) prepared by Intertek and critically reviewed by Intertek. They interpret the results as showing that lead has lower environmental impacts (in terms of the measures produced by LCA) in certain categories than the two alternatives.

8.2.3. Socioeconomic impacts

According to (EUROMOT et al. 2023a), if this exemption is not renewed and include all of the applications in engines made by EUROMOT's members, engine and end-product manufacturers will be forced to stop selling products that do not comply with RoHS. At this stage, it is not known which products would be affected for the following reason. (Baron et al. 2022) have recommended the renewal of 7cI but with a limited scope. The proposed scope will include many of the components used by EUROMOT's members, but may not include all of them for the reasons explained above in section 4 (B). Therefore, this could affect many types of end-users in the EU. For example, construction and other industries may not be able to operate if essential equipment is not available. If supply of emergency generators is affected, this may affect, for example, hospitals who use these during power cuts. There would be a risk to patient's survival during operations or other medical procedures (such as MRI examinations and monitoring patients in intensive care) may not be possible if emergency generators are not available. Manufacturers of affected engines and their end-products would also be negatively affected causing loss of competitiveness, potentially leading to loss of jobs. Due to the uncertainty over which products would be affected, it is not possible for (EUROMOT et al. 2023a) to determine quantitative impacts.

(TMC 2023b) ask to keep in mind that cat. 9 IMCI manufacturers have to manage suppliers' declarations for hundreds of thousands of items. Additionally, after reviewing the current state of the evolution of technology for the cat. 9 industrial measurement and control instruments, TMC members have difficulty in understanding how the rewording and relisting and/or splits recommended by the consultants will lead to greater protection of human health and the environment compared to the wording in its current form. The recommended rewording/split would only lead to significant unnecessary burden for stakeholders without commensurate benefits.

(EPPA 2023) further elaborate that there are currently no suitable lead-free alternatives that meet RoHS exemption criteria on the EU market for cat. 9 IMCI and that re-designing of the cat. 9 IMCI equipment could take five to seven years per product line. Hence, losing the ability to apply Annex III, exemption 7(c)-I when considering RoHS conformity for the associated test and measurement industrial products would entail the development of a fairly large number of new alternative compliant materials as well as the increased costs connected to the redesign, retesting, requalification, and replacement of the assembly process.

Overall, (EPPA 2023) monetize in their SEA the total impact of a non-renewal of exemption 7(c)(I) in the range of 3.1 billion EUR and 4.3 billion EUR (conservative estimates in net losses; potential gains for suppliers of other components have been already taken into account), consisting of: economic impacts (EBIT loss) on test and measurement industrial type products' manufacturers; substitution costs and social impacts (i.e., unemployment in the EU-27).

(Werfen 2023) request that this application for an extension of the current exemption be approved because otherwise the supply of vital analytical instruments that support hospitals and laboratories across the entire EU will be jeopardized with a clear negative impact on the EU Health Care Sector. Meanwhile, they have a project plan and are diligently evaluating new piezoceramic materials compliant to RoHS.

8.2.4. Roadmap towards substitution or elimination of the restricted substance

(EUROMOT et al. 2023a)

As to their past compliance efforts, (EUROMOT et al. 2023a) *state that manufacturers of lead in glass and ceramic in electronic components have been carrying out research on substitutes for lead in glass and ceramic for over 20 years. When promising lead-free alternative becomes available, EUROMOT members will have to test them in systems they are used in and for some components the systems as a part of the engine to ensure that they offer the necessary technical performance and will be no less reliable. Due to the operational environment and an expected service for up to and beyond 20 years, material testing and development activities necessarily take many years to complete to ensure long term reliability.*

After laboratory tests of materials / components, extensive "on-engine" and field testing must be executed to evaluate the reliability and durability of the substitute material/parts. This testing needs to be undertaken by each engine manufacturer to ensure the testing reflects the demands of their application and the tolerances that are inherently in-built into each system. The reliability of the system then needs to be proven with an estimated 500,000+ cumulative hours of testing to understand if the alternative is equal to that of current leaded materials.

It should also be mentioned that the EEE industry and automotive industry have an extensive overlap in their supply chains. For example, many components are used in both EUROMOT's members engines that are in scope of RoHS as well as by the automotive industry. EUROMOT would recommend that the EU maintain consistent wording between this exemption and ELV exemption 10 where feasible.

When manufacturers are qualifying changes to specific components the following are some of the tests which engine manufacturers must undertake. The following tests are not intended to be an exhaustive list, as different manufacturers have different testing requirements, but rather indicate the number and variety of tests which have to be undertaken.

Sensors:

- Vibration testing
- Vibration resonant sweep: a shaker test used to detect if any resonances in the component may adversely affect the device
- Humidity testing
- Water intrusion testing
- Thermal Shock: extreme temperature swings are used to stress the assembly
- Salt fog testing
- Electromagnetic compatibility testing
- Connector housing testing, such as durability testing, chemical stress fracture etc.

- Combined Environment: sensors are subjected to a combination of temperature and vibration to evaluate the component assembly for the expected life of the item, testing functionality such as pressure, differential pressure, temperature, positions, speed of sensor results and performance.
- Engine system testing to ensure that, as a system, the component is suitable for the application and has the necessary performance

In addition to these there are also sensor specific testing which is required for certain sensors such as gravel bombardment testing or exhaust system mounted sensors, flow velocity testing for sensors in high flow locations, or chemical compatibility if there are external material changes.

Actuators:

In addition to many of the tests required for sensors, actuators also commonly have to undergo the following additional tests:

- Circuit analysis- examined at maximum temperature voltage and duty cycle combinations and shown to be in the devices specified operational envelope
- Immersion testing
- Electrostatic discharge (ESD) exposure robustness testing
- Temperature cycling durability
- Electrical field immunity testing-radiated immunity and high voltage spike
- Software testing to ensure compatibility and no errors
- Lifetime mechanical wear

Each of these tests would need to be undertaken for each sensor or actuator used, with testing times varying from around 15 hours per test to around two months per test. Testing timeframes for each of these tests cannot be further accelerated as some attributes are non-linear, such as long-term reliability or durability.

Timescale once substitute components become available to EUROMOT members

If a promising lead-free alternative is developed, then this must next be tested under realistic engine conditions by EUROMOT's members. The timescale will vary depending on how significant the changes, the types of engine and their end-uses. For example, if the component's electrical and functional properties are apparently identical, then minimal testing is necessary. However, substitute materials often given different characteristics so more extensive testing is needed. Sometimes substitution results in component suppliers withdrawing their products from the market and replacement by a different component (this is common with ICs) in which case EUROMOT's members may need to redesign circuits and this could affect engine emissions and so recertification will be required.

This will involve some or all of the following:

- Production of prototype parts/ circuits and laboratory testing to determine suitability and reliability. This would include accelerated environmental testing such as thermal cycling, vibration, high humidity, corrosion tests, functional testing of circuits, etc. However, if there are many components to assess, this could take longer due to limitations in the availability of suitable trained engineers.

- Construction of engines using the lead-free replacement components and bench testing to determine reliability. This is the only reliable way of assessing new bonding methods.
- Field trials in end-use equipment. This is important because it is not possible to reliably reproduce field conditions in laboratory testing environments. This is realistically essential to assess long term reliability.
- If use of substitute bonding materials or new components requires significant changes, such as re-design of circuits or of the engine, then approvals under the Non-Road Mobile Machinery (NRMM) Emissions legislation will be required.

The timescales for these stages vary between five and up to eight years depending on the type of component substitution, type of engine and its end-uses. For example, assuming the exemption is used in a large number of parts (200-300 assemblies in the case of EUROMOT applications), it could take more than five years to integrate an available alternative. If those alternatives were not „drop-in replacements" the estimated time would be much longer to produce emission certificates and safety approvals.

Timescales for above:

- Without NRMM Emissions Regulation re-approval 5 - 7 years after lead-free substitutes become available
- With NRMM Emissions Regulation approvals at least 6 - 8 years after lead-free substitutes become available

In addition to the above timescale, as a minimum, to consume existing stocks of components, 7 years is required from confirmation that a substitute exists and is reliable.

(TMC 2023a)

As to their past compliance efforts, (TMC 2023a) contacted their component suppliers to inquire if, since the submission of the renewal request in 2020 by other stakeholders (e.g., the Umbrella Project), new technological developments have occurred that would allow the substitution of lead as used in RoHS exemption 7(c)-I. It was reported back that no alternative substance with the same required characteristics of lead for the respective components is known to the manufactures of those components.

As to their future compliance activities, (TMC 2023a) point out that that they principally rely on their component suppliers to find alternatives to the use of restricted substances since most of the components utilizing exemption 7(c)-I incorporated into cat. 9 IMCI are COTS[27] parts (and so forth, potentially many levels down). Implementation of change necessitated by regulatory pressures typically starts with raw material manufacturers and the cat. 9 IMCI manufacturers who have the largest economic stake. Intermediate manufacturers are geographically and jurisdictionally diverse and are often SMEs. As such, this part of the supply chain is slower and more inconsistently able to adapt. Assuring full adaption in the supply chain and validating the alternatives in the final product application can and often does require up to 4 years. The general process involves communicating with the supply chain, evaluating samples, conducting design impact studies, reconfiguring the instrument

[27] Commercial off-the-schelf

and its software where necessary and testing in manufacture and validating the final assembly.

The companies reported that the validation period alone would take a minimum of 6 months and up to a year after the delivery of suitable alternatives per product. It is significant to note that this validation period would only apply if the component were a fit, form, and function drop-in replacement. If any design changes to the exemption-free part of the product would be required to accommodate for the alternative, a validation period would be required for each redesigned product that used to utilize the component that relied on the exemption. Moreover, the validation would lead to the organizations incurring additional expenses. These include labour costs and costs arising from potential product resubmission requirements for testing to various notified bodies to ensure that substitution does not create any electrical and functional safety concerns.

If a new substance free part is available, this part must be qualified for use by performing a variety of tasks, as described above. Due to the complexity and diversity of the applications, this must be done individually by each company for each product group. This process would divert resources from other projects and increase the cost to ensure continued availability of these products. This validation and testing process varies according to part complexity and impact upon the final product design; which can be categorised as low, medium, and high:

- **Low complexity** parts are the off-the-shelf components or hardware parts that do not have a substantial performance impact. Replacement can be done based on supplier information, assuming a form/fit/function compliance, with standard manufacturing, testing, and validation processes. Based on process timescales reported by a T&M coalition company, the average time that it can take for these parts to be replaced ranges from **3 to 6 months**.
- **Medium complexity** parts are more complex sub-assembly electronic parts, such as small motors, which need additional validation for their performance. These parts are often commercial assemblies that are generally available to the electronic industry, and are utilised by the Test & Measurement coalition companies. Replacement of these assemblies, like-for-like, requires testing and validation prior to being integrated into the manufacturing process. The average time to find an alternative for medium complexity parts for production is reported to range from **6 to 12 months**.
- **High Complexity** parts are the complex sub-assemblies or parts that have a significant impact on performance of the company's products or play a critical role in overall safety of the products. These parts need to go through extensive validation for performance and/or compliances for varying regulations before the appropriate files can be updated and the proper competent authorities or regulatory bodies can be notified prior to purchase of parts for validation. The average time that it would take to find an alternative for high complexity parts for production is up to 1 year for additional testing. Where the exemption directly impacts the performance of that component (e.g., a centrifuge rotor) the evaluation of the replacement could take from **3 to 5 years**.

(Werfen 2023)

Actions to develop alternative substances are currently in progress. Project phases are defined in the Design Control Procedure (QMDD-20001-00) for Design Control projects.

- Project Proposal
- Design Input (Phase 1)
- Design Output (Phase 2)
- Design Verification (Phase 3)
- Design Transfer (Phase 4)
- Design Validation (Phase 5)
- Product Launch (Phase 6)

Currently, Project MARS is still a Design Control project within Phase III – Verification. See the project schedule below. The development cycle covers the Design Input and Design Output phases. Product Launch will be beginning after FDA and IVDR submission when approval is attained.

8.3. Critical review

(Baron et al. 2022) conclude in their review of exemption 7(c)(I) 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. The current exemption wording is not confined to specific applications. 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.

(Baron et al. 2022) had circulated a proposal for exemption specification to stakeholders and after integrating their views, two more detailed exemption wordings were formulated. 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.

As a result of their above considerations, (Baron et al. 2022) elaborate two options for the renewal of the exemption and recommend the option displayed in Table 8-4 on page 131 for the renewal of exemption 7(c)(I) as exemptions 7(c)(V) and 7(c)(VI).

8.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds (cf. section 4.2 on page 51). None of these entries are, however, relevant for the use of lead in the scope of exemption 7(c)(I) in EEE of cat. 9 IMCI and 11.

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

8.3.2. Substitution and elimination of the restricted substance

(Baron et al. 2022) conclude as a result of their review that substitution and elimination of lead are scientifically and technically not yet practicable and hence recommend renewing the exemption, however, with the attempt to structure the scope. The recommended structure is not intended to restrict the scope compared to the current exemption 7(c)(I) since (Baron et al. 2022) did not identify applications of lead in the scope of the exemption for which substitution or elimination of lead would be scientifically and technically practicable.

All applicants mention that exemption 7(c)(I) is used in manifold electrical and electronic components in their categories of EEE, i.e. categories cat. 8 IVD, cat. 9 IMCI and cat. 11. The scientific and technical practicability of lead substitution or elimination therefore mostly depends on the availability of lead-free alternatives on component level rather than on the EEE categories in which these components are used, even though there may be components that are only used in specific categories of EEE.

The conclusion of (Baron et al. 2022) as to the impracticability of lead substitution and elimination in the context of exemption 7(c)(I) is therefore applicable to all categories of EEE, including cat. 8 and 9 that were part of the review of (Baron et al. 2022). The review of the requested exemption renewals in this current round was therefore focused on the potential adoption of the recommended exemptions 7(c)(V) and 7(c)(VI), in particular with view to the applicability of the structured exemption scope.

EUROMOT

EEE of cat. 11 was not included in any of the renewal requests reviewed by (Baron et al. 2022). Nevertheless, (Baron et al. 2022) recommend the expiry of the recommended exemptions 7(c)(V) and 7(c)(VI) for all categories on 21 July 2026.

EUROMOT were asked whether the renewed exemptions 7(c)(V) and 7(c)(VI) recommended by (Baron et al. 2022) could be adopted for cat. 11.

(EUROMOT et al. 2023b) state to require the current scope of 7(c-I), rather than the proposed 7(c-V) and 7(c-VI) for internal combustion engines, associated components, and end-products in which these are used. The proposed scopes of 7(c-V) and 7(c-VI) are too restrictive and will likely preclude to necessary technical use of components containing lead in glass or ceramic in applications not listed. EUROMOT members are not able to determine if all lead in glass or ceramic in applications are captured by the proposed 7(c-V) and 7(c-VI) and to differentiate them, as they use a wide variety of electronic components utilising exemption 7(c-I), but electronics suppliers do not provide information as to whether this is covered by the proposed 7(c-V) or 7(c-VI). As such, it is essential that sufficient time is provided where the 7(c-I) scope remains valid for EUROMOT members, to engage with their supply chain to identify which exemption would be applying to their uses. Without the continued provision of 7(c-I) engine and end-product manufacturers will be forced to stop selling products that do not comply with RoHS. At this stage, it is not known which EUROMOT products would be affected, but could affect many types of end-users in the EU.

It is plausible that users of electrical components do not know in which exact application under exemption 7(c)(I) lead is actually used as long as producers and suppliers of these components do not provide additional information besides the fact that the component contains lead as authorised by exemption 7(c)(I). Producers of electrical and electronic components are, however, not obliged to specify the exact use of lead. Such information thus actually may not be readily available at the level of EEE producers. Applicants like producers of EEE and their associations are, however, expected to substantiate their renewal requests with the technical evidence that substitution or elimination of lead are still scientifically and technically unpracticable to justify granting an exemption in line with Art. 5(1)(a). This implies that they either include component producers in their supply chain into the consortium requesting the renewal, or they access the supply chain to be able to provide adequate technical expertise.

With view to the adoption of the recommended exemptions 7(c)(V) and 7(c)(VI) in their current wordings, the absence of the respective expertise actually bears the risk for producers of cat. 11 EEE that uses of lead remain out of scope for which its substitution or elimination are scientifically and technically not yet practicable. (EUROMOT et al. 2023a) want to avoid this risk by extending the scope of the exemption in its wording by adding to the current wording of exemption 7(c)(I) that these components can be *"used in engines, engine components and ancillary components and in end-products"* of cat. 11 (cf. Table 8-2 on page 129).

This addition neither fits the architecture of the current exemption 7(c)(I) if it shall remain applicable for other categories of EEE as well, nor the intention of the recommended exemptions 7(c)(V) and 7(c)(VI) which attempt specifying and structuring the exemption scope by specific technical application criteria instead of renewing the exemption with the current material specific exemption scope.

TMC

Cat. 9 IMCI was included in the review of exemption 7(c)(I) of (Baron et al. 2022) since its renewal was requested by applicants including the Umbrella Project at that time.

(TMC 2023b) do not agree to adopt the recommended renewed exemption 7(c)(V) and 7(c)(VI) for cat. 9 IMCI because exemption 7(c)-I is the most frequently used exemption in test and measurement electronic products; most electronic products contain this exemption

because of the broad range of applications. As further outlined in TMC's submission there is no single substitute available that would be suitable to all the applications identified. The Test & Measurement Coalition therefore applies for a renewal of exemption 7(c)-I for the maximum validity period, as it considers the criteria of RoHS art. 5(1)(a) are met.

This answer does not explain why the recommended renewed exemptions cannot be adopted for cat. 9 IMCI since the recommended renewals target structuring the scope but not to exclude uses of lead for which its substitution and elimination is scientifically and technically not yet practicable. TMC do not provide technical justifications.

TMC are in the same situation as EUROMOT, i.e. they do not know the specific applications of lead that are applied in electrical and electronic components used in cat. 9 IMCI. Adopting the recommended renewed exemption 7(c)(V) and 7(c)(VI) in their current wordings bears the risk for producers of cat. 9 IMCI that uses of lead remain out of scope for which its substitution or elimination are scientifically and technically not yet practicable. However, like in the case of EUROMOT, producers of EEE and their associations requesting the renewal of exemptions are obliged to organise adequate technical expertise so that they can substantiate their renewal requests.

Werfen

(Werfen 2024) confirm that exemption III-7(c)(VI)(1) for PZT in category 8 IVD for diagnostic medical devices for the analysis of whole blood would cover Werfen's exemption renewal application completely.

(Werfen 2022) had originally requested the exemption for 5 years only. (Werfen 2023) amended the original request extending the requested validity period to 7 years.

(Werfen 2024) *explain that at the time of filing the original exemption application in January 2022, 5 years were deemed sufficient time for implementation, based on initial benchtop data from external consultants. Since then, internal feasibility activities have progressed toward developing an alternative lead-free material:*

- Additional benchtop studies expanding the scope and sample sizes compared to studies conducted by consultants
- Integration into the full GEM system to evaluate complete functionality
- Assessing impacts on the constraints of the established GEM system

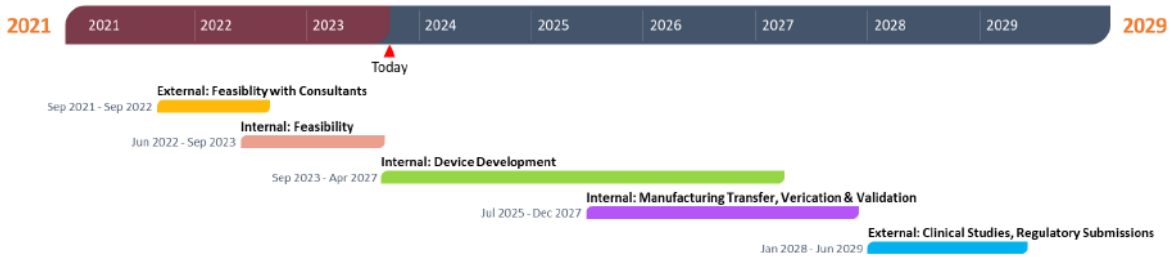
After initial testing, currently available lead-free alternatives have not proven to have the performance that is required to move forward with implementation. The result is that 5 additional years from our proposed exemption extension in the January 2022 application are required for internal development, to the full 7-year maximum validity (also referred to 2026 + 2 or 2028). Testing thus far has shown that the available lead-free alternatives are not a viable solution to implement as all options are accompanied by substantial impact to the existing architecture of the system.

Optimization to achieve equivalent performance would require multiple rounds of high-volume testing in conjunction with modifying the manufacturing process. The goal of additional development is to implement a solution that does not compromise safety, effectiveness, and reliability of the current device utilizing PZT. It is for this reason the application is being updated to request the maximum validity renewal of 7 years. The

additional timeline for compliance includes both the internal development required as well as the external regulatory processes with IVDR.

The timeline requested allows for internal timeline completion and factors in time for any external process completion that may follow making any changes to the product once it is on-market. Below table shows the project timeline for compliance with the RoHS directive.

Figure 8-1: Amended timeline for compliance



Source: (Werfen 2024)

The above plan shows that substitution should be achieved until end of 2029.

Stakeholder contribution PARI Pharma

(Pari Pharma 2023) request that the scope under III-7(c)(VI) be expanded to include the use of "Category 8 vibrating membrane nebulizers in active medical devices for inhalation therapy" in addition to the scope expansion "IVD for the analysis of blood" proposed by (Werfen 2023). The stakeholder uses a piezo element made of PZT to operate the membrane.

Like in the case of the applicant Werfen, the renewed exemption 7(c)(VI) recommended by (Baron et al. 2022) covers the above use of lead. Lead-zirconium-titanate (PZT) ceramics are explicitly mentioned in sub-clause 7(c)(VI)(1).

Stakeholder contribution SRT

(SRT 2023a, 2023b) criticise the resistivity limits of sub-clause 7(c)(V)(4) (cf. Table 8-4 on page 131) and demand their expansion. They announced that they successfully produced several lead-free resistors from pastes with resistivities of 1 Ω/square, 10 kΩ/square and 10 MΩ/square. They still need, however, to test their life time, and whether they are trimmable (cf. section "Stakeholder contributions" on page 143).

Asked why sub-clause 7(c)(V)(4) is still required for lower resistivities in the light of their above information, (SRT 2024b) report about the results of their tests with these lead-free resistivity pastes. The lead-free pastes from 1 MOhm/square upwards are not usable for their trimming processes (Nd:YAG laser-trimming). They cannot achieve the tolerance which their customers are ordering. To their knowledge the pastes below 1 MOhm/square are different to the pastes at 1 MOhm/square and above regarding the chemistry. The material is conducting phase changes there and is different. This and the higher resistance region is – to their knowledge – are the reasons for failing the trimming process. The printing process itself is fairly good, but does not have the quality to have most of the parts within +-1% accuracy (more like +-10 %).

(SRT 2024b) need more time of testing to find a workaround for the trimming problem, and for environmental testing, especially for durability at different climatic conditions. They adhere mostly to a standard test catalogue (MIL-STD202 or/and IEC60068-2) or a mixture of it, also depending on the customers. Some tests are done within a few days (e.g. resistance to soldering heat or short time overload), but some tests take half a year or more (load life test 1000 h or 8000 h, high temperature exposure 1000 h or 8000 h, high humidity test 1000 h or more). These tests have to be done for different case sizes (at least 6 different SMD sizes) and resistance values (e.g. every decade) which means that a huge amount of work. They neither have the equipment nor the manpower to do all these tests; they have to engage a company whose is specialised in such tests.

As to the lower end of the resistivity range, (SRT 2024b) produce resistance values below 1 Ohm down to 0.1 Ohm for which they use pastes below 1 Ohm/square that are not lead-free. Using a conducting paste is probably too low in resistance value. To the best knowledge of (SRT 2024b), there is no supplier of a lead-free paste below 1 Ohm/square, for example 0.5 Ohm/square or 0.3 Ohm/square.

SRT undertake efforts to find lead-free solutions and the provided information suggests that lead-free pastes are available for some resistivity ranges but they need to be qualified to ensure their reliability.

(Baron et al. 2022) justify the applied resistivity limits stating that lead is used in Resistor Networks, Power Resistors, Chip Resistors/Arrays, Fuel cards, PTCs, Sensors, and Diodes to name some examples. 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. 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.

The consultants conclude from the above reasoning that the resistivity limits in exemption clause III-7(c)(V)(4) are based on example values for which lead-free solutions were not available. Examples for very low and very high resistivity pastes may not have been available at that time and were thus excluded from the exemption scope. The available examples of (Baron et al. 2022) and SRT suggest that the substitution or elimination of lead is scientifically and technically impracticable in resistivity pastes and inks independently from the resistivity values.

The consultants therefore recommend removing the resistivity ranges in the wording of this sub-clause.

(SRT 2023b, 2024a) further state that they use a wrap-around material which is not lead-free, and where no alternative material is available. This wrap-around of their resistors establishes the electrical path from the lower side of the resistor to the upper side where the resistive layer is printed. It is very resistant to leaching (with a high content of platinum) which is important for soldering, and it is also used as contact material. This application is not covered by the recommended renewed exemption 7(c)(V) either.

(SRT 2023a) mention a lead-free glazing paste which they can use. (SRT 2024b) specify that they have started to use this lead-free passivation in first projects for only a small number (<10) of batches and therefore have only limited production experience with this lead-free paste. Some problems are still to overcome, for example, this paste seems to be more prone to air bubbles at printing. Completely missing are long term production data and

climate/environmental data e.g. humidity, high temperature, and so on. This will take one to one and a half year.

The above potential substitute for lead can be taken into account in the next review of exemption 7(c)(I) to specify and/or narrow the exemption scope.

In the light of the information provided, the consultants conclude that adopting exemption sub-clause 7(c)(V)(4) as recommended by (Baron et al. 2022) may exclude uses of lead for which substitution or elimination is scientifically and technically still impracticable. The consultants propose adapting the wording as illustrated in the below wording to include these uses of lead.

Table 8-6: Proposed modification of exemption sub-clause 7(c)(V)(4) recommended by (Baron et al. 2022)

No.	*Exemption*	*Scope and dates of applicability*
7(c)(V)	*Electrical and electronic components containing lead in a glass or glass matrix compound that fulfils the following functions:* … *4) Used as resistance materials such as ink or paste* … *6) Used as contact, passivation and wrap-around contact material (pastes, inks) for resistors*	Applies to cat. 1 to 11 Expires on 21 July 2026

Stakeholder contribution of the Umbrella Project

Coverage of applications requiring the use of lead

(UP 7(c) (I) 2023) state that the applications listed in 7(c)(V) and 7(c)(VI) were provided in the exemption request issued by the UP in 2020 and reviewed by (Baron et al. 2022) as illustrative non-exhaustive examples. They wanted to explain why lead is essential to achieve the required properties and performance of the material. By no means it covers all applications and relevant components within the scope of 7(c)(I).

Upon request, (UP 7(c) (I) 2024a) provide more examples for applications which in their view are not covered:

- In 7(c)(V)(4), ink denotes only one technology, there are others like thin film, or foils employed. The clause currently refers to a thick film paste technology in the range of 1 to 10 MΩ/square, which could be used to make i.e. 1 Ω to 10 MΩ lead-free resistors with certain specifications, in this case with a temperature coefficient (TCR) of 100 ppm/K, but not for a TCR of 50 ppm/K where this paste could not be used, but maybe a leaded paste was required. This means that the resistivity value R is not sufficient to define a lead-free and lead-bearing resistor, respectively.
- In 7(c)(V)(1), the proposed wording limits the scope to glass beads for high voltage diodes and to specific materials. This would not cover uses like

- electrical passivation layers of semiconductor chips and wafers
- glass as part of the package (i.e. pressure contact glass sleeve packages) of electronic discrete components
- 7(c)(VI(1) excludes
- lead containing piezoelectric ceramics that are not PZT
- lead containing pyroelectric ceramics
- lead containing ferroelectric ceramics

The stakeholder contribution of (SRT 2023a, 2023b) is in line with the above statement for the case of resistivity materials (see above section) and confirm the above statement.

The consultants derive from the above examples that the recommended exemptions 7(c)(V) and 7(c)(VI) actually may not cover all uses of lead that are in the scope of the current exemption 7(c)(I) for which substitution and elimination of lead is scientifically and technically not yet practicable based on the conclusions of (Baron et al. 2022).

Impracticability of the splitting approach

(UP 7(c) (I) 2023) also criticise that splitting the exemption as proposed is not a feasible solution and would create more work for the EU as applications that are not covered by the proposed split/wording would force requests for additional exemptions to be raised. They believe that it is almost unrealistic to provide an exhaustive list that identifies the application categories in which lead is essential. Even if the applications could be categorized and split scientifically and technically correct, the number of different scopes is unpredictable, with some in industry predicting that the number will exceed 100. A technical assessment of such a large number of applications and related renewal requests would not be feasible and would cause extreme administrative burden without measurable benefit to the environment.

Considering the above, industry would like to reiterate that the recommended wording of exemptions 7(c)(V) and 7(c)(VI) is not fully developed to cover both the European market and the global supply chain. The adoption of this wording would prevent an unpredictable range of electrical and electronic equipment essential to society, such as medical equipment, from being placed on the European market, contrary to the intent of Article 5(1) of the RoHS Directive.

(UP 7(c) (I) 2023) state that the criteria for applications indicated in 7(c)-V and 7(c)-VI are an arbitrary mixture of materials, process parameters and products, which cannot be related to actual electrical and electronic components as well as the equipment using them in terms of physical properties, electrical properties, and applications, and their proper classification and information.

UP claim that they provided the examples which (Baron et al. 2022) listed under the recommended renewed exemptions 7(c)(V) and 7(c)(VI). This raises questions as to the above statement of (UP 7(c) (I) 2023) in the context that they submitted these materials, process parameters and products as examples for the use of lead in the scope of exemption 7(c)(I).

(UP 7(c) (I) 2024a) refer their statement to the fact that the approach used to develop the wording is inapplicable. The proposal is constructed in a way to list criteria for applications,

specific materials and parameters, where lead is indispensable. To cover all uses of lead, where alternatives are not available would create a nearly endless "positive" list. In addition, this approach is in contradiction to the current construction of 7(c), where 7(c)(I) is used as a joker to cover non-identified and special applications, where 7(c)(II) and the following parts identify applications, where alternatives are available and certain materials and applications can become restricted. Thus, we strongly recommend continuing that applicable approach and to identify future candidates for restrictions.

Another fact is, according to (UP 7(c) (I) 2024a), that criteria are defined, which are not accessible in the supply chain, thus prevent verification of RoHS compliance:

- 7(c)(V)(3) defines a process parameter window for a specific glass used for bonding purposes. Such information normally is company proprietary and not disclosed to customers of the components manufactured with such materials. RoHS compliance cannot be verified in such a situation.
- 7(c)(V)(4) defines a resistivity range of a material. Like in the above case, such information is not available to the customers of the component and RoHS compliance cannot be verified.

The consultants understand from the above explications that process parameters like in exemption 7(c)(V)(3) applied to manufacture a certain component cannot be verified from this component. An indirect verification would be feasible if this component could only be manufactured with one specific process which still requires lead. The latter seems not to be applicable to the case at hand, and if it was applicable, the component itself could be used to define the scope of the exemption.

The same seems to apply to 7(c)(V)(4), where resistors with the same resistance (indicated in Ω (Ohm) can be produced from materials with different resistivity/sheet resistance (Ohm/square) depending on the resistor size, area covered by the resistivity material on the resistor, thickness of the resistivity material, trimming of the resistor, etc. While the resistance of a resistor can be measured on the product, the resistivity of the material that was used to produce this resistor cannot be verified from the product. Additionally, as the consultants understand from the information provided by (UP 7(c) (I) 2024a), the interplay of the various parameters is proprietary knowledge of producers. To summarize, the exemption wording for the above cases should be based on component properties – type of component and/or its performance parameters - that can be verified rather than properties of materials and process parameters that were used to produce the component.

<u>Alternative approach proposed by (UP 7(c) (I) 2024a)</u>

As an alternative to the above approach of (Baron et al. 2022), (UP 7(c) (I) 2024a) propose continuing the current approach in 7(c) to identify and list such applications where lead-free alternatives or advanced technologies can become available to replace the current lead containing materials, as is visible in the current exemptions 7(c)-III and 7(c)-IV, which already have expired.

Even though the consultants understand that the approach of (Baron et al. 2022) may adverse implications, the above suggested strategy seems to be the perpetuation of the current situation. The attempt to structure the scope of the renewed exemption 7(c)(I) in exemptions 7(c)(V) and 7(c)(VI) is an attempt to change this situation.

(UP 7(c) (I) 2024b), following up on their above proposal, are fully aware of industry's obligation to provide a substantial proposal and a feasible way to realize that in practice.

The Umbrella Project technical Working group 7(c)-I fully understand the legislators concerns that the wide and undifferentiated scope of 7(c)-I would allow the use of lead, even where it is not essential anymore. However, knowledge of solid-state physics, chemistry, material science, and electrical and electronic component technology is necessary. Additionally, the ability to convert these constraints into a legally sound and also for non-scientists understandable text is essential for the formulation of a new and more differentiated wording of the exemption.

(UP 7(c) (I) 2024b) therefore started activities to develop a concept for a new wording clarifying that lead is allowed only in applications in electrical and electronic components where it is essential to fulfil the needed requirements. This proposal would fall into several classifications, if necessary, and would identify alternative technologies to replace lead containing materials. It is planned to provide these recommendations in conjunction with the exemption renewal request, which is due to be issued in January 2025 assuming an expiry date of current 7(c)-I on 31 July 2026. This initiative continues the efforts undertaken by component industry and material suppliers to make electrical and electronic components lead-free, and part of these efforts was included in their previous renewal requests (submitted in 2015 and 2020). As soon as they identify alternatives which fulfil the requirements of Article 5(1) of the RoHS Directive, they feel committed to identify and classify scopes for which lead phase-out would be possible during renewal requests (and propose expiry of exemptions for those scopes on a planned basis).

In the reviews of exemption 7(c)(I) by (Gensch et al. 2016) and (Baron et al. 2022), applicants and stakeholders objected all attempts to specify the scope of exemption 7(c)(I), which hampered progress and affected the success of such efforts. In this respect, the above commitment can offer a chance to access the expertise of industry as to the actual applications of lead in 7(c)(I), and to arrive at a concise and well applicable wording for a structured scope of exemption 7(c)(I) rather than in the past where consultants had to work against industry.

Weighting the risk that the scope structure proposed by (Baron et al. 2022) currently does not cover all still required uses of lead, versus the risk that the above UP proposal will not bring progress either, the renewal of exemption 7(c)(I) with the current wording until 21 July 2026 may be acceptable and the most practicable solution. (Baron et al. 2022) recommend this expiry date for their recommended exemptions 7(c)(V and VI). If the COM renews the current exemption 7(c)(I) until 21 July 2026 – or a later date to ensure sufficient time between the COM's official decisio and the deadline for submission of renewal requests – applicants like UP could present their alternative approach to structure the scope. Should this turn out to be inexpedient, the consultants reviewing the exemption next time could, for example, still try to amend the current approach of (Baron et al. 2022) based on the insights obtained from the stakeholder feedbacks of this review as how to better formulate such conditions.

8.3.3. Environmental, health, and safety impacts

(Werfen 2023) had an LCA prepared which they interpret as showing that lead has lower environmental impacts (in terms of the measures produced by LCA) in certain categories than the two alternatives. Further details of the LCA were provided as confidential information. The LCA can therefore not be considered in the consultants' recommendation for the applicant's exemption renewal request. Recommendations as to granting – or not granting – requested exemptions can only be based on publicly available information.

(EUROMOT et al. 2023a) reference the Life Cycle Assessment (LCA) of lead-free piezoelectrics submitted by the Umbrella Project to the last review of exemption 7(c)(I) by (Baron et al. 2022) where the lead-free alternatives assessed have a greater total negative environmental impact.

(Baron et al. 2022) did not review this LCA as base for their recommendations stating their understanding that the applicant's main arguments for the renewal of exemption 7(c)(I) were based on the scientific and technical impracticability of lead substitution or elimination.

The consultants' mandate for this review is to assess whether the recommendations of (Baron et al. 2022) can be adopted to cat. 8 IVD, cat. 9 IMCI and cat. 11 in the light of the renewal requests at hand, not to re-evaluate the recommendations of (Baron et al. 2022). The consultants therefore followed that same approach like (Baron et al. 2022) and focused their review on the applicants' arguments concerning the scientific and technical practicability of lead substitution or elimination.

8.3.4. Socioeconomic impacts

If the exemption is not renewed, the consultants cannot exclude that negative socio-economic impacts elaborated by the applicants (cf. section 8.2.3 on page 144) may actually arise.

(TMC 2023b) point out that it needs to be kept in mind that industrial monitoring and control instrument manufacturers have to manage suppliers' declarations for hundreds of thousands of items. TMC members have difficulty in understanding how the rewording and relisting and/or splits recommended by the consultants (Baron et al. 2022) will lead to greater protection of human health and the environment compared to the wording in its current form. The recommended rewording/split would only lead to significant unnecessary burden for stakeholders without commensurate benefits.

In the consultants' view, this administrative aspect is part of the compliance obligations of all manufacturers of all categories of EEE. Even though it should be kept in mind that changes of exemption wordings and exemption scopes may cause administrative burdens for affected manufacturers, articles 4 and 5(1)(a) require priority of substitution and elimination of use of restricted substances, and well-defined exemption scopes are a pre-condition for this. The attempt of (Baron et al. 2022) to structure the exemption scope is motivated by this priority. It is at the discretion of the COM to decide whether specific cases would justify different priorities, e.g. administrative or other socio-economic impacts.

8.3.5. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria[28] is fulfilled:

[28] Differently from Art. 5(1)(a) in the RoHS Directive, the criteria are numbered so that they can be addressed in the below text.

4. *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;*
5. *the reliability of substitutes is not ensured;*
6. *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.*

EUROMOT (cat. 11), TMC (cat. 9 IMCI) and Werfen (cat. 8 IVD) applied for the renewal of exemption III-7(c)(I) – in case of EUROMOT and Werfen with a modified wording - for the maximum validity period claiming that substitution or elimination of lead is scientifically and technically not yet practicable for the applications of lead in the scope of this exemption. These statements are in line with the conclusions of (Baron et al. 2022) so that granting the requested exemptions would be covered by Art. 5(1)(a) but the modifications of the exemption wording for a renewed exemption 7(c)(I) as proposed by EUROMOT and Werfen are not practicable.

As to the adoption of the exemptions 7(c)(V) and 7(c)(VI) recommended by (Baron et al. 2022), two stakeholders (SRT and Pari Pharma) request adding or changing sub-clauses to the these renewed exemptions to ensure that they cover their specific uses of lead in the scope of the current exemption 7(c)(I). While Pari Pharma's lead application is included into the scope of 7(c)(VI), the use case of SRT seems to be excluded so that the respective exemption sub-clause would have to be amended accordingly.

The Umbrella Project (UP) contributed their perspective on the approach of (Baron et al. 2022) stating that the recommended exemptions 7(c)(V) and 7(c)(VI) by far do not cover all uses of lead in the scope of the current 7(c)(I) for which substitution and elimination are scientifically and technically not yet practicable. They provide examples to substantiate their statement, and the case of SRT is a further hint that not all still required lead applications may be covered. UP point out that, in order to cover the manifold uses of lead under exemption 7(c)(I), a long list with up to 100 sub-clauses may have to be defined for the renewed exemptions 7(c)(V and VI).

UP also put forward that at least part of the wordings of the various sub-clauses in the recommended exemptions 7(c)(V) and 7(c)(VI) are not practicable as they refer to process parameters or specific material properties that cannot be verified from the component/EEE. Examples for verifiable component properties are exemptions 7(c)(II and III) and 7(c)(IV) where voltage thresholds or specific uses of a lead-containing material in a component demarcate the exemption scope in a way that can be verified on the component.

The above stakeholder requests and information suggest that the recommended exemptions 7(c)(V and VI) in their current wordings are neither complete nor fully applicable and implementable, and should therefore not be adopted to the requested exemption renewals for cat. 9 IMCI and cat. 11. Even though the changes requested for cat. 8 IVD would be covered, it can be assumed that this would not be the case for all other uses of lead in cat. 8 and in all other categories of EEE since the current exemption 7(c)(I) is of relevance across all categories of EEE in manifold applications.

Nevertheless, the attempt of (Baron et al. 2022) should be considered as an important and valuable incentive for industry to take initiative and use their expertise to elaborate a better approach. The Umbrella Project declared their commitment to develop a concept for a new

wording would imply several classifications, if necessary, and identify alternative technologies to replace lead containing materials until January 2025.

Considering all information submitted by applicants and stakeholders, the consultants recommend renewing exemption 7(c)(I) taking over the expiry date 21 July 2026 set by (Baron et al. 2022) for cat 8 IVD, cat. 9 IMCI and cat. 11, as well as for all other categories of EEE. Applicants like the Umbrella Project can then submit their new concept, and, should this be inexpedient, the consultants reviewing the exemption renewal requests could try amending the current proposal of (Baron et al. 2022) based on the insights obtained from the information submitted to this review.

8.4. Recommendation

The information provided suggests, in line with the conclusions of (Baron et al. 2022), that elimination or substitution of lead in the applications in scope of the current exemption 7(c)(I) is scientifically and technically not yet fully practicable. Art. 5(1)(a) thus would justify renewing the exemptions for cat. 8 IVD and for cat. 9 IMCI as proposed as a result of the previous review by (Baron et al. 2022) already, as well as for cat. 11, which was not included in that previous review but also relies on exemption 7(c)(I).

The information provided by the applicants and stakeholders also suggests, however, that the recommended renewal of exemption 7(c)(I) with a split and structures exemption scope as proposed by (Baron et al. 2022) does not yet cover all uses of lead for which its substitution or elimination are scientifically and technically are currently in and the coming years not practicable. Furthermore, some of the proposed wordings seem not yet to be applicable to precisely and verifiably describe the scope of the renewed exemptions.

Following up on the recommendation of (Baron et al. 2022) to structure the scope of the current exemption 7(c)(I), the Umbrella Project announced to elaborate an alternative proposal to structure the scope of exemption 7(c)(I) and committed themselves to submit their approach to the next review of exemption 7(c)(I) in 2026.

Overall, in the light of the information made available and the above commitment of the Umbrella Project, the consultants recommend renewing exemption 7(c)(I) for cat. 8 IVD, cat. 9 IMCI and cat. 11. (Baron et al. 2022) recommend 21 July 2026 as expiry date of the renewed exemptions for all categories of EEE. This expiry of the renewed exemption 7(c)(I) should be adopted to enable the review of the exemption for cat. 9 IMCI and cat. 11 together with all other categories of EEE to arrive at a more application-specific scope of this exemption for all EEE covered by the RoHS Directive.

Adding to this, both applicants highlight that they depend on their suppliers to provide them with RoHS-compliant materials and components but do not have such suppliers in their consortia that requested the renewal of the exemption. A joint next review of the exemption with other consortia representing material and component manufacturers as well is therefore considered to be a precondition to further develop the exemption from the current purely material- to a more application-specific the announced contribution of the Umbrella Project found to be inexpedient in the next review after 2026, the reviewers may consider amending the approach of the Umbrella Project.

Alternatively, as a fall-back option, the current proposal of (Baron et al. 2022) could be amended taking into account the stakeholder inputs of this review.[29].To ensure that all applications of lead in the scope of the renewed exemption 7(c)(I) are covered, a salvatory clause could be added that covers all uses of LHMPS that are not yet defined in the scope. This approach would require producers to specifically declare the use of lead in the specific applications at least. For the applications of lead under the salvatory clause, the practicability of the approach proposed by (KEMI 2023) for exemption 7(a) could be assessed *to require that the exemption is justified in the technical documentation if applied*, and to declare the specific uses of lead.

The below table shows the recommended renewed exemption.

No.	Exemption	Scope and dates of applicability
III-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 This exemption does not include the uses of lead in the scope of the following exemptions: - 32 and 34 of Annex III - 1(a), 4 and 39 of Annex IV	Applies to categories 8 in vitro diagnostic medical devices, category 9 industrial monitoring and control instruments, and category 11. Expires on 21 July 2026 for categories 8 in vitro diagnostic medical devices, category 9 industrial monitoring and control instruments, and for category 11.

Exemptions III-32 and III_34, as well as IV-1(a), IV-4 and IV-39 should be excluded[30] from the scope of the renewed exemption III-7(c)(I) to avoid scope overlaps.

The consultants further recommend that the COM ensures sufficient time between the official publication of the COM's decision and the expiry date of the exemption to allow for the preparation and timely submission of renewal requests 18 months prior to the expiry of the exemption.

Applicants' and stakeholders' feedback on the recommendation

(EUROMOT et al. 2024) support the recommended wording and recognised that the aligned expiration dates for all categories would be beneficial from an administrative viewpoint. EUROMOT members reiterate the need for at least 5 years to qualify alternatives.

(TMC 2024) agree with the recommended wording but contest the expiry date in the light of the information provided in their application dossier where a 7 years renewal was requested.

[29] Cf. sections "Stakeholder contribution SRT" and "Stakeholder contribution of the Umbrella Project".

[30] The COM should take into account potential changes in the exemption numbering due to pending renewals of some of these exemptions.

(Werfen 2024) criticise the 2026 expiry date as inadequate in the light of lacking commercially available piezo replacements.

(SRT 2024c) support the exemption wording and the 2026 expiry date for all categories of EEE as the best way for SRT provided the possibility to start a new request.

(UP 7(c)(I) 2024b) agree to the above recommendation but criticise the early expiry date with respect to the time remaining for submitting renewal requests.

The consultants are confident that they considered all relevant arguments made available by applicants and stakeholders during the review, and that the arguments have been evaluated taking into account the requirements of Art. 5(1)(a) and the mandate commissioned by the COM for the review of this exemption.

8.5. References

Baron et al. (2022): 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. In cooperation with Yifaat Baron, Carl-Otto Gensch, Andreas Köhler, Ran Liu, Clara Löw, Katja Moch, Oeko-Institut e. V. (Pack 22). Retrieved from https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_22/RoHS_Pack-22_final_report_amended_February_2022.pdf.

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9. Exemption 8(b)-series of Annex III: Cadmium in electrical contacts

The below Table 9-1 shows the wording, scope and expiry dates of the exemption.

Table 9-1: Current wording of the exemption 8(b)-series

No.	Current exemption wording	Current scope and dates of applicability
III-8(b)	Cadmium and its compounds in electrical contacts	Applies to categories 8, 9 and 11. Expires on - 21 July 2021 for categories 8 other than in vitro diagnostic medical devices and for cat. 9 other than industrial monitoring and control instruments; - 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.
III-8(b)(I)	Cadmium and its compounds in electrical contacts used in: - circuit breakers, - thermal sensing controls, - thermal motor protectors (excluding hermetic thermal motor protectors) - AC switches rated at: - 6 A and more at 250 V AC and more, or - 12 A and more at 125 V AC and more - DC switches rated at 20 A and more at 18 V DC and more, and - switches for use at voltage supply frequency ≥ 200 Hz	Applies to categories 1 to 7 and 10. Expires on 21 July 2021 for categories 1 to 7 and 10.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instruments
Cadmium-free	Not containing cadmium in the applications covered by the scope of the exemption to be reviewed
RoHS 1	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	Directive 2011/65/EU, current RoHS Directive
TMC	Test & Measurement Coalition

9.1. Background and technical information

On 20 January 2023, (TMC 2023a) requested the renewal of exemption III-8(b) for cat. 9 industrial monitoring and control instruments (IMCI) for the maximum validity period of 7 years as displayed in the below table.

Table 9-2: Wording and scope of the requested exemption

No.	*Requested exemption*	*Requested scope and dates of applicability*
III-8(b)	*Cadmium and its compounds in electrical contacts*	*Applies to category 9 industrial monitoring and control instruments.* *Expires on 21 July 2031 (2024 + 7) for cat. 9 industrial monitoring and control instruments.*

9.1.1. History of the exemption

The use of cadmium in electrical contacts was already exempted under exemption no. 8 in the Annex of Directive 2002/95/EC (RoHS 1) when RoHS 1 entered into force in 2003:

> *8. Cadmium plating except for applications banned under Directive 91/338/EEC amending Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations.*

With the Commission Decision 2005/747/EC in October 2005, the exemption wording was changed to:

> *8. Cadmium and its compounds in electrical contacts and cadmium plating except for applications banned under Directive 91/338/EEC amending Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations.*

The exemption was first reviewed by (Gensch et al. 2006), later again by (Gensch et al. 2009) and thus gradually transferred into the below status with a split into exemption 8a and 8b:

> *8(a) Cadmium and its compounds in one shot pellet type thermal cut-offs*
>
> *Expires on 1 January 2012 and after that date may be used in spare parts for EEE placed on the market before 1 January 2012*
>
> *8(b) Cadmium and its compounds in electrical contacts"*

(Gensch et al. 2009) recommended the expiry date 31 July 2014 for exemption 8(b), which was the maximum duration (i.e., 4 years) under RoHS Directive 2002/95/EC (RoHS 1). Cadmium-free contact materials were available for applications under exemption 8(b), but industry required time to adapt and test their use to their applications to make sure the cadmium-free contacts suffice in terms of safety and other requirements. The COM adopted the exemption with a validity period of four years.

The exemptions in the Annex of RoHS 1 including exemptions 8(a) and 8(b) were transferred into the recast RoHS Directive 2011/65/EU (RoHS 2). During that process, the expiry dates of all exemptions with maximum validity of four years were systematically extended to five years starting from July 2011 on. This gave industry a total of seven years since 2009 to substitute or eliminate cadmium in contacts.

(Sensata et al. 2015)nevertheless requested the renewal of exemption 8(b) for another five years in 2015. The review by (Gensch et al. 2016) resulted in the split into two exemptions 8(b) and 8(b)(I) with the current wordings and scopes. (Sensata et al. 2020) submitted another request on 16 January 2020 for another renewal of the exemption so that the two exemptions had become due for review again. (Deubzer et al. 2022) recommended to renew exemption 8(b) as exemption 8(b)(II) for cat. 8 and for cat. 9. IMCI:

Table 9-3: Potential renewal of exemption III-8(b) as exemption III-8(b)(II)

No.	Exemption	Scope and dates of applicability
8(b)	Cadmium and its compounds in electrical contacts	Applies to categories 8, 9 and 11 Expires on - [date of official publication of the COM decision in the Official Journal + 12 months] for cat. 11 - [date of official publication of the COM decision in the Official Journal + 18 months] for category 8 medical devices including in-vitro diagnostic medical devices, and category 9 monitoring and control instruments including industrial monitoring and control instruments

8(b)(II)	Cadmium and its compounds in electrical contacts used in: - circuit breakers - thermal sensing controls - thermal motor protectors (excluding hermetic thermal motor protectors) - AC switches - DC switches	Applies to categories 8 and 9 from [date of the official publication of the COM decision in the Official Journal + 18 months + 1 day] on. Expires on - 31 December 2023 for circuit breakers in rotating parts of computer tomography (CT) medical devices (category 8 medical devices other than in-vitro diagnostic medical devices) - 31 December 2025 for portable emergency defibrillators (cat. 8 medical devices other than in-vitro diagnostic medical devices) with a Declaration of Conformity (DOC) issued for the first time before 1 January 2015 - **31 December 2025** for other cat. 8 medical devices including in-vitro diagnostic medical devices, and **for category 9 monitoring and control instruments including industrial monitoring and control instruments**.

Source: (Deubzer et al. 2022)

9.1.2. Focus of the review of this renewal request

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status March 2024). The applicant therefore applied for the renewal of the current exemption 8(b) for cat. 9 IMCI since it was earmarked for expiry on 21 July 2024 for this subcategory of cat. 9 EEE. The exemption thus became due for review even though the recommendation for the renewal of exemption 8(b) and 8(b)(I) of (Deubzer et al. 2022) included cat. 9 IMCI.

In the light of this situation, the COM tasked the consultants to assess in their review of the exemption renewal request at hand whether and how far the recommendation of (Deubzer et al. 2022) can be adopted to cat. 9 IMCI in line with Art. 5(1)(a). A re-evaluation of the previous review by (Deubzer et al. 2022) is not intended. The consultants will rely on the critical review conducted by the previous consultants and on the resulting conclusions and recommendation unless the renewal request or stakeholder contributions give reasons to reassess the state of science and technology.

9.1.3. Summary of the renewal request

(TMC 2023a) summarise their renewal request explaining that under Exemption 8(b) cadmium and its compounds, such as silver cadmium oxide (AgCdO), are used for electrical isolation purposes in electrical contacts. The need for creating an open contact (vs solid state switching) is typical for electrical isolation purposes, where the safety standards require a minimum electrical clearance between contacts if it is being relied upon for safety isolation. A common example includes supplemental circuit breakers on equipment for configuration or servicing, where relying on the power cord as the disconnect device is not practical.[31]

The function of Cd and AgCdO as well as the chemical and physical advantageous properties of Cd/AgCdO in the components used for cat. 9 IMCI include:

- *Resistance to arcing*
- *Resistance to corrosion / pitting / material transfer*
- *Resistance to oxidation in order to keep the electrical contacts clean and free of insulating oxides. This enhances the life-span of connectors, especially those that are high frequency.*
- *Resistance against contact welding*
- *High electrical conductivity*
- *High thermal conductivity, which helps the effective dissipation of heat*
- *High melting point, which is required to avoid accidental overheating as a consequence of the fusion of contact points.*

Since the RoHS directive was adopted, electric contact and switch manufacturers have researched potential alternative materials. The substitution or elimination of cadmium and its compounds is, in principle, scientifically and technically practicable for some applications. Each substitute that has been evaluated had differing properties and therefore, to the best knowledge of the Test & Measurement Coalition, no single "drop-in" replacement exists for cadmium and its compounds for all applications.

Pursuant to Article 5 of the RoHS Directive a continuation of exemption 8(b) should thus be granted on the basis that ***alternatives are not suitable for substitution or replacement for all applications****. These applications include circuit breakers, thermal sensing controls, and high power / high frequency switches. This echoes the stance of the Oeko-Institut Report published in 2016.*

A thorough Socio-Economic Analysis was conducted in addition to the technical assessment and attached to this submission, further illustrating the negative socio-economic impacts a non-renewal of exemption 8(b) would have. Overall, the analysis concludes that the ***total impact of a non-renewal of this exemption is monetized in the range of 1.6 billion EUR and 2.3 billion EUR*** *(conservative lower bound estimate).*

[31] See EN 61010-1:2017 clause 6.11 for disconnect requirements for Category 9, industrial equipment. Additionally, the circuit breaker itself needs to comply with IEC 60947-2; source as referenced by TMC 2023a.

9.1.4. Technical description of the exemption and use of the restricted substance

(TMC 2023a) describe the advantages of Cd and AgCdO which have been used in electrical contacts due to its below properties:

- Resistance to arcing
- Resistance to corrosion / pitting / material transfer
- Resistance to oxidation in order to keep the electrical contacts clean and free of insulating oxides. This enhances the life-span of connectors, especially those that are high frequency.
- Resistance against contact welding
- High electrical conductivity
- High thermal conductivity, which helps the effective dissipation of heat
- High melting point, which is required to avoid accidental overheating as a consequence of the fusion of contact points.

The technical background of cadmium uses and requirements for electrical contacts was described in more details in the review reports of (Gensch et al. 2016) and (Gensch et al. 2009), and in Deubzer et al. (2022).

(TMC 2023b) claim that currently available alternatives are not suitable for substitution or replacement in T&M instruments' critical components and their applications.

9.1.5. Amount(s) of restricted substance(s) used under the exemption

(TMC 2023a; EPPA 2023) estimate between 5 kg and 6 kg of Cd to be placed on the EU market contained in applications in the scope of the requested exemption, based on the replies provided by the TMC members.

Since not all producers of cat. 9 IMCI are members of TMC, the actual amount of cadmium could be higher.

9.2. Justification of the requested exemption

9.2.1. Substitution and Elimination of the restricted substance

(TMC 2023a) claim that currently available alternatives are not suitable for substitution or replacement in cat. 9 IMCI critical components and their applications. These applications include circuit breakers, thermal sensing controls, and high power / high frequency switches. Cd and AgCdO exhibit certain unique physical and technical characteristics. The advantageous properties of AgCdO especially in relation to the impact of repeated arcs from high current DC loads is further outlined in a dissertation by Frederic Pons from the Georgia

Institute of Technology.[32] The study investigates said impacts switched from a resistive load for a uniform and repeatable arc format and analysed the results on the contact faces using a scanning electron microscope to compare the response of AgCdO coated contact to arcs to $AgSnO_2$. When the arc occurs, it causes the silver to melt but due to the close melting point temperature of the silver and CdO, there are CdO clusters finely distributed in the layer. This effectively restores the contact material skin reducing the impact of repeated arcs and yielding a consistent contact resistance. The $AgSnO_2$ did not yield as good a result as predicted by the dissimilar decomposition temperature of the alternate oxide to silver.

(TMC 2023a) put forward scientific research, as well as testing by several manufacturers, that has shown that alternative substances are more prone to electrical arc erosion and tack welding.[33] This will result in more product failures that are anticipated to impact product safety. Each substitute that has been evaluated had differing properties and therefore no single "drop-in" replacement exists for all applications that rely on cadmium and its compounds.

Therefore, (TMC 2023a) argue, based on the current state of the art, AgCdO still represents a stable solution to the repeated arc model which is inherent to an inductive switching load or other high voltage switching that currently continues to require the 8(b) and 8(b)-I exemption. The alternatives, thus far, will yield a poorer contact surface which will ultimately lead to premature component failure and potential unreliable results leading up to total component failure. (EPPA 2023) claim that there are currently no suitable cadmium-free alternatives that meet RoHS exemption criteria on the EU market for cat. 9 IMCI and that the re-designing of the cat. 9 IMCI could take four to six years per product line. Hence, losing the ability to apply Annex III, exemption 8(b) when considering RoHS conformity for the associated test and measurement industrial products would entail the development of a fairly large number of new alternative compliant materials as well as the increased costs connected to the redesign, retesting, requalification and replacement of the assembly process.

(TMC 2023a) are of the opinion that the renewal of exemption 8(b) should be granted on the basis that currently available alternatives are not suitable for substitution or replacement in cat. 9 IMCI critical components and their applications like circuit breakers, thermal sensing controls, and high power / high frequency switches. More time is required to adapt designs, find contact materials, and for qualifying cadmium-free solutions in the supply chain and in the products of EEE manufacturers. This is required since the cadmium-free contact materials are not "drop-in" replacements. This echoes the stance of the Oeko-Institut Report of (Gensch et al. 2016) published in 2016. No further technological developments have, to the best knowledge of the participating companies, occurred since then. Thus, the unavailability of alternatives for all applications that use cadmium-based electrical contacts warrants the renewal of this exemption. More time is required to adapt

[32] F.Pons, "Electrical contact material arc erosion: experiments and modelling towards the design of an AgCdO substitute", PhD Thesis, May 210, Georgia Institute of Technology, https://smartech.gatech.edu/bitstream/handle/1853/33816/pons_frederic_201005_phd.pdf; source as referenced by TMC 2023a.

[33] Building a Better Cadmium Replacement. Available at: https://connectorsupplier.com/a-mil-plating-cadmium-061912/; source as referenced by TMC 2023a.

designs, find contact materials, and for qualifying cadmium-free solutions in the supply chain and in the products of EEE manufacturers.

9.2.2. Environmental, health, safety and socioeconomic impacts

(EPPA 2023) prepared a socio-economic analyses (SEA) for TMC showing the impacts which a non-renewal of the exemption for cat. 9 IMCI would cause. (EPPA 2023) declare that the SEA was prepared in line with the official ECHA guidance on the preparation of the Socio-Economic Analysis. The SEA is based on information and data gathered from the industrial and professional test and measurement equipment manufacturers. A survey has been conducted by providing a detailed questionnaire to gather information and data from actors likely to be affected by a non-renewal of the RoHS exemption in the EU. TMC member manufacturers of cat. 9 IMCI participated in the survey. The market share covered by this survey represents approximately 70 % of the EEA market so that (EPPA 2023) consider the survey as highly representative so that it can serve as a basis for defining the anticipated socio-economic impacts resulting from the non-renewal of the RoHS exemption.

(EPPA 2023) inform that participating TMC member companies report no releases to the environment of cadmium can be anticipated during neither equipment production nor use phases of the concerned products over the next seven years as a consequence of the revocation of the RoHS exemption. During equipment production, the cadmium is not exposed because it is internal to the component. At component manufacturers level, exposure and waste and exposure to cadmium is considered controlled through good occupational health and safety management practices.

Under normal conditions of equipment use, the cadmium content associated with the application of the exemption is encapsulated within the equipment enclosure and will neither be touched nor released to the environment. As this equipment is sold B2B for professional/industrial use only, equipment that finally reaches end-of-life will be appropriately processed by professional recyclers who are obligated to have suitable controls to avoid any environmental releases and are notified of the presence of the substance under the producers' obligation to provide a SCIP notification.

The TMC member companies have only indicated a minor risk for substances to be released to the environment during the manufacture of the components. These are not produced by TMC members. Thus, data are not available, however the estimate is expected to be bounded by the total use of the substance (i.e., release to the environment is expected to be less than the mass of substance incorporated into the components).

(EPPA 2023) are of the opinion that due to the participating TMC member companies' relatively low consumption of parts, in comparison to the product Categories 1-7 and 10, renewing this exemption for Category 9 will have a minimal impact on the environment. Category 9 Industrial producers are only responsible for 0.2 % of annual WEEE production. cat. 9 IMCI contribute to the Waste Electrical and Electronic Equipment stream only around 0.2 % by weight of EU WEEE, with industrial WEEE being collected through B2B systems. Consequently, the environmental impact of cat. 9 IMCI is negligible.

(EPPA 2023) expect "[ ] no, or at least minimal, expected additional waste before the end of the regular lifetime (non-compliant stock) reported by the companies. Finished goods inventory is typically minimal as T&M equipment manufacturers' production is based on short-term demand, or even per order. Any non-compliant materials will be consumed

through sale into markets where there isn't a similar restriction". TMC member manufacturers of cat. 9 IMCI emphasise, however, that the exemption is utilized in part to improve reliability and longevity of components. A reduced product lifetime would be expected leading to an increase in electronic waste and virgin material use in the replacement in apparent conflict to the concepts proposed under the proposed Eco-design for Sustainable Product Regulation. Moreover, in the case of a discontinuation of exemption 15 for category 9 products, factories using products with older designs may need to re-tool their test process, adding to electronic waste from the replaced equipment.

The majority of the components that utilize this exemption, that constitute Category 9 industrial usage, are common to all product categories. The component manufacturers therefore rely on volume use of the other categories to justify their continued production. Renewing this exemption only for Category 9 for the full 7 years will not extend the production life of these higher volume components beyond the exemption renewal period assigned to Categories 1-7 and 10. It will, however, enable the Test & Measurement coalition members to buy sufficient (relatively small) quantities to update the design and continue to use the relevant components for an extended period. As a result, a renewal of this exemption will a minimal environmental impact and has a positive socio-economic impact by enabling the continued production of Category 9 products critical to the health and welfare of the EU (and global) society whilst the multi-year redesign process is executed.

Overall, (EPPA 2023) monetise the total impact of a non-renewal of this exemption in the range of 1.6 billion EUR and 2.3 billion EUR (conservative estimates in net losses; potential gains for suppliers of other components have been already taken into account. (EPPA 2023) calculated the total socioeconomic impacts by summarising business impacts on manufacturers, impacts on the wider economy and social impacts caused by unemployment.

Further details are available in the report prepared by (EPPA 2023).

9.2.3. Roadmap towards substitution or elimination of the restricted substance

As to actions taken in the past to achieve RoHS compliance, (TMC 2023a) repeat their statements with which they justify their request in section 9.2.1 on page 171. They do not provide any information concerning such activities in the past.

As to future efforts, (TMC 2023a) add that each substitute that has been evaluated had differing properties and therefore, to the best knowledge of TMC, no single "drop-in" replacement exists for cadmium and its compounds for all applications. The renewal of exemption 8(b) should thus be granted on the basis that alternatives are not suitable for substitution or replacement for all applications. These applications include circuit breakers, thermal sensing controls, and high power / high frequency switches. This echoes the stance of the review of the exemption 8(b) series by (Gensch et al. 2016).

According to (TMC 2023a), this lack of a "drop-in" alternative enhances the difficulty of replacing or substituting cadmium in several applications especially (i.e., circuit breakers, thermal sensing controls, and high power / high frequency switches).

Members of the Test & Measurement Coalition have pointed out that they principally rely on their suppliers to find alternatives since most of the exemptions used in their products

are not produced by the suppliers but bought off-the-shelf from their suppliers (and so forth, potentially many levels down). Therefore, meeting with suppliers to understand their (potential) alternatives, getting samples, measuring, and testing are part of the typical process to evaluate the suitability of potential alternatives. The process would then be followed by the validation of the potential suitable alternatives.

The companies reported that the validation period alone would take a minimum of 6 months and up to a year after the delivery of suitable alternatives per product. It is significant to note that this validation period would only apply if the component were a fit, form, and function drop-in replacement. If any design changes to the exemption-free part of the product would be required to accommodate for the alternative, an additional validation period would be required for each redesigned product that used to utilize the component that relied on the exemption. Moreover, the validation would lead to the organizations incurring additional expenses. These include labour costs and costs arising from potential product resubmission requirements for testing to various notified bodies to ensure that substitution does not create any electrical and functional safety concerns.

If a new cadmium free part is available, this part must be qualified for use by performing a variety of tasks, as described above. Due to the complexity and diversity of the applications, this must be done individually by each company for each product group. This process would divert resources from other projects and increase the cost to ensure continued availability of these products. This validation and testing process varies according to part complexity; which can be categorised as low, medium, and high:

- **Low complexity** parts are the off-the-shelf components or hardware parts that do not have a substantial performance impact. Replacement can be done based on supplier information, assuming a form/fit/function compliance, with standard manufacturing, testing, and validation processes. Based on process timescales reported by a T&M coalition company, the average time that it can take for these parts to be replaced ranges from **3 to 6 months**.
- **Medium complexity** parts are more complex sub-assembly electronic parts, such as small motors which need additional validation for their performance. These parts are often commercial assemblies that are generally available to the electronic industry, and are utilised by the Test & Measurement coalition companies. Replacement of these assemblies, like-for-like, requires testing and validation prior to being integrated into the manufacturing process. The average time to find an alternative for medium complexity parts for production is reported to range from **6 to 12 months**.
- **High complexity** parts are complex sub-assembly parts and have a significant impact on the performance of the companies' products. These also have a critical role in the overall safety of the products. These parts need to go through extensive validation for performance and/or compliances, according to varying regulations, before the appropriate files can be updated and the proper competent authorities or regulatory bodies can be notified prior to the purchase of parts for validation. The average time that it would take to find an alternative for high complexity parts for production is up to 1 year of additional testing. Where the exemption directly impacts the performance of that component (e.g., a centrifuge rotor) the evaluation of the replacement could take **3 to 5 years**.

9.3. Critical review

9.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several restrictions of cadmium and its compounds are listed on Annex XVII (cf. section 4.1 on page 48). None of those, however, is applicable to the use of cadmium in the recommended exemption 8(b)(II) for cat. 9 IMCI.

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

9.3.2. Substitution and elimination of the restricted substance

(TMC 2023a) highlight the advantages of Cd in contacts and point out the concerns against its substitution that have been raised – and acknowledged as justification for the renewal of the respective exemptions - against the substitution of Cd in electrical contacts in the past decade of exemption reviews prior to 2021. TMC sources, however, are from 2010 and 2012 respectively (cf. section 9.2.1 on page 171). These referenced sources describe the challenges that or had to be overcome for the reliable substitution or elimination of cadmium in electrical contacts but they do not reflect the current scientific and technical practicability of substitution or elimination of cadmium.

Furthermore, (TMC 2023a) identified in their renewal request the technical status assessed by (Gensch et al. 2016) as the point in time where "No further technological developments have, to the best knowledge of the participating companies, occurred since then."

This statement suggests that TMC members do not follow the technical developments on the market and that they are thus not aware of the technical status of cadmium replacement. The statement is factually incorrect. Deubzer et al. (2022) assessed in 2021/2022 that exemptions 8(b) and 8(b)(I) can expire latest on 31 December 2025, including cat. 8 and cat. 9 IMCI. Differently from TMC, the consultants at that time concluded in agreement with the applicants – representatives of the Umbrella Project - that substitution or elimination of cadmium is scientifically and technically practicable for all applications in the scope of exemptions 8(b) and 8(b)(I). This statement included EEE of cat. 8 and cat. 9 IMCI for which the renewal had been requested as well at that time. Sensata and Marquardt, the members of the Umbrella Project who managed the renewal request, announced that the conversion to cadmium-free contacts will have been achieved by 31 December 2025 latest in cooperation with their customers. *(Sensata et al. 2022) stated in (Deubzer et al.*

2022) that "[…] all thermal controls, motor protectors and circuit breakers with Cadmium free electrical contacts can be completely approved internally, by agencies and customers during the fourth quarter of 2022. Additional time till the end of 2023 is needed to cover any unforeseen issues and for cleaning the supply pipeline." For the switches, *(Sensata et al. 2022) announced that the exemption clause for switches used at voltage supply frequency ≥ 200 Hz is no longer required so that its renewal has become obsolete. Marquardt – a producer of switches - will have substituted cadmium in all electrical contacts until end of 2025.*

TMC's claim is thus incorrect that cadmium-free alternatives are not available and/or not suitable for cat. 9 IMCI, and that this applies in particular to circuit breakers, thermal sensing controls, and high power / high frequency switches.

(TMC 2023b) also put forward that more time is required to adapt designs, find contact materials, and for qualifying cadmium-free solutions in the supply chain and in the products of EEE manufacturers. This is required since the cadmium-free contact materials are not "drop-in" replacements. If producers of protective and other switches stop the production of cadmium-containing electrical contacts, (TMC 2023b) want to perform life (last) time buys of components to complete projected production and support needs to avoid re-design and requalification for equipment. Furthermore, in highly specialized applications where cadmium contacts cannot be substituted, niche manufacturers can provide the required parts where the criticality of the part can bear the cost of such a premium part. This represents a small fraction of the already limited amount of CdO used for cat 9 IMCI (< 600 g year), but will enable the continued manufacturing of highly specialized equipment (like Electron Microscopes).

The principal fact that cadmium-free solutions are not drop-in replacement actually was the core reason why the exemption 8(b) series was renewed several time in the past years, and it can be followed that this requires redesigns of EEE and requalification and possibly recertification of devices using such contacts. (Deubzer et al. 2022) understood during the review of exemption 8(b) and 8(b)(I) at that time that cadmium-free electrical contacts are *approved internally, by agencies and customers, i.e.* producers like Marquardt and Sensata developed their cadmium-free products in cooperation with their customers to ensure the reliability of the substitutes. This means that this time for the application-specific adaptation and qualification of the cadmium-free contacts is already included in the timeline ending on 31 December 2025. It should also be noted that producers of cat. 9 IMCI were members of the consortium (Umbrella Project) that had submitted the renewal request for the exemption 8(b) series which was reviewed by (Deubzer et al. 2022). Further, TMC's claim to be allowed last-time buys to avoid redesign and requalification of equipment is not in line with Art. 5(1)(b) which expects producers to undertake efforts including the redesign of EEE to achieve RoHS compliance.

TMC contributed to the stakeholder consultation of the 2021/2022 review by (Deubzer et al. 2022) expressing their disagreement that cat. 9 IMCI, even though expiring in 2024 only, was nevertheless included into the review of the 8(b) series exemptions upon the request of other applicants, including the Umbrella Project whose members include producers of cat. 9 IMCI as well. The COM rejected TMC's objections stating that exemption requests will be processed as requested, i.e. including cat. 9 IMCI (cf. (Deubzer et al. 2022).

In the light of the information provided by the applicant, the consultants do not see reasons why the recommendation of (Deubzer et al. 2022) for category 9 IMCI should not be maintained. TMC appear to be unaware of the current status and practicability of cadmium

substitution in electrical contacts, and they neither present any specific past nor future efforts to achieve RoHS compliance without exemptions 8(b) or 8(b)(I). Other manufacturers of cat. 9 IMCI seem to be able to comply with the timeline of the proposed renewed exemptions displayed in Table 9-3 on page 168. Furthermore, the applicant missed the opportunity to bring in the views of their members during the stakeholder consultation of the previous review by (Deubzer et al. 2022).

(TMC 2023a) request the renewal of exemption 8(b) with a broad, unspecific scope which (Deubzer et al. 2022) propose to renew for cat. 9 IMCI as exemption 8(b)(II) with an application-oriented scope. TMC was therefore asked to provide examples of applications which the scope of the recommended renewed exemption 8(b)(II) would not cover.

(EPPA 2023) highlight that the need for creating an open contact (vs solid state switching) is typically for electrical isolation purposes, where the safety standards require a minimum electrical clearance between contacts if it is being relied upon for safety isolation. Cadmium-free solutions available do not cover all the electrical contacts that cat 9 utilizes to isolate circuits from high voltage circuits, inductive load switching and control relays. We therefore recommend that the original verbiage of electrical contacts remain in place for this renewal.

The applicant thus wishes exemption 8(b) to be maintained for cat. 9 IMCI, without, however, providing any specific reasoning, for example as to which electrical contacts would not be covered by the narrower exemption 8(b)(II). The consultants rate the above explanation as technically insufficient as argument for not adopting the recommendation of (Deubzer et al. 2022) to include cat. 9 IMCI into the scope of the renewed exemption 8(b)(II).

9.3.3. Environmental, health, safety and socioeconomic impacts

TMC state that cat. 9 IMCI contribute to the Waste Electrical and Electronic Equipment (WEEE) stream only around 0.2 % by weight of EU WEEE so that the environmental impact of cat. 9 IMCI is negligible. They also state that there is no exposure of humans and the environment to cadmium contained in electrical contacts during manufacturing and use of cat. 9 IMCI.

The current RoHS Directive does not define any thresholds for use of restricted substances or contributions to the overall waste generation for which Art. 5(1)(a) would justify granting an exemption if these thresholds are not exceeded. Exemptions are to be granted in line with Art. 5(1)(a) if – next to “REACH-compliance” - any of its three sub-clauses (cf. section 9.3.4 on page 179) is fulfilled. TMC address environmental, health and safety impacts but do not claim that the third sub-clause of Art. 5(1)(a) would be applicable, which would require a more detailed and life-cycle-oriented assessment.

(EPPA 2023) claim that there are currently no suitable cadmium-free alternatives that meet RoHS exemption criteria on the EU market for cat. 9 IMCI and that the re-designing of the cat. 9 IMCI could take four to six years per product line. Hence, losing the ability to apply Annex III, exemption 8(b) when considering RoHS conformity for the associated test and measurement industrial products would entail the development of a fairly large number of new alternative compliant materials as well as the increased costs connected to the redesign, retesting, requalification and replacement of the assembly process.

Timely start of compliance efforts are part of producers’ compliance obligations. The above situation applies to all producers of EEE which is in the scope of the RoHS Directive. Exemptions cannot be granted to avoid such compliance efforts.

EPPA monetise the total impact of a non-renewal of this exemption in the range of 1.6 billion EUR and 2.3 billion EUR, which they summarise from business impacts on cat. 9 IMCI manufacturers, impacts on the wider economy and socioeconomic impacts cause by unemployment. The individual contributions of each of these types of impacts are marked as confidential and are not publicly available. Even though not explicitly stated, the data for the SEA seem to have been collected from TMC member companies which, according to (EPPA 2023), cover 70 % of the EEA market. In this context, it needs to be kept in mind that the other 30 % of cat. 9 IMCI producers serving the EEA market, from which at least some were involved in the previous review of the exemption 8(b) series, did not object the expiry of the exemption like recommended by (Deubzer et al. 2022).

The consultants base their recommendation on the result of the technical assessment in the light of the three sub-clauses of Art. 5(1)(a). If the exemption will not be granted on this ground, the consultants cannot exclude that adverse impacts described by TMC/EPPA (cf. section 9.2.2 on page 173) arise. The consultants consider beyond their mandate any judgement as to which degree of socioeconomic impact would justify granting an exemption on socioeconomic grounds in the case that none of the three sub-clauses of Art. 5(1)(a) is fulfilled. [34]

9.3.4. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria[35] is fulfilled:

1. 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**;
2. the **reliability** of substitutes is not ensured;
3. 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.

TMC request the renewal of exemption 8(b) for 7 years claiming that cadmium-free substitutes are not available for cat. 9 IMCI, not suitable for cat. 9 IMCI, or do not cover all applications of cadmium in contacts of cat. 9 IMCI.

The applicant's justification for the renewal of the exemption is based on the scientific and technological status reflected in the review report of (Gensch et al. 2016) which was updated by (Deubzer et al. 2022) during the previous review of the exemption 8(b) series. They recommended that exemption 8(b) should be renewed for cat. 9 IMCI as exemption 8(b)(II)

[34] Art. 5(1)(a) stipulates that any of the three sub-class must be *fulfilled*, and that decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV *shall take into account* the socioeconomic impact of *substitution*.

[35] Differently from Art. 5(1)(a) in the RoHS Directive, the criteria are numbered so that they can be addressed in the below text.

which can expire on 31 December 2025 as by then substitution of cadmium is scientifically and technically practicable. The expiry date was understood as including time to ensure the reliability of substitutes.

The information provided by the applicant is outdated, general, and not consistent. The actual reason for the renewal request implied in some of TMC's arguments seems to be that TMC members want to avoid redesign of their products, or 7 more years of time to do this redesign. This raises the question why other producers of cat. 9 IMCI, e.g. those that contributed to the previous review by (Deubzer et al. 2022) seem to be able to comply with the 2025 expiry. Further, TMC missed the opportunity to contribute to the stakeholder contribution at that time. It should also be taken into account that not all producers of cat. 9 IMCI are members of TMC, and none of these supported TMC's renewal request. (Deubzer et al. 2022) state that *"The 2025 expiry date for other cat. 8 EEE and cat. 9 EEE also reflects the time from which on the reliability of cadmium-free switches can be ensured."*

The applicant raised objections against the approach in this current review of exemption 8(b) to adopt the recommendation of (Deubzer et al. 2022), i.e. the renewal of exemption 8(b) as 8(b)(II) for cat. 9 IMCI. The consultants rate these objections as technically unspecific and thus insufficient.

Overall, the consultants conclude that substitution of cadmium in electrical contacts has become scientifically and technically practicable, and that the reliability of substitutes can be ensured also for cat. 9 IMCI, until 31 December 2025, cf. Table 9-3 on page 168. Taking account of remaining uncertainties concerning the exemption expiry in 2025, (Deubzer et al. 2022) state: *"Should cases arise where the reliability proves to still be compromised in specific application cases, the 2025 expiry date would still allow timely renewal requests."*

Such applications would have had to be submitted 18 months prior to the recommended exemption expiry on 30 June 2022 and 30 June 2024 latest. The consultants recommend that the COM sets an expiry date beyond 31 December 2025 that allows sufficient time after the official publication of the COM's decision for preparing and submitting such specific renewal requests.

9.4. Recommendation

The consultants recommend adopting the recommendation of (Deubzer et al. 2022) for cat. 9 IMCI including the proposed expiry date for cat. 9 IMCI as shown in the below table. Substitution of cadmium is scientifically and technically practicable, and the reliability of substitutes can be ensured by timely redesigns of EEE including cat. 9 IMCI.

The applicant's justification for the requested 7 year renewal of exemption 8(b) is based on the scientific and technical status of cadmium substitution assessed by (Gensch et al. 2016) and thus outdated, and the applicant's justification for the exemption renewal is unspecific and not consistent.

The consultants therefore recommend adopting the exemption proposed by (Deubzer et al. 2022), i.e. renewing exemption 8(b) as exemption 8(b)(II) as shown in the below table.

No.	Exemption	Scope and dates of applicability
8(b)	Cadmium and its compounds in electrical contacts	Applies to categories 8, 9 and 11.

		Expires on - [date of official publication of the COM decision in the Official Journal + 12 months] for cat. 11 - [date of official publication of the COM decision in the Official Journal + 18 months] for category 8 medical devices including in-vitro diagnostic medical devices, and category 9 monitoring and control instruments including industrial monitoring and control instruments
8(b)(II)	Cadmium and its compounds in electrical contacts used in: - circuit breakers - thermal sensing controls - thermal motor protectors (excluding hermetic thermal motor protectors) - AC switches - DC switches	Applies to categories 8 and 9 from [date of the official publication of the COM decision in the Official Journal + 18 months + 1 day] on. Expires on - 31 December 2023 for circuit breakers in rotating parts of computer tomography (CT) medical devices (category 8 medical devices others than in-vitro diagnostic medical devices) - 31 December 2025 for portable emergency defibrillators (cat. 8 medical devices others than in-vitro diagnostic medical devices) with a Declaration of Conformity (DOC) issued for the first time before 1 January 2015 - **31 December 2025** for other cat. 8 medical devices including in-vitro diagnostic medical devices, and **for category 9 monitoring and control instruments including industrial monitoring and control instruments**.

The COM may consider, as recommended by (Deubzer et al. 2022), setting the expiry date for cat. 9 IMCI leaving sufficient time for the preparation and timely submission of renewal requests for potentially remaining specific cases where the reliability of substitutes could not yet be ensured. Applicants should then submit specific renewal requests including detailed descriptions of compliance efforts, when they were started for which type of EEE, and why the substitution or elimination of cadmium remained scientifically and technically impracticable despite these efforts. Support of the renewal request from suppliers of cadmium-containing/cadmium-free contacts would add plausibility to the renewal request.

Applicant's feedback on the recommendation

(TMC 2024) consider, with reference to the information they had provided, that the criteria laid down in Article 5 of the RoHS Directive are fulfilled and reiterate their request to renew the exemption III-8(b) for cat. 9 IMCI for the maximum validity period of 7 years.

The consultants are confident that they considered all relevant arguments made available by applicants and stakeholders during the review, and that the arguments have been evaluated taking into account the requirements of Art. 5(1)(a) and the mandate commissioned by the COM for the review of this exemption.

9.5. References

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10. Exemption 13(a) of Annex III: Pb in white glasses used for optical applications

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instruments
IVD	In vitro diagnostic medical devices
MTE	MedTech Europe
Pb	lead [chem.]
RoHS 1	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	Directive 2011/65/EU, current RoHS Directive
TMC	Test & Measurement Coalition

10.1. Background and technical information

The below Table 10-1 shows the wording, scope and expiry dates of the exemption.

Table 10-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
III-13(a)	Lead in white glasses used for optical applications	Applies to all categories; expires on: - 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; - 21 July 2021 for all other categories and subcategories.

On 20 January 2023, (TMC 2023a) requested the renewal of the exemption as displayed in Table 10-2 for EEE of category (cat.) 9 industrial monitoring and control instruments (IMCI).

Table 10-2: Wording and scope of the requested exemption

No.	*Requested Exemption*	*Requested scope and dates of applicability*
III-13(a)	*Lead in white glasses used for optical applications*	*Applies to category 9 industrial monitoring and control instruments and expires on 21 July 2031.*

TMC submitted a socio-economic analysis (SEA) of the impacts of the non-renewal of this exemption performed by (EPPA 2023). One contribution to the stakeholder consultation was submitted by (MTE 2023).

10.1.1. History of the exemption

Exemption 13 was added to the Annex of RoHS 1 in October 2005 as “Lead and cadmium in optical and filter glass.” Exemption 13(a) with the current wording “Lead in white glasses used for optical applications” was published in the Official Journal of the European Union on 25. September 2010 [36].

Exemption 13(a) was reviewed by (Gensch et al. 2016a), concluding that the elimination and substitution of lead in white optical glasses was at the time not practical for the full range of applications, stating that a large part of the potential for substitution had already been realised and that the development of further alternatives and their implementation was likely more challenging and more time-consuming. (Gensch et al. 2016a) discussed the possibility to exclude consumer products from the scope of the exemption in order to narrow the scope to equipment used by professionals, which tends to be associated with higher requirements, however, the applicants at the time, SPECTARIS et al., explained that even consumer equipment required the exemption, such as for sophisticated photographic lenses, binoculars or digital projectors. Differentiating between consumer and professional-grade equipment was also said to be not feasible, as many products may be used by professionals and consumers alike. (Gensch et al. 2016a) also discussed the specification

[36] Publication in the Official Journal of the European Union: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010D0571

of a refractive index threshold to narrow the scope to only include such types of glasses in scope of the exemption that cannot be manufactured without the addition of lead. However, adjustment of the scope to include only a specified part of the refractive index range from the Abbe diagram was also found to be impractical. Performance thresholds for different properties of glass could also not be set due to the complexity of interdependent variables (refractive index, dispersion, temperature dependent dispersion, transmission of different light wave lengths, birefringence, etc.).

Gensch et al. (2016a) recommended the exemption to be renewed for all categories at the time. The European Commission renewed the exemption accordingly and published in the decision in the Official Journal[37] on 16 June 2017.

The last review of exemption 13(a) was conducted by (Deubzer et al. 2022). At the time, the applicants, SPECTARIS et al., requested a renewal of the exemption using the same wording until 21 July 2028 for cat. 8 in vitro diagnostic medical devices (IVD) and cat. 9 IMCI, and until 21 July 2026 for all other categories and subcategories. (Deubzer et al. 2022) concluded that substitution of lead-containing glasses with lead-free glasses or optical polymers had already taken place in applications where it was technically feasible. In recent years, no ground-breaking new developments have been achieved regarding the development of new substitutes.

The term ‘white glass’ was found to denote ‘transparent glass’ and is not a precise technical term. Therefore, the consultants proposed another wording option to delineate glasses in optical applications covered by this exemption from the glasses covered by exemption 13(b) series, in which the latter are explicitly excluded from the scope of exemption 13(a). The applicants agreed to this wording option in principle, but stated to prefer the current wording, as a change in wording would create administrative burden in the relevant value chains.

Due to a lack of evidence that the exemption was required in all RoHS Annex I EEE categories, (Deubzer et al. 2022) considered it justified to either exclude the affected categories from the exemption scope or to include them with a reduced validity period, to give the applicants more time to gather evidence regarding the types of equipment in which the leaded glass is used in practice before a possible next evaluation of the exemption.

(Deubzer et al. 2022) recommended two exemption wording options reproduced below.

Table 10-3: Wording option 1 recommended by (Deubzer et al. 2022)

No.	Exemption	Scope and dates of applicability
13(a)	Lead in white glasses used for optical applications	Applies to categories 1-11 and expires on: - 21 July 2025 for categories 1, 2, 5, and 10; - 21 July 2026 for categories 3, 4, 6, 7, 8, 9, and 11; - 21 July 2028 for category 8 in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments.

[37] Publication in the Official Journal of the European Union: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017L1011&from=EN

Table 10-4: Wording option 2 recommended by (Deubzer et al. 2022)

No.	Exemption	Scope and dates of applicability
13(a)	Lead in glasses used for optical applications excluding applications falling under points 13(b), 13(b)(I), 13(b)(II), 13(b)(IV) of this Annex	Applies to categories 1-11 and expires on: - 21 July 2025 for categories 1, 2, 5, and 10; - 21 July 2026 for categories 3, 4, 6, 7, 8 medical devices others than in-vitro diagnostic medical devices, 9 monitoring and control instruments others than industrial monitoring and control instruments, and 11; - 21 July 2028 for category 8 in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments.

A third option was proposed to the COM that relies on either of the above wording options, but removes categories 1, 2, 5, and 10 from the scope, due to a lack of evidence that the exemption was required in EEE covered by those categories.

Table 10-5: Option 3 recommended by (Deubzer et al. 2022)

No.	Exemption	Scope and dates of applicability
13(a)	Lead in […]* * following sentence depending on wording options 1 or 2 above	Applies to categories 3, 4, 6, 7, 8, 9, and 11 and expires on: - 21 July 2026 for categories 3, 4, 6, 7, 8, 9, and 11; - 21 July 2028 for category 8 in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments.

At the time of the current evaluation of exemption 13(a), the COM have not yet officially published their decision as to the adoption of the above recommendation. The COM wish the consultants to assess in this current review round whether there are any substantial reasons in line with Art. 5(1)(a) against the adoption of the above recommendation for EEE of categories 8, 9 and 11.

10.1.2. Focus of the review of this renewal request

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status January 2024). (TMC 2023a) therefore applied for the renewal of the current exemption 13(a) for cat. 9 IMCI since it was earmarked for expiry on 21 July 2024 for this subcategory of cat. 9 EEE. The exemption thus became due for review even though the recommendation for the renewal of exemption 13(a) of (Deubzer et al. 2022) included cat. 9 IMCI.

In the light of this situation, the COM tasked the consultants to assess in their review of the exemption renewal request at hand whether and how far the recommendation of (Deubzer et al. 2022) can be adopted to cat. 9 IMCI in line with Art. 5(1)(a). A re-evaluation of the previous review by (Deubzer et al. 2022) is not intended. The consultants will rely on the critical review conducted by (Deubzer et al. 2022) and on the resulting conclusions and

recommendation unless the renewal request or stakeholder contributions give reasons to reassess the state of science and technology.

10.1.3. Summary of the requested exemption and stakeholder contributions

Summary of the requested exemption

"Exemption 13(a) is an exemption to allow the addition of lead into glass for specific optical components. These optical components (glass lenses, filters, and fibres) are highly specialised, individually specified components that perform a key part of the functionality of the instruments in which they reside. Their use within the heart of the measurement system is such that replacement of these components, even if an equivalent fit, form, and function part is available must undergo rigorous and extensive testing and validation.

The addition of lead (typically as PbO) into glass introduces unique properties. As lead is a heavy element, it increases the density of the glass, thereby increasing its refractive index. The typical refractive index of lead glass is ~1.6, compared to 1.46 of typical (soda) glass. In addition to increased refractive index, the addition of lead increases the transmission of light through glass, particularly in the UV spectrum.

As further outlined in this submission, the Test & Measurement Coalition has no knowledge suggesting that there is a substitute available that would be suitable for lead-glass in high accuracy measurement instruments. At this point, eliminating the use of leaded-glass is not possible without the reduction of performance of critical instrumentation. The Test & Measurement Coalition therefore applies for a renewal of the exemption 13(a) for the maximum validity period.

A thorough Socio-Economic Analysis was conducted in addition to the technical assessment and attached to this submission, further illustrating the negative socio-economic impacts a non-renewal of exemption 13(a) would have. Overall, the analysis concludes that the total impact of non-renewal of this exemption is monetized in the range of 1.2 billion EUR and 1.6 billion EUR (conservative lower bound estimate)." (TMC 2023a)

Summary of the stakeholder contribution

MedTech Europe (MTE 2023), the European trade association representing the medical technology sector express their support for the renewal of this exemption specifically under category 8 medical equipment including in vitro diagnostic medical devices for the maximum validity period.

As this renewal request only pertains to category 9 IMCI, the statements in support of a renewal for category 8 are not reproduced here.

10.1.4. Technical description of the exemption and use of the restricted substance

A technical description of this exemption was provided by (Deubzer et al. 2022), which the consultants consider to cover the essential information provided by (TMC 2023a). The

following information was provided by (TMC 2023a) to indicate for which equipment falling under cat. 9 IMCI the exemption is needed.

The addition of lead (typically as PbO) into glass introduces unique properties. As lead is a heavy element, it increases the density of the glass, thereby increasing its refractive index. The typical refractive index of lead glass is ~1.6, compared to 1.46 of typical (soda) glass. In addition to increased refractive index, the addition of lead increases the transmission of light through glass, particularly in the UV spectrum.

Industrial test and measurement instruments (cat. 9 IMCI) are very different from low mix, high-volume consumer products which are frequently re-designed to follow consumer trends and are placed on the market for a limited duration. Industrial test and measurement are high mix, low volume producers, managing portfolios of thousands of highly complex instruments. Each instrument is intentionally designed for high reliability and serviceability to support long useful lifespans, and are made available on the market for at least a decade. These instruments are designed: exclusively for professional and industrial use; to meet high performance requirements in critical applications; and last up to 40 years. Redesign is not frequent and happens every seven years on average (as compared to every 1.5 years or less for consumer products). Once test and measurement instruments are placed onto the market, they are typically accompanied with a long-term customer support arrangement to maintain reliability and calibration.

Product portfolios are widely diversified, with TMC members each having typically 2,000 to 3,000 products currently made available on the market. These are highly complex, sophisticated electronic instruments such as signal generators, power analysers, oscilloscopes, spectrum analysers, digital multi-meters, electron microscopes, chemical and biological analysers, complex chromatography systems and their detectors, each having necessary options and accessories. Each instrument can have a minimum of 2,000 and up to 40,000 parts; requiring a vast supply chain involving tens of thousands of suppliers and hundreds of thousands of unique components.

Considering the EU added-value, test and measurement equipment is manufactured and sold in relatively small volumes (per instrument design) and placed on the global market.

The professional test and measurement products provide the tools for engineers to develop new solutions and businesses to bring them to market. These instruments are used in Research, Quality Control and Testing laboratories (including field testing) in Universities, Manufacturing and clinical facilities and by Governmental Agencies for conformance verification and environmental testing. They are essential to the good functioning of electronic communications networks, heavy industrial processes such as steel manufacturing, the testing of vehicles for compliance with emissions standards, and the monitoring of complex and critical systems of all types. The nature of the tests and measurements made by industrial equipment necessitates that the equipment itself is highly complex; with upwards of 40,000 components necessary to produce a single instrument. Even a relatively simple hand-held instrument incorporates significantly more components that a typical consumer product.

(TMC 2023a) provided a comprehensive list of the relevant product groupings and equipment types relevant to exemption 13(a), reproduced in the below table.

Table 10-6: List of relevant product groupings and equipment types

Product grouping	*Equipment types*
Generators, Sources and Power	*Waveform and Function Generators*
Application-Specific Test Systems and Components	
Photonic Test & Measurement Products	
Laser Interferometers and Calibration Systems	*Monolithic Laser Combiners & Precision Optics*
Used Equipment	
Liquid Chromatography	
Gas Chromatography	
Cell Analysis	
Laboratory Products and Industrial Monitoring Capital Equipment	*Autoclave; Sterilizers; Baths and Circulators; Biological Safety Cabinets; Blood Culturing Devices; Centrifuges; Chillers; Electrophoresis; Environmental Chambers; Freeze Dryers; Furnaces; Heat Controllers/Exchangers; Ovens; Refrigerators; Freezers; Mixers; Water Purification; Electron Microscopes; Spectroscopy Equipment*

Source: (TMC 2023a)

(EPPA 2023) further specified that the optical components in the scope of exemption 13(a) are glass lenses, filters, and fibres that are highly specialised, individually specified components that perform a key part of the functionality of the instrument in which they reside. Optical systems and fibre optics are used in a wide variety of test and measurement instrumentation over large application areas. Some of the instrumentation using leaded glass optics and fibre optics include cell imaging systems, multimode UV/visible plate readers, and chromatography systems.

10.1.5. Amount(s) of restricted substance(s) used under the exemption

(TMC 2023a) indicate the quantity of lead utilized in the TMC's homogeneous materials varies based on the application. Therefore, the homogeneous materials can contain between 37% and 65% lead by weight. (TMC 2023a) estimate the amount of lead entering the EU market annually through applications for which this exemption is requested to be approximately 0.9 kg.

10.2. Justification of the requested exemption

10.2.1. Substitution and Elimination of the restricted substance

(TMC 2023a) state that, to the best of their knowledge, there is no substitute available that would be suitable for lead-glass in high accuracy measurement instruments. There are many available alternative glasses that do not contain lead, and low-grade consumer optics are now commonly manufactured from plastics. The alternatives do not match the optical properties of lead-glass, and even throughout the visible spectrum many of these alternatives have a decrease in transmission leading to losses in the signal. As spectroscopy and imaging plays a greater role in the scientific industries from chemistry to drug discovery and environmental monitoring, it is essential that the industries are able to use the most sensitive and accurate instrumentation.

(TMC 2023a) further state that since the introduction of RoHS 1, and the restriction of the use of lead, there has been a dramatic improvement in the availability of lead-free glass, and where appropriate these glasses are used. This investment in new glass types continues, and as lead-free glasses approach the performance characteristics of leaded glass then the use of lead glass will naturally diminish. TMC anticipate that, with continued technical advances, the use of lead glass may reduce to negligible levels within the next two decades. However, at this point, eliminating the use of leaded-glass is not possible without the reduction of performance of critical instrumentation.

10.2.2. Environmental, health, safety, and socioeconomic impacts

(EPPA 2023) performed a socio-economic analysis (SEA) at the request of TMC, in view of providing regulators with strong evidence-based findings on the expected social and economic impacts that are expected to occur should the use of lead (Pb) be impacted by the non-renewal of the RoHS exemption.

In line with the existing official guidance from ECHA on the preparation of the Socio-Economic Analysis, the SEA therefore gathers technical and economic information to describe ex-ante in both qualitative and (if feasible) quantitative terms the (orders of magnitude of) socio-economic impacts TMC as well as the relevant EEA supply chain and society are expected to face from the non-renewal of the lead (Pb) exemption in white glasses used for optical applications, which would otherwise expire on 21 July 2024.

The main findings from the SEA conclude that, the total impact of a non-renewal is monetized in the range of 1.2 billion EUR and 1.6 billion EUR (conservative estimates in net losses; potential gains for suppliers of other components have been already taken into account), consisting of: economic impacts (EBIT loss); substitution costs and social impacts (i.e., unemployment in the EU-27) for test and measurement industrial type products' manufacturers.

10.2.3. Roadmap towards substitution or elimination of the restricted substance

(TMC 2023a) explain that research has already been carried out for all applications and in the cases where lead-free alternatives have been found, they are being used. In virtually all applications of optical glass, a combination of three or more properties contribute to the technical performance of lead-based optical white glasses; it is therefore not possible to pick a single property as a criterion of distinction under RoHS. The renewal of exemption 13(a) should accordingly be granted on the ground that there are no alternatives available for the use of lead in white glasses used for optical applications.

(TMC 2023a) elaborate that further research, by the optical glass manufacturers, into alternative designs is uncertain and may never be successful due to the demanding combinations of essential characteristics obtained when using lead in white glass. It is therefore not possible for the test and measurement equipment manufacturers, who use the optical glass to predict how much time this type of R&D will take or whether substitutes can be found for all of the diverse applications. It is very probable that it will never be possible to replace leaded glass in all applications. Lead-based glass manufacturers constantly review the published literature on new glass formulations but, in recent years, no new glass types have been discovered that could replace lead-based optical glass. Unless a new formulation is discovered, it is difficult to see what other steps can be taken by glass manufacturers to replace lead. Equipment manufactures also regularly review their design to assess whether lead-free glass can be used but, for the reasons discussed above, this has not been possible. This echoes the findings by (Deubzer et al. 2022).[38]

Independent of these findings, the Test & Measurement Coalition has contacted their component suppliers to inquire if since the submission of the renewal request by other stakeholders (e.g., Spectaris) new technological developments have occurred that would allow the substitution of cadmium and lead as used in RoHS exemption 13(a). It was reported back that no alternative substance with the same required characteristics of lead and cadmium for the respective components is known to the manufactures of those components.

(TMC 2023a) claim that should new lead-free optical parts become available, the participating companies would need to perform a variety of tasks in order to qualify a new part from suppliers. This would divert resources from other projects. It would also increase the cost to ensure the continued availability of the device due to the additional resources required by optics manufactures and by the TMC members. The validation and testing processes would vary according to part complexity and impact upon the final product design which can be categorized as either be of a medium or high complexity:

- *Medium complexity optical parts are when a like-for-like replacement can be substituted and when the part performs a relatively simple optical function. Despite these characteristics, the change in the optical parameters will require testing and*

[38] Consultants' comment: Indeed, the applicant during the previous review of this exemption, SPECTARIS et al., a German industrial association for optics, photonics, analysis, and medical technology, made these same claims and the consultants at the time confirmed to not have identified any evidence that would contradict this position.

performance validation. The average time to switch a medium complexity part for production is reported to range from 6 to 12 months.

- *High complexity parts are optical components that perform a complex function or are part of an optical subassembly. These parts will be critical to the performance and accuracy of the device and will require extensive characterisation as the first step of the replacement process. The output of the characterisation will likely impact other parts of the instrument (for example, the analysis/interpretation software). Once fully characterised, these high complexity optical parts will require testing and validation for their performance and functionality in the instrument. Depending on the application, updated documentation of the device may require notification to the appropriate competent authorities or regulatory bodies. The average time that it would take to perform a high complexity component change for production is between 2 and 5 years.*

10.3. Critical review

10.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds (cf. section 4.2 on page 51). None of these entries are, however, relevant for the use of lead in the scope of exemption 13(a).

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

10.3.2. Substitution and elimination of the restricted substances

TMC argue the justification of the exemption first and foremost on the basis that a substitution or elimination of lead in the applications in scope of this renewal request are technically impracticable. The previous review of this exemption by (Deubzer et al. 2022) concluded that lead had largely been substituted and eliminated where this was technically feasible, such as consumer products, and remains to be used only in applications in which substitution and elimination is not yet technically feasible, as eliminating the use of leaded-glass is not possible without the reduction of performance of critical instrumentation. A comprehensive list of affected equipment was provided by TMC and is reproduced in section 10.1.4 (page 188 ff.).

TMC claim that instrument manufacturers largely depend on the supply chain for the development of substitution options, such as speciality glass makers. TMC state to have inquired with SPECTARIS, representing the latter, but no breakthroughs in the development of substitutes for lead in glasses could be reported.

The consultants conclude the technical arguments that justify the exemption that were discussed during the previous review remain valid for equipment for cat. 9 IMCI. It is currently not yet practicable to phase out lead from all applications, therefore consultants consider the request for the maximum validity period justified in principle. However, following the mandate to assess whether the recommendations of (Deubzer et al. 2022) can be adopted to cat. 9 IMCI in line with Art. 5(1)(a), the consultants consider the recommended validity period until 21 July 2028 can be maintained.

The consultants note that the list of applications provided by TMC is identical between exemptions 13(a) and 13(b). In case of a future renewal request for these exemptions, the consultants consider it necessary for the applicants to differentiate the types of equipment for each exemption.

10.3.3. Adoption of the recommendation from the previous evaluation report

Exemption III-13(a) was reviewed by (Deubzer et al. 2022) who recommended a renewal, providing two wording options to the European Commission (COM): Wording option 1 and wording option 2, reproduced in section 10.1.1 “History of the exemption” in Table 10-3 and in Table 10-4, respectively. During the review of the current exemption renewal request, the applicants were informed that if this review shows that the applicants’ arguments justify the renewal of the exemption, the consultants would recommend the wordings, scopes and expiry dates given in Table 10-3 (reflecting option 1) and Table 10-4 (reflecting option 2).

When requested to comment on and explain any obstacles to the adoption of the above proposal for the requested exemption for category 9 IMCI, (TMC 2023b) responded that they apply for renewal of exemption III-13(a) in its current wording and for the maximum validity period, i.e., 7 years.

(TMC 2023b) emphasize the importance of retaining the initial wording and numbering as published in the original RoHS annexes. Amending the scope of the exemption by changing the application or substance restriction value has a significant administrative burden to industry and negatively impacts the compliance.

Further, (TMC 2023b) highlight that industrial monitoring and control instrument manufacturers have to manage suppliers’ declarations for hundreds of thousands of items. Additionally, after reviewing the current state of the evolution of technology for the cat. 9 industrial measurement and control instruments, TMC members have difficulty in understanding how the rewording and relisting and/or splits recommended by the consultants will lead to greater protection of human health and the environment compared to the wording in its current form. The recommended rewording/split would only lead to significant unnecessary burden for stakeholders without commensurate benefits.

Therefore, (TMC 2023b) state to favour and apply for the wording of option 1 with an extension of the applicability dates for category 9 industrial test and measurement instruments until 21 July 2031.

Regarding wording option 2, (TMC 2024a) further highlighted that the exclusion of 13(b)(I), 13(b)(II), 13(b)(IV) does not make sense, given that they are not relevant for equipment of category 9. The consultants note that this is only partially correct, as exemptions 13(b)(I), 13(b)(II), 13(b)(IV) and the newly added 13(b)(V) were recommended to apply to category 9 by (Deubzer et al. 2022). In fact, only the recommended exemption 13(b)(III) was recommended to expire for categories 1 to 7 and 10, as it is superseded by exemption 13(b)(IV), if the COM follows the recommendations made by (Deubzer et al. 2022).

10.3.4. Environmental, health, safety, and socioeconomic impacts

The publicly available version for the SEA does not report data on the individual indicators, being economic impacts (losses in earnings before interest and taxes), substitution costs, and social impacts, which are, however, provided in a confidential version of the SEA.

(EPPA 2023) describe that the SEA is based on information collected from surveying TMC member companies, which represent more than 70 % of the entire European Economic Area test and measurement equipment market.

The consultants cannot exclude that at least some of these impacts would actually arise if the COM does not renew the exemption. The consultants do, however, not recommend revoking the exemption, or restricting its scope so that cat. 9 IMCI would be excluded from the scope of the future exemption so, that no adverse environmental or socioeconomic impacts can be expected to arise.

TMC stated that the equipment falling into cat. 9 IMCI placed on the EU market per anno only contains 0.9 kg of lead. This is in stark contrast to the 275 tonnes per anno that were estimated by SPECTARIS et al. during the previous review of this exemption, albeit the latter being an estimate for all RoHS categories. The SEA provided by TMC included a statement on this as follows: *As a result of the participating companies' relatively low consumption of parts, in comparison to the product Categories 1-7 and 10, renewing this exemption for Category 9 will have a minimal impact on the environment. As previously indicated, Category 9 Industrial producers are only responsible for 0.2% of annual WEEE production.*

The consultants consider that in case of a future renewal request for this exemption, the applicants should provide an approximation of the amount of lead that is used in equipment differentiated by RoHS equipment category to highlight the relevance of this exemption for the individual categories.

10.3.5. Summary and conclusions

TMC request the 7-year renewal of exemption III-13(a) with its current wording for cat. 9 industrial monitoring and control instruments (IMCI) until 21 July 2031. Following their mandate for this exemption, the consultants assessed whether the result of the previous review of this exemption by (Deubzer et al. 2022) - which included cat. 9 IMCI - can be adopted for cat. 9 IMCI in the light of the applicant at hand.

The consultants conclude the technical arguments that justify the exemption that were discussed during the previous review remain valid for equipment for cat. 9 IMCI.

In the last review, (Deubzer et al. 2022) recommended to renew the exemption using the same wording as the previous exemption (option 1), or, based on the applicants' request at the time, using an adjusted wording that omits the term 'white' glass (option 2). The applicants of this current review round agreed to the adoption of the renewal of this exemption recommended by (Deubzer et al. 2022), but emphasize that they favour and apply for wording option 1, preserving the currently valid wording, as changes to wording and numeration of existing exemptions leads to high administrative burdens through the supply chain. The applicants also emphasized that the renewal is requested for the maximum validity period of 7 years.

10.4. Recommendation

The consultants recommend maintaining the exemption renewal proposed by (Deubzer et al. 2022), which includes cat. 9 IMCI.

If the COM decides to follow the approach of (Deubzer et al. 2022), the below wording is recommended for the renewed exemption III-13(a):

No.	Exemption	Scope and dates of applicability
13(a)	Lead in white glasses used for optical applications	Applies to categories 1-11 and expires on: - 21 July 2028 for category 8 in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments; - 21 July 2026 for all other categories.

(Deubzer et al. 2022) recommended a shorter expiry date for equipment falling into categories 1, 2, 5, and 10 until 21 July 2025. However, applicants would not be able to apply for a renewal of this exemption 18 months before its expiry, given that the COM's decision on the adoption of this recommendation cannot be published 18 months before this date. The consultants therefore recommend granting the renewal for all other categories, besides cat. 8 IVD and cat. 9 IMCI for at least 24 months after the publication of the COM's decision.

If the COM wish to remove the ambiguity of the term 'white' glasses from the exemption wording, despite both the current and previous applicants stating this would cause additional administrative burdens throughout the supply chains, the below wording is recommended for the renewed exemption III-13(a):

No.	Exemption	Scope and dates of applicability
13(a)	Lead in glasses used for optical applications excluding applications falling under points 13(b), 13(b)(I), 13(b)(II), 13(b)(IV) of this Annex	Applies to categories 1-11 and expires on: - 21 July 2028 for category 8 in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments; - 21 July 2026 for all other categories.

It should be noted that this wording is interlinked with exemption 13(b) series, for which the COM also has not yet published their decision on the adoption of the recommendations of the previous review, and which has also been reviewed as part of this current pack of

exemption reviews. It should further be noted that (TMC 2024a) explicitly disagree with the adoption of this exemption wording.

If the COM wish to not renew the exemption for those categories for which the previous applicant could not provide evidence that the exemption was in fact required, while maintaining that it is required, the below wording and scope are recommended for the renewal of exemption III-13(a):

No.	Exemption	Scope and dates of applicability
13(a)	Lead in […]* * following sentence depending on wording options 1 or 2 above	Applies to categories 3, 4, 6, 7, 8, 9, and 11 and expires on: - 21 July 2026 for categories 3, 4, 6, 7, 8, 9, and 11; - 21 July 2028 for category 8 in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments. -

If the COM wish to align the validity periods for different EEE categories to enable a joint review, if it was requested again in the future, an aligned renewal of all categories for which the exemption is to be renewed is recommended until 21 July 2028.

The adverse socioeconomic impacts assessed by EPPA will not arise until 2028 since the consultants do not recommend revoking the exemption, but TMC will have to bear the cost for preparing and processing a renewal request prior to 2031, which they requested as expiry date in their current renewal request.

Lastly, the consultants consider that in case of a future renewal request for this exemption, the applicants should provide an approximation of the amount of lead that is used in equipment differentiated by RoHS equipment category to highlight the relevance of this exemption for the individual categories.

Applicants' feedback on recommendation

(TMC 2023b) stated to favour and apply for the wording of option 1 with an extension of the applicability dates for category 9 IMCI until 21 July 2031. They criticise that the recommendation favors a stronger consideration of the expiry dates recommended by Deubzer et al. in the previous review to enable the review of the exemption for all categories of EEE. This approach counters the RoHS Directive's logic of having different product categories with different validity periods and neglects the specificities of cat. 9 IMCI. The recommendation increases business uncertainty and enhances the likelihood of negative socio-economic impact across the EU as a consequence of potential pre-mature market withdrawal.

The consultants are confident that they considered all relevant arguments made available by applicants and stakeholders during the review, and that the arguments have been evaluated taking into account the requirements of Art. 5(1)(a) and the mandate commissioned by the COM for the review of this exemption.

10.5. References

Deubzer et al. (2022): Study to assess requests for renewal of 12 exemptions to Annex III of Directive 2011/65/EU 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. Final Report. Pack 23. In cooperation with von Dr. Otmar Deubzer (Fraunhofer IZM and UNITAR], Jana Rückschloss (Fraunhofer IZM) und Christian Clemm (UNITAR). Hg. v. Publication Office of the European Union. European Commission (RoHS 28, Pack 23). Retrieved from https://data.europa.eu/doi/10.2779/507661.

EPPA (2023): Socio-economic analysis. Of the impacts of non-renewal of Cadmium (Cd) and Lead (Pb) exemption for test & measurement industrial type products (Category 9) Exemption 13(b) – Annex III. EPPA (RoHS 29). Retrieved from https://rohs.biois.eu/TMC_SEA_Exemption_13(b)_2023_PUBLIC_VERSION.pdf.

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TMC (2023a): Request for renewal of exemption III-13(a). RoHS Pack 27 (RoHS 29). Retrieved from https://rohs.biois.eu/RoHS_Application_Form_15.pdf.

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TMC (2024a): Answers to questionnaire 2, sent by Tobias Steinbrecher, Eppa, to Christian Clemm. RoHS Pack 27. TMC (RoHS 29).

TMC (2024b): Comments on recommendation, sent by Tobias Steinbrecher, Eppa, to Christian Clemm. RoHS Pack 27. TMC (RoHS 29).

11. Exemption 13(b) of Annex III: Cd and Pb in filter glasses and reflectance standards

The below Table 11-1 shows the wording, scope and expiry dates of the exemption.

Table 11-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
III-13(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards	Applies to categories 8, 9 and 11; expires on: - 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; - 21 July 2021 for other subcategories of categories 8 and 9.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
Cd	cadmium [chem.]
COM	European Commission
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instruments
MTE	MedTech Europe
Pb	lead [chem.]
RoHS 1	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	Directive 2011/65/EU, current RoHS Directive
TMC	Test & Measurement Coalition

11.1. Background and technical information

On 20 January 2023, (TMC 2023a) requested the renewal of the exemption as displayed in Table 11-2 for EEE of category (cat.) 9 industrial monitoring and control instruments (IMCI).

Table 11-2: Wording and scope of the requested exemption

No.	*Requested wording*	*Requested scope and dates of applicability*
III-13(b)	*Cadmium and lead used in filter glasses and glasses used for reflectance standards*	*Applies to category 9 industrial monitoring and control instruments and expires on 21 July 2031.*

TMC submitted a socio-economic analysis (SEA) of the impacts of non-renewal of this exemption performed by (EPPA 2023). One contribution to the stakeholder consultation was submitted by (MTE 2023).

11.1.1. History of the exemption

According to (Deubzer et al. 2022), exemption 13 was added to the Annex of RoHS 1 in October 2005 as “Lead and cadmium in optical and filter glass.” Exemption 13(b) with the wording “Cadmium and lead in filter glasses and glasses used for reflectance standards” was published in the Official Journal of the European Union on 25. September 2010 [39].

Exemption 13(b) was reviewed by (Gensch et al. 2016a), who recommended splitting the exemption into a series of more specific exemptions, resulting in the current four exemptions under number 13 series, in which Exemption 13(b) has maintained its wording and only includes categories 8, 9, and 11 in its scope, while all other categories are in scope of the more specific exemptions 13(b)(I), (II), and (III).

[39] Publication in the Official Journal of the European Union: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010D0571

Table 11-3: Currently valid wording of exemption 13(b)-series

No.	Exemption	Scope and dates of applicability
13(b)	Cadmium and Lead used in filter glasses and glasses used for reflectance standards	Applies to categories 8, 9 and 11; expires on: - 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; - 21 July 2021 for other subcategories of categories 8 and 9.
13(b)(I)	Lead in ion coloured optical filter glass types	Applies to categories 1 to 7 and 10; expires on 21 July 2021 for categories 1 to 7 and 10.
13(b)(II)	Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex	
13(b)(III)	Cadmium and lead in glazes used for reflectance standards	

The last review of exemption 13(b) was conducted by (Deubzer et al. 2022), who concluded that substitution and elimination of lead and/or cadmium in the filter glasses and reflectance standards are scientifically and technically impracticable where their unique properties are needed in a range of applications. A renewal of the exemption 13(b)-series was recommended as displayed in the following table:

Table 11-4: Recommended renewal of exemption 13(b)-series by (Deubzer et al. 2022)

No.	Exemption	Scope and dates of applicability
13(b)	Cadmium and lead used in filter glasses and glasses used for reflectance standards	Applies to categories 8, 9 and 11. Expires on [date of publication in Official Journal + 12 months] for - category 8 medical devices including in vitro diagnostic medical devices; - category 9 monitoring and control instruments including industrial monitoring and control instruments; - category 11.

13(b)(I)	Lead in ion coloured optical filter glass types	Applies to categories 1 to 7 and 10 and from [date of publication in Official Journal + 12 months + 1 day] to categories 8, 9 and 11. Expires on - 21 July 2025 for categories 1, 4; - 21 July 2026 for categories 2, 3, 5, 6, 7, 10 and 11; - 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices and category 9 monitoring and control instruments including industrial monitoring and control instruments.
13(b)(II)	Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex	
13(b)(III)	Cadmium and lead in glazes used for reflectance standards	Expires on [date of publication in Official Journal + 12 months] for categories 1 to 7 and 10.
13(b)(IV)	Cadmium in glazes used for reflectance standards	Applies to cat. 8 and 9 from [date of publication in Official Journal + 12 months+ 1 day] on. Expires on 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices and category 9 monitoring and control instruments including industrial monitoring and control instruments.
13(b)(V)	Lead compound coatings in infrared interference filters used in infrared gas analysis and mid-far-infrared spectroscopy	Applies to category 9 industrial monitoring and control instruments from [date of publication in Official Journal + 12 months + 1 day] on. Expires on 21 July 2028 for category 9 industrial monitoring and control instruments.

EEE of categories 8, 9 and 11, currently in the scope of exemption 13(b), were recommended to be integrated into the scopes of exemptions 13(b)(I), 13(b)(II), and 13(b)(III) so far only covering EEE of cat. 1-7 and 10. Formally, this is equivalent to narrowing the exemption scopes for these categories of EEE which is considered a partial revocation of the exemption. For this reason, a transition period of 12 months was recommended. Exemption 13(b)(III) was updated to reflect that lead was no longer required in glazes used for reflectance standards, leading to the recommendation of exemption 13(b)(IV). A new exemption 13(b)(V) was recommended to reflect that infrared interference filters require the exemption but are only covered by exemption 13(b) which shall expire.

11.1.2. Focus of the review of this renewal request

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status January 2024). (TMC 2023a) therefore applied for the renewal of the current exemption 13(b) for cat. 9 IMCI since it was earmarked for expiry on 21 July 2024 for this subcategory of cat. 9 EEE. The exemption thus became

due for review even though the recommendation for the renewal of exemption 13(a) of (Deubzer et al. 2022) included cat. 9 IMCI.

In the light of this situation, the COM tasked the consultants to assess in their review of the exemption renewal request at hand whether and how far the recommendation of (Deubzer et al. 2022) can be adopted to cat. 9 IMCI in line with Art. 5(1)(a). A re-evaluation of the previous review by (Deubzer et al. 2022) is not intended. The consultants will rely on the critical review conducted by (Deubzer et al. 2022) and on the resulting conclusions and recommendation unless the renewal request or stakeholder contributions give reasons to reassess the state of science and technology.

11.1.3. Summary of the requested exemption and stakeholder contributions

Summary of the requested exemption

"Exemption 13(b) is an exemption to allow the addition of cadmium (Cd) and lead (Pb) into glass specifically for the creation of filters and reflectance standards. Category 9 products use glass filters within the optical design for highly specialist applications. These optical systems are part of sensitive measuring apparatus used throughout a wide variety of applications and industries, where highly sensitive accurate measurements are needed.

As further outlined in this submission, to the best of knowledge of the Test & Measurement Coalition no alternatives have been developed for the applications described in this exemption renewal request and other applications that require cadmium and lead filter glasses. The Test & Measurement Coalition therefore applies for a renewal of the exemption 13(b) for the maximum validity period.

A thorough Socio-Economic Analysis was conducted in addition to the technical assessment and attached to this submission, further illustrating the negative socio-economic impacts a non-renewal of exemption 13(b) would have at this stage. Overall, the analysis concludes that the total impact of non-renewal of this exemption is monetized in the range of 1 billion EUR and 1.5 billion EUR (conservative lower bound estimate)." (TMC 2023a)

Summary of the stakeholder contribution

MedTech Europe (MTE 2023), the European trade association representing the medical technology sector express their support for the renewal of this exemption specifically under category 8 medical equipment including in vitro diagnostic medical devices for the maximum validity period.

As this renewal request only pertains to category 9 IMCI, the statements in support of a renewal for category 8 are not reproduced here.

11.1.4. Technical description of the exemption and use of the restricted substance

A technical description of this exemption was provided by (Deubzer et al. 2022), which the consultants consider to cover the essential information provided by (TMC 2023a). The following information was provided by (TMC 2023a) to indicate for which equipment falling under cat. 9 IMCI the exemption is needed.

Industrial test and measurement instruments (category 9 – Industrial under the RoHS Directive) are very different from low mix, high-volume consumer products which are frequently re-designed to follow consumer trends and are placed on the market for a limited duration. Industrial test and measurement are high mix, low volume producers, managing portfolios of thousands of highly complex instruments. Each instrument is intentionally designed for high reliability and serviceability to support long useful lifespans, and are made available on the market for at least a decade. These instruments are designed: exclusively for professional and industrial use; to meet high performance requirements in critical applications; and last up to 40 years. Redesign is not frequent and happens every seven years on average (as compared to every 1.5 years or less for consumer products). Once test and measurement instruments are placed onto the market, they are typically accompanied with a long-term customer support arrangement to maintain reliability and calibration.

Product portfolios are widely diversified, with T&M Coalition members each having typically 2,000 to 3,000 products currently made available on the market. These are highly complex, sophisticated electronic instruments such as signal generators, power analysers, oscilloscopes, spectrum analysers, digital multi-meters, electron microscopes, chemical and biological analysers, complex chromatography systems and their detectors, each having many necessary options and accessories. Each instrument can have a minimum of 2,000 and up to 40,000 parts; requiring a vast supply chain involving tens of thousands of suppliers and hundreds of thousands of unique components.

The professional test and measurement products provide the tools for engineers to develop new solutions and businesses to bring them to market. These instruments are used in Research, Quality Control and Testing laboratories (including field testing) in Universities, Manufacturing, and clinical facilities and by Governmental Agencies for conformance verification and environmental testing. They are essential to the good functioning of electronic communications networks, heavy industrial processes such as steel manufacturing, the testing of vehicles for compliance with emissions standards, and the monitoring of complex and critical systems. The nature of the tests and measurements made by industrial equipment necessitates that the equipment performing those tests are itself is highly complex; with upwards of 40,000 components necessary to produce a single instrument. Even a relatively simple hand-held instrument incorporates significantly more components that a typical consumer product.

(TMC 2023a) provided a comprehensive list of the relevant product groupings and equipment types relevant to exemption 13(b), reproduced in the table below.

Table 11-5: List of relevant product groupings and equipment types

Product Grouping	*Equipment Types*
Generators, Sources and Power	*Waveform and Function Generators*
Application-Specific Test Systems and Components	
Photonic Test & Measurement Products	
Laser Interferometers and Calibration Systems	*Monolithic Laser Combiners & Precision Optics*

Used Equipment	
Liquid Chromatography	
Gas Chromatography	
Cell Analysis	
Laboratory Products and Industrial Monitoring Capital Equipment	*Autoclave Sterilizers; Baths and Circulators; Biological Safety Cabinets; Blood Culturing Devices; Centrifuges; Chillers; Electrophoresis; Environmental Chambers; Freeze Dryers; Furnaces; Heat Controllers/Exchangers; Ovens; Refrigerators; Freezers; Mixers; Water Purification*
Material and Structural Analysis	*Electron Microscopes; Spectroscopy Equipment*

Source: (TMC 2023a)

11.1.5. Amount(s) of restricted substance(s) used under the exemption

(TMC 2023a) indicate that cadmium-based filter glass typically contains approximately 0.4% cadmium by weight and lead-based filter glass contains between 13% and 28% of lead by weight. Overall, through application for which the exemption is requested, approximately 0.08 kg of Cd and 0.58 kg of Pb enter the EU market annually.

11.2. Justification of the requested exemption

11.2.1. Substitution and Elimination of the restricted substance

(TMC 2023a) state that since the introduction of RoHS 1, and the restriction of the use of lead and cadmium, there has been a dramatic improvement in the development of lead- and cadmium-free glass. These glasses are used where appropriate. Glass with lead and cadmium is only used where their optical properties are required, and where no suitable alternative is available. The TMC members anticipate that the use of these glasses will continue to reduce, however, the participating companies do not foresee a removal of the need of Pb and Cd containing glass from the specialist industrial applications. Eliminating the use of lead and cadmium-glass for optical applications is not possible without the removal of some instrumentation from the EU market, and a reduction of the performance of instrumentation.

According to (TMC 2023a), there are three main alternative types of optical filters that are used for some applications identified by Spectaris. These alternatives, however, cannot replace cadmium-based optical filter glass where the essential characteristics of cadmium filters are required. These alternatives are: alternative additives in glass; coatings on glass; and coloured "plastic fibres."

- *Alternative additives to the glass. Various other elements are added to cadmium to make a material that contains microparticles of cadmium as mixed sulphide, selenide, and telluride. The cut-off wavelength is controlled by the ratio of these elements and by their heat treatment conditions. The exact form of the cadmium compound is unclear but can be seen as very small particles in a colourless matrix. To obtain the same optical properties, alternative inorganic compounds would be needed that are thermally stable at the melting temperature of the types of glass used and gives the same optical spectrum with sharp wavelength cut-offs. Research has been conducted for decades to search for alternatives to cadmium, but with no success.*

- *Thin film coatings on transparent substrates. Interference filters (or, equivalently, dichroic filters) are widely used for certain applications but their properties are very different to glass filters based on cadmium compounds. Their main characteristic is that they absorb light within a specific but rather narrow wavelength range with sharp cutoffs at both ends of this wavelength range. Spectra of light that has passed through this type of filter are quite different to spectra obtained with cadmium glass filters. Interference filters also depend on the viewing angle and can give "ghost images." These filters may also transmit light in unwanted side-bands at lower intensities. The light spectrum transmitted through a cadmium-based optical filter will always be the same, whereas spectra of light transmitted through dichroic filters varies according to the angle of incidence*

- *Transparent plastics with organic pigments. These are used as optical filters and have advantages and disadvantages; these disadvantages, however, make them unsuitable for many applications. The addition of organic dyes and organic pigments to molten glass is impossible as all are thermally unstable at glass melting temperatures. Only heat stable inorganic compounds such as cadmium chalcogenides can be used. Achieving optical clarity is not possible for all combinations of coloured compounds and polymers. Most polymers are available only as opaque materials and most pigments will not dissolve so give opaque dispersions. The main disadvantages of coloured transparent plastics are: plastics are easily scratched; they are affected by humidity as all plastics absorb water from humid air; they are affected by high temperatures (distort, degrade, change colour); organic pigments fade when exposed to ultraviolet light and polymers are also affected causing changes in colour (brittle fracture may also occur when exposed to ultraviolet light); image quality tends to be poor as the surfaces of plastic filters are easily warped, so are not optically flat; some polymer filters with organic pigments have relatively poor maximum transmission percentages at wavelengths of light that should pass through the filter; and some polymer filters transmit light at wavelengths where light needs to be blocked.*

For lead, (TMC 2023a) explain that only one type of filter glass is currently produced that contains lead and it is used because of its unique combination of properties. The interaction between the coloured metal ions and lead atoms in a glass matrix is what gives the required performance of lead-based applications. Research has not identified an alternative material with the same combination of essential properties. Glass filter manufacturers have evaluated many other combinations of ions in lead-free glass, but none give the required properties.

11.2.2. Environmental, health, safety, and socioeconomic impacts

(EPPA 2023) performed a socio-economic analysis (SEA) at the request of TMC, in view of providing regulators with strong evidence-based findings on the expected social and economic impacts that are expected to occur should the use of cadmium and lead be impacted by the non-renewal of the RoHS exemption.

In line with the existing official guidance from ECHA on the preparation of the Socio-Economic Analysis, the SEA therefore gathers technical and economic information to describe ex-ante in both qualitative and (if feasible) quantitative terms the (orders of magnitude of) socio-economic impacts TMC as well as the relevant EEA supply chain and society are expected to face from the non-renewal of the cadmium and lead exemption in filter glasses and glasses used for reflectance standards, which would otherwise expire on 21 July 2024.

The main findings from the SEA conclude that the total impact of a non-renewal is monetized in the range of 1 billion EUR to 1.5 billion EUR (conservative estimates in net losses; potential gains for suppliers of other components have been already taken into account), consisting of: economic impacts (EBIT loss); substitution costs and social impacts (i.e., unemployment in the EU-27) for test and measurement industrial type products' manufacturers.

11.2.3. Roadmap towards substitution or elimination of the restricted substance

(TMC 2023a) explain that most of the alternatives to cadmium and lead in filter glasses do not exhibit the required sharp wavelength "cut-offs." Interference filters can sometimes be used as they do have sharp "cut-offs" but the wavelength at which this occurs depends on the viewing angle and so these filters are unsuitable for many applications. Most of the apparent alternatives are, in addition, detrimentally affected by harsh environmental conditions such as moisture, heat, and UV light which makes them unsuitable for many applications.

Further, according to (TMC 2023a), research has been carried out for decades and alternatives to lead and cadmium have already been used where these are suitable. So far, alternatives have not been developed for the applications described in this exemption renewal request and other applications that require cadmium and lead filter glass. It is also not possible to envisage alternative designs of equipment that would provide the same function and performance without these filters; research timelines can accordingly not be estimated. No substitutes are therefore likely to be developed in the foreseeable future and by extension in the validity period required for this exemption.

Independent of these findings, the Test & Measurement Coalition has contacted their component suppliers to inquire if since the submission of the renewal request by other stakeholders (e.g., Spectaris) new technological developments have occurred that would allow the substitution of cadmium and lead as used in RoHS exemption 13(b). It was reported back that no alternative substance with the same required characteristics of lead and cadmium for the respective components is known to the manufacturers of those components.

(TMC 2023a) describe that if a new substance-free part became available, this part must be qualified for use by performing a variety of tasks. Due to the complexity and diversity of the applications, this must be done individually by each company for each product group. This validation and testing process varies according to part complexity and impact upon the final product design.

- *Medium complexity optical parts are where a like-for-like replacement can be substituted, and the part performs a relatively simple optical function. Despite this, the change in the optical parameters will require testing and performance validation. The average time to switch a medium complexity part for production is reported to range from 6 to 12 months.*
- *High complexity parts are optical components that perform a complex function, or are part of an optical subassembly. These parts will be critical to the performance and accuracy of the device and will require extensive characterisation, as the first step of the replacement process. The output of the characterisation will likely impact other parts of the instrument (for example, the analysis/interpretation software). Once fully characterised, these high complexity optical parts will then require testing and validation performing their function in the instrument. Depending on the application, updated documentation of the device may require notification to the appropriate competent authorities or regulatory bodies. The average time that it would take to perform a for high complexity component change for production is between 2 and 5 years.*

11.3. Critical review

11.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed on Annex XIV. The applicants, SPECTARIS et al., *explained in the previous review of this exemption by* (Deubzer et al. 2022) *that Pb compounds contained in batches for filter glass are present as a complex multi-element mixed oxide in the new substance glass (CAS 65997-17-3) after the melting process, so there is not necessarily an exact stoichiometric chemical formula. SPECTARIS and JBCE, another applicant, confirmed, however, that the lead compounds listed on REACH Annex XIV are not contained in glasses relevant for this exemption.*

Additionally, Annex XVII contains several restrictions for lead and its compounds (cf. section 4.2 on page 51). Additionally, restrictions of cadmium and its compounds are listed on

Annex XVII (cf. section 4.1 on page 48). None of those entries, however, are applicable to the use of cadmium in the recommended exemption 13(b).

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

11.3.2. Substitution and elimination of the restricted substances

TMC argue the justification of the exemption first and foremost on the basis that a substitution or elimination of cadmium and lead in the applications in scope of this renewal request are technically impracticable. The previous review of this exemption by (Deubzer et al. 2022) concluded that lead had largely been substituted and eliminated where this was technically feasible and remains to be used only in applications in which substitution and elimination is not yet technically feasible.

TMC claim that instrument manufacturers largely depend on the supply chain for the development of substitution options, i.e. speciality glass and component makers. TMC state to have inquired with SPECTARIS and others, representing the latter, but no breakthroughs in the development of substitutes for lead in glasses could be reported.

The consultants conclude the technical arguments that justify the exemption that were discussed during the previous review remain valid for equipment for cat. 9 IMCI. As it is currently not feasible to phase out lead from all applications, the consultants consider the request for the maximum validity period justified in principle. However, the consultants consider it would also be justified to rely on the validity periods recommended on the basis of the previous exemption review.

The consultants note that the list of applications provided by TMC is identical between exemptions 13(a) and 13(b). In case of a future renewal request for these exemptions, the consultants consider it necessary for the applicants to differentiate the types of equipment for each exemption.

11.3.3. Adoption of the recommendation from the previous evaluation report

Exemption III-13(b) was reviewed by (Deubzer et al. 2022) who recommended a renewal, as reproduced in section 11.1.1 in Table 11-4. During the review of the current exemption renewal request, the applicants were informed that if this review hows that the applicants' arguments justify the renewal of the exemption, the consultants would recommend the wordings, scopes and expiry dates given in Table 18-6, adapted from the recommendations by (Deubzer et al. 2022).

Table 11-6: Renewal of exemption 13(b)-series, adapted from (Deubzer et al. 2022)

No.	Exemption	Scope and dates of applicability
13(b)	Cadmium and lead used in filter glasses and glasses used for reflectance standards	Applies to categories 8, 9 and 11. Expires on [date of publication in Official Journal + 12 months] for - category 8 medical devices including in vitro diagnostic medical devices; - category 9 monitoring and control instruments including industrial monitoring and control instruments; - category 11.
13(b)(I)	Lead in ion coloured optical filter glass types	Applies to categories 1 to 7 and 10 and from [date of publication in Official Journal + 12 months + 1 day] to categories 8, 9 and 11. Expires on - 21 July 2025 for categories 1, 4; - 21 July 2026 for categories 2, 3, 5, 6, 7, 10 and 11; - 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices; - 21 July 2028 for category 9 monitoring and control instruments other than industrial monitoring and control instruments; - 21 July [2028 **+ X**] for category 9 industrial monitoring and control instruments.
13(b)(II)	Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex	
13(b)(III)	Cadmium and lead in glazes used for reflectance standards	Expires on [date of publication in Official Journal + 12 months] for categories 1 to 7 and 10.
13(b)(IV)	Cadmium in glazes used for reflectance standards	Applies to cat. 8 and 9 from [date of publication in Official Journal + 12 months+ 1 day] on. Expires on - 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices; - 21 July 2028 for category 9 monitoring and control instruments other than industrial monitoring and control instruments; - 21 July [2028 **+ X**] for category 9 industrial monitoring and control instruments.
13(b)(V)	Lead compound coatings in infrared interference filters used	Applies to category 9 industrial monitoring and control instruments from [date of publication in Official Journal + 12 months + 1 day] on.

	in infrared gas analysis and mid-far-infrared spectroscopy	Expires on 21 July [2028 **+ X**] for category 9 industrial monitoring and control instruments.

X can be a maximum of 3 years

When requested to comment on and explain any obstacles to the adoption of the above proposal for the requested exemption for category 9 IMCI, (TMC 2023a) *responded that they apply for renewal of exemption III-13(b) in its current wording and for the maximum validity period, i.e., 7 years.*

(TMC 2023a) emphasize the importance of retaining the initial wording and numbering as published in the original RoHS annexes. Amending the scope of the exemption by changing the application or substance restriction value has a significant administrative burden to industry and negatively impacts the compliance.

Further, (TMC 2023a) highlight that industrial monitoring and control instrument manufacturers have to manage suppliers' declarations for hundreds of thousands of items. Additionally, after reviewing the current state of the evolution of technology for the cat. 9 industrial measurement and control instruments, TMC members have difficulty in understanding how the rewording and relisting and/or splits recommended by the consultants will lead to greater protection of human health and the environment compared to the wording in its current form. The recommended rewording/split would only lead to significant unnecessary burden for stakeholders without commensurate benefits.

Therefore, (TMC 2023a) did not agree with the consultants' proposed renewal as outlined above.

The consultants note that TMC did not described any technical barriers to the adoption of the recommendations made following the previous review of this exemption but base their arguments on administrative burdens that would arise.

11.3.4. Environmental, health, safety, and socioeconomic impacts

While the publicly available version of the SEA does not report data on all individual indicators, being economic impacts (losses in earnings before interest and taxes), substitution costs, and social impacts, TMC also submitted a confidential version that includes more specific data. (EPPA 2023) describe that SEA is based on information collected from surveying TMC member companies, which represent more than 70 % of the entire European Economic Area test and measurement equipment market.

In the consultants' view, the described impacts seem plausible and in case the exemption is not renewed, it cannot be excluded that the impacts occur as described. The consultants do, however, not recommend revoking the exemption, or restricting its scope so that cat. 9 IMCI would be excluded from the scope of the future exemption so, that no adverse environmental or socioeconomic impacts can be expected to arise.

The consultants note that the amounts of Cd and Pb that have been stated by TMC to enter the EU market annually through equipment being placed on the market appear very low. In case of a future review of this exemption, applicants should be expected to provide more detailed information on the basis of their estimates.

11.3.5. Summary and conclusions

TMC request the 7-year renewal of exemption III-13(b) with its current wording for cat. 9 industrial monitoring and control instruments (IMCI) until 21 July 2031. Following their mandate for this exemption, the consultants assessed whether the result of the previous review of this exemption by (Deubzer et al. 2022) - which included cat. 9 IMCI - can be adopted for cat. 9 IMCI in the light of the applicant at hand.

The applicants did not agree to the adoption of the renewal of this exemption recommended by (Deubzer et al. 2022) on the basis that they do not see how the rewording and relisting and/or splits recommended by the consultants will lead to greater protection of human health and the environment compared to the wording in its current form. Further, they emphasize that the rewording and splitting will lead to additional administrative burden throughout the supply chain.

The consultants note that the splitting of exemption 13(b) into 13(b) series is already in force, and that the previous review by (Deubzer et al. 2022) established that the integration of the remaining categories covered by exemption 13(b) into the more specific 13(b) series exemptions was feasible. TMC did not provide any arguments based on technical impracticability of the transition of equipment under category 9 IMCI from exemption 13(b) to 13(b) series. Therefore, although the consultants acknowledge that additional administrative burdens associated with a managing conformity declarations of a potentially long list of affected equipment throughout the supply chains, as stated by TMC, may indeed occur, it seems feasible to maintain the recommendations made by (Deubzer et al. 2022). In line with the consultants' mandate, this also applies to the validity periods recommended by (Deubzer et al. 2022).

When requested to comment on this proposal, (TMC 2023b) did not agree, reiterating that they request the renewal of 13(b) with its currently valid wording and scope.

11.4. Recommendation

The consultants recommend maintaining the exemption renewal proposed by (Deubzer et al. 2022), which includes cat. 9 IMCI. However, it becomes necessary to adapt the validity periods, as (Deubzer et al. 2022) proposed a shorter period until 21 July 2025 for categories 1 and 4, for which the previous applicants did not produce evidence that the exemption was in fact required. As a publication of the COM's decision will not be available at least 18 months before that date, therefore making it impossible for stakeholders to apply for a renewal of the exemption for these categories, the consultants recommend aligning the validity period with those recommended for categories other than 8, 9, and 11.

If the COM decides to follow the approach of (Deubzer et al. 2022), the below wording is recommended for the renewed exemption III-13(b) and 13(b) series:

No.	Exemption	Scope and dates of applicability
13(b)	Cadmium and lead used in filter glasses and glasses used for reflectance standards	Applies to categories 8, 9 and 11. Expires on [date of publication in Official Journal + 12 months] for - category 8 medical devices including in vitro diagnostic medical devices; - category 9 monitoring and control instruments including industrial monitoring and control instruments; - category 11.
13(b)(I)	Lead in ion coloured optical filter glass types	Applies to categories 1 to 7 and 10 and from [date of publication in Official Journal + 12 months + 1 day] to categories 8, 9 and 11. Expires on - 21 July 2026 for categories 1 to 7, 10, and 11; - 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices and category 9 monitoring and control instruments including industrial monitoring and control instruments;
13(b)(II)	Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex	
13(b)(III)	Cadmium and lead in glazes used for reflectance standards	Expires on [date of publication in Official Journal + 12 months] for categories 1 to 7 and 10.
13(b)(IV)	Cadmium in glazes used for reflectance standards	Applies to cat. 8 and 9 from [date of publication in Official Journal + 12 months+ 1 day] on. Expires on - 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices and category 9 monitoring and control instruments including industrial monitoring and control instruments;
13(b)(V)	Lead compound coatings in infrared interference filters used in infrared gas analysis and mid-far-infrared spectroscopy	Applies to category 9 industrial monitoring and control instruments from [date of publication in Official Journal + 12 months + 1 day] on. Expires on 21 July 2028 for category 9 industrial monitoring and control instruments.

If the COM wish to align the validity periods for different EEE categories to enable a joint review in case a renewal was requested again in the future, an aligned renewal of all categories for which the exemption is renewed is recommended until 21 July 2028. This could be applied uniformly to the recommended exemptions 13(b)(I), 13(b)(II), 13(b)(IV), and 13(b)(V), for all covered EEE categories.

The adverse socioeconomic impacts assessed by EPPA will not arise until 2028 since the consultants do not recommend revoking the exemption but TMC will have to bear the cost for preparing and processing a renewal request prior to 2031, which they requested as expiry date in their current renewal request.

Applicants' feedback on the recommendation

(TMC 2024 a/b) stated to favour and apply for the wording of option 1 with an extension of the applicability dates for category 9 IMCI until 21 July 2031. They criticise that the recommendation favors a stronger consideration of the expiry dates recommended by Deubzer et al. in the previous review to enable the review of the exemption for all categories of EEE. This approach counters the RoHS Directive's logic of having different product categories with different validity periods and neglects the specificities of cat. 9 IMCI. The recommendation increases business uncertainty and enhances the likelihood of negative socio-economic impact across the EU as a consequence of potential pre-mature market withdrawal.

The consultants are confident that they considered all relevant arguments made available by applicants and stakeholders during the review, and that the arguments have been evaluated taking into account the requirements of Art. 5(1)(a) and the mandate commissioned by the COM for the review of this exemption.

11.5. References

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TMC (2024a): Answers to questionnaire 2 sent by Tobias Steinbrecher, Eppa, to Christian Clemm. RoHS Pack 27. TMC (RoHS 29).

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12. Exemption 15-series of Annex III: Lead in solders of flip chip packages

The below Table 12-1 shows the wording, scope and expiry dates of the exemption.

Table 12-1: Current wording of the exemption 15-series

No.	Current exemption wording	Current scope and dates of applicability
III-15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	Applies to categories 8, 9 and 11. Expires on - 21 July 2021 for category 8 other than in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments; - 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
III-15(a)	Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the following criteria applies: - a semiconductor technology node of 90 nm or larger; - a single die of 300 mm² or larger in any semiconductor technology node; - stacked die packages with die of 300 mm² or larger, or silicon interposers of 300 mm² or larger.	Applies to categories 1 to 7 and 10. Expires on 21 July 2021 for categories 1 to 7 and 10.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
FCP	Flip chip package
IMCI	Industrial monitoring and control instruments
Lead-free	Not containing lead in the applications covered by the scope of the exemption to be reviewed
RoHS 1	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	Directive 2011/65/EU, current RoHS Directive
TMC	Test & Measurement Coalition

12.1. Background and technical information

On 20 January 2023, (TMC 2023a) submitted a request for the renewal of exemption III-15 with its current wording for the maximum validity period of 7 years as shown in the below table.

Table 12-2: Wording and scope of the requested exemption renewal

No.	*Requested exemption*	*Requested scope and dates of applicability*
III-15	*Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages*	*Applies to category 9 industrial monitoring and control instruments and expires on 21 July 2031 (2024 +7 years)*

12.1.1. History of the exemption

The exemption was added to the Annex of RoHS 1 in 2005 after a review of the related exemption request by (Goodman 2004) with an expiry date in 2010. (Zangl et al. 2010) reviewed the exemption in 2008/2009 under RoHS 1. The consultants recommended to extend the exemption's validity until 2014, the maximum allowed validity period for exemptions under RoHS 1. Exemption 15 was transferred to Annex I of RoHS 2, and the maximum validity period was thereby extended to July 2016. Upon a request for renewal, (Gensch et al. 2016) reviewed the exemption under RoHS 2 resulting in the split of the exemption into exemption 15, which maintained the previous status of the exemption for

EEE of cat. 8 and cat. 9, and introduced exemption 15(a) with a restricted scope for the other categories of EEE in the scope of RoHS.

The exemption was reviewed again in 2021/2022 by (Deubzer et al. 2022). Applicants had requested the renewal of exemption 15 for a specific application, and of exemption 15(a) for EEE of categories 1 to 11. (Deubzer et al. 2022) recommend not to renew the exemptions because the applicants failed to demonstrate that the exemption was still required so that recommending the exemption to be granted would have infringed Art. 5(1)(a) in the consultants' understanding.

In case that the COM decide to still grant the renewal of exemption 15(a), (Deubzer et al. 2022) recommended the expiry of exemption 15 and the integration of cat. 8, 9 and 11 into the scope of the renewed exemption 15(a).

Table 12-3: Potential renewal of exemption III-15(a)

No.	Exemption	Scope and dates of applicability
15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	Applies to categories 8, 9 and 11. Expires on [date of publication in Official Journal + 12 months] for categories 8, 9 and 11
15(a)	Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the following criteria applies: - a semiconductor technology node of 90 nm or larger; - a single die of 300 mm^2 or larger in any semiconductor technology node; - stacked die packages with die of 300 mm^2or larger, or silicon interposers of 300 mm^2 or larger.	Applies - to categories 1-7 and 10 - from [date of publication in Official Journal + 12 months + 1 day] on, to cat. 8, 9 and 11 Expires on [DATE] for categories 1 to 11.

Source: (Deubzer et al. 2022)

12.1.2. Focus of the review of this renewal request

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status March 2024). The applicant therefore applied for the renewal of the current exemption 15 for cat. 9 IMCI since it was earmarked for expiry on 21 July 2024 for this subcategory of cat. 9 EEE. The exemption thus became due for review even though the recommendation for the renewal of exemptions 15 and 15(a) of (Deubzer et al. 2022) included cat. 9 IMCI.

In the light of this situation, the COM tasked the consultants to assess in their review of the exemption renewal request at hand whether and how far the recommendation of (Deubzer et al. 2022) can be adopted to cat. 9 IMCI in line with Art. 5(1)(a). A re-evaluation of the previous review by (Deubzer et al. 2022) is not intended. The consultants will rely on the

critical review conducted by the previous consultants and on the resulting conclusions and recommendation unless the renewal request or stakeholder contributions give reasons to reassess the state of science and technology.

12.1.3. Summary of the renewal request by (TMC 2023a)

Exemption Annex III, 15 permits lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip-chip packages and is currently in force for Industrial Monitoring and Control equipment. Alternatives have entered the market in recent designs, a change to 15(a) restricting Pb-containing solder by die and node size has occurred, and some older components have been updated with these changes. However, there are still a significant number of suppliers that have not investigated or implemented these changes.

Given the intrinsic physical and technical characteristics of lead, solders containing Pb exhibits certain advantages that lead-free solders lack, including:

- Solders containing lead are more ductile and softer than Pb-free alternatives and can therefore better absorb stresses originating from mismatch in the coefficient of thermal expansion between semiconductor die and carrier. Subsequently, they are less prone to develop solder cracks.
- The die attach reflow temperature is reduced given the lower melting temperature of eutectic tin-lead solders. Consequently, the internal package stress during flip-chip die attach is reduced. Package failures, including package material interface delamination (the glue under the chip delaminates from the package substrate) are hence prevented.
- An additional failure mechanism for packages with flip-chip die is electro-migration. This mechanism causes solder joint failure when high current density (amps per square millimetre) causes atoms to migrate from one side of the joint to the other, depleting metal at the connection. Exemption 15(a) has been defined to address this; however, many suppliers have not yet investigated or implemented the effect of this change.

The T&M Coalition acknowledges that there are suitable alternatives available to substitute lead in solders for new components into newly designed instruments. Indeed, industry has demonstrated a strong commitment to developing lead-free flip-chip devices as new technologies become available.

However, while exemption 15 will be designed out over time as new lead-free components become available, a continuation of exemption 15 for category 9 industrial test and measurement instruments is still warranted as these lead-free components cannot be used for existing T&M products. Additionally, given the long lifetime of T&M instruments as well as the greater inventory of older parts used for the repair of products currently placed on the market, a discontinuation of exemption 15 for category 9 products would counter the logic of an increased circular economy and create avoidable EEE waste.

A thorough Socio-Economic Analysis was conducted in addition to the technical assessment and attached to this submission, further illustration the negative socio-economic impacts a non-renewal of exemption 15 would have. Overall, the analysis

concludes that the total impact of a non-renewal of this exemption is monetized in the range of 309 million EUR and 442 million EUR (conservative lower bound estimate).

12.1.4. Technical description of the exemption and use of the restricted substance

A technical description of this exemption was provided by (Deubzer et al. 2022) and (Gensch et al. 2016). The information and facts provided by the applicant were addressed in these previous reviews.

12.1.5. Amount(s) of restricted substance(s) used under the exemption

(TMC 2023a) estimate around 1.3 kg of lead to be placed annually on the EU market in applications in the scope of the exemption. This figure is based on information provided by the TMC members. Since not all cat. 9 IMCI producers are members of TMC, the actual amount of lead could be higher.

12.2. Justification of the requested exemption

(TMC 2023a) reference their thorough socioeconomic analyses performed by (EPPA 2023) in view of providing regulators with evidence-based findings on the expected social and economic impacts that are expected to occur should the use of lead (Pb) be impacted by the non-renewal of the RoHS exemption.

In line with the existing official guidance from ECHA on the preparation of the Socio-Economic Analysis, the SEA therefore gathers technical and economic information to describe ex-ante in both qualitative and (if feasible) quantitative terms the (orders of magnitude of) socio-economic impacts TMC ell as the relevant EEA supply chain and society are expected to face from the non-renewal of the lead (Pb) exemption in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages, which would otherwise expire on 21 July 2024.

(EPPA 2023) inform that many suppliers have implemented lead-free alternatives on the EU market for test & measurement industrial type products, or have changed the applied exemption to 15(a) with restrictions on die and node size. In the sector of the participating companies, there are still some niche and specialty suppliers with components claiming exemption 15 and not exemption 15(a). The components either meet the unique requirements of the sector, such as more demanding precision, performance, or reliability or are older parts that are still used in the product designs of the TMC members from 5 to 20 years ago. The sector of the participating companies has long-lived product designs that are still in demand by their customers. The re-designing of the test & measurement equipment could take four to six years per product line. Hence, losing the ability to apply Annex III, exemption 15, when considering RoHS conformity for the associated test and measurement industrial products would entail the development of a fairly large number of new alternative, compliant materials, as well as the increased costs connected to the redesign, retesting, requalification, and replacement of the assembly process.

12.2.1. Substitution and Elimination of the restricted substance

The status of substitution and elimination of lead in the applications in scope of this exemption was discussed by (Deubzer et al. 2022).

12.2.2. Environmental, health, and safety impacts

(EPPA 2023) inform that participating TMC member companies report no releases to the environment of lead can be anticipated during neither equipment production nor use phases of the concerned products over the next seven years as a consequence of the revocation of the RoHS exemption. During equipment production, the lead is not exposed because it is internal to the component. At component manufacturers level, exposure and waste and exposure to lead is considered controlled through good occupational health and safety management practices.

Under normal conditions of equipment use, the lead content associated with the application of the exemption is encapsulated within the equipment enclosure and will neither be touched nor released to the environment. As this equipment is sold B2B for professional/industrial use only, equipment that finally reaches end-of-life will be appropriately processed by professional recyclers who are obligated to have suitable controls to avoid any environmental releases and are notified of the presence of the substance under the producers' obligation to provide a SCIP notification.

The TMC member companies have only indicated a minor risk for substances to be released to the environment during the manufacture of the components. These are not produced by TMC members. Thus, data are not available, however the estimate is expected to be bounded by the total use of the substance (i.e., release to the environment is expected to be less than the mass of substance incorporated into the components).

(EPPA 2023) are of the opinion that due to the participating TMC member companies' relatively low consumption of parts, in comparison to the product Categories 1-7 and 10, renewing this exemption for Category 9 will have a minimal impact on the environment. Category 9 Industrial producers are only responsible for 0.2 % of annual WEEE production. cat. 9 IMCI contribute to the Waste Electrical and Electronic Equipment stream only around 0.2 % by weight of EU WEEE, with industrial WEEE being collected through B2B systems. Consequently, the environmental impact of cat. 9 IMCI is negligible.

(EPPA 2023) expect "[ ] no, or at least minimal, expected additional waste before the end of the regular lifetime (non-compliant stock) reported by the companies. Finished goods inventory is typically minimal as T&M equipment manufacturers' production is based on short-term demand, or even per order. Any non-compliant materials will be consumed through sale into markets where there isn't a similar restriction". TMC member manufacturers of cat. 9 IMCI emphasise, however, that the exemption is utilized in part to improve reliability and longevity of components. A reduced product lifetime would be expected leading to an increase in electronic waste and virgin material use in the replacement in apparent conflict to the concepts proposed under the proposed Eco-design for Sustainable Product Regulation. Moreover, in the case of a discontinuation of exemption 15 for category 9 products, factories using products with older designs may need to re-tool their test process, adding to electronic waste from the replaced equipment.

The majority of the components that utilize this exemption, which constitute Category 9 industrial usage, are common to all product categories. The component manufacturers therefore rely on volume use of the other categories to justify their continued production. Renewing this exemption only for Category 9 for the full 7 years will not extend the production life of these higher volume components beyond the exemption renewal period assigned to Categories 1-7 and 10. It will, however, enable the Test & Measurement coalition members to buy sufficient (relatively small) quantities to update the design and continue to use the relevant components for an extended period. As a result, a renewal of this exemption will a minimal environmental impact and has a positive socio-economic impact by enabling the continued production of Category 9 products critical to the health and welfare of the EU (and global) society whilst the multi-year redesign process is executed.

12.2.3. Socioeconomic impacts

(EPPA 2023) prepared a socio-economic analyses (SEA) for TMC showing the impacts which a non-renewal of the exemption for cat. 9 IMCI would cause. (EPPA 2023) declare that the SEA was prepared in line with the official ECHA guidance on the preparation of the Socio-Economic Analysis. ***The*** *SEA is based on information and data gathered from the industrial and professional test and measurement equipment manufacturers. A survey has been conducted by providing a detailed questionnaire to gather information and data from actors likely to be affected by a non-renewal of the RoHS exemption in the EU.* ***TMC member manufacturers of cat. 9 IMCI participated in the survey****. The market share covered by this survey represents approximately 70 % of the EEA market so that (EPPA 2023) consider the survey as highly representative so that it can serve as a basis for defining the anticipated socio-economic impacts resulting from the non-renewal of the RoHS exemption.*

Overall, the total impact of a non-renewal of this exemption is monetized in the range of 309 million EUR and 442 million EUR (conservative estimates in net losses; potential gains for suppliers of other components have been already taken into account). (EPPA 2023) calculated the above total economic impacts by summarising business impacts on manufacturers, impacts on the wider economy and social impacts caused by unemployment.

Further details are available in the report prepared by (EPPA 2023).

12.2.4. Roadmap towards substitution or elimination of the restricted substance

As to their actions taken to develop further potential lead-free alternatives, (TMC 2023a) acknowledge that there are suitable alternatives available to substitute lead in solders for new components into newly designed instruments. Indeed, industry has demonstrated a strong commitment to developing lead-free flip-chip devices as new technologies become available.

However, while exemption 15 will be designed out over time as new lead-free components become available, a continuation of exemption 15 for category 9 industrial test and measurement instruments is still warranted as these lead-free components cannot be used for existing T&M products. Additionally, given the long lifetime of T&M instruments as well

as the greater inventory of older parts used for the repair of products currently placed on the market, a discontinuation of exemption 15 for category 9 products would counter the logic of an increased circular economy and create avoidable EEE waste.

As to their roadmap to achieve RoHS compliance without exemption 15, (TMC 2023a) understand that new products can be designed to use lead-free components that utilize the restricted scope of exemption 15(a), the challenges of substitution are substantial for the vast majority of their portfolio that are in production but may have been designed while only exemption 15 was available.

Components which benefit from exemption 15 typically do not have form-fit-function drop-in replacements that are either lead-free or can benefit from exemption 15(a). Older product designs utilizing exemption 15 components would therefore need to be redesigned to match new component parameters, including a revised layout for PCB. Such changes require product-by-product projects to manage the change, including verification of each product against published performance specifications.

For products that will be newly designed, members of the Test & Measurement Coalition have pointed out that they mainly rely on their suppliers to find alternatives since most of the exemptions used in their products are not produced on-site by the company but bought off-the-shelf from suppliers. Therefore, meeting with suppliers to understand their (potential) alternatives, getting samples, measuring, and testing is the typical process to evaluate the suitability of potential alternatives which can take up to 4 years, as reported by the companies. The process would then be followed by the validation of the potential suitable alternatives accompanied by testing done by the manufacturers of the finished T&M equipment, with the validation of the functionality and performance being their responsibility as well. However, the companies noted the impacts deriving from their suppliers as, depending on the complexity, there can be little to significant time and resources needed to validate alternatives.

The companies reported that the validation period alone would take a minimum of 6 months and up to a year after the delivery of suitable alternatives per product. It is significant to note that this validation period would only apply if the component were a fit, form, and function drop-in replacement. If any design changes to the exemption-free part of the product would be required to accommodate for the alternative, an additional validation period would be required for each redesigned product that used to utilize the component that relied on the exemption. Moreover, the validation would lead to the organizations incurring additional expenses. These include labour costs and costs arising from potential product resubmission requirements for testing to various notified bodies to ensure that substitution does not create any electrical and functional safety concerns.

Contrary to the statement of the Commission's external consultant BIOIS, made in the recent exemption assessment report (pack 23, i.e., (Deubzer et al. 2022)*, the Test and Measurement sector did not start incorporating lead-free components (much less in lead-free flip chip) in 2007. In fact, customers of T&M equipment demand continued sales of products designed before this sector's compliance date of 2017; this allows their manufacturing test processes to have consistent equipment and software. Re-design of these older products with new-technology components is not feasible or practical because of the number of products and relatively low volume and thus lower payback.*

If a new substance free part is available, this part must be qualified for use by performing a variety of tasks, as described above. Due to the complexity and diversity of the applications,

this must be done individually by each company for each product group. This process would divert resources from other projects and increase the cost to ensure continued availability of these products. This validation and testing process varies according to part complexity; which can be categorised as low, medium, and high:

- **Low complexity** parts are the off-the-shelf components or hardware parts that do not have a substantial performance impact. Replacement can be done based on supplier information, assuming a form/fit/function compliance, with standard manufacturing, testing, and validation processes. Based on process timescales reported by a T&M coalition company, the average time that it can take for these parts to be replaced ranges from **3 to 6 months**.
- **Medium complexity** parts are more complex sub-assembly electronic parts, such as small motors which need additional validation for their performance. These parts are often commercial assemblies that are generally available to the electronic industry, and are utilised by the Test & Measurement coalition companies. Replacement of these assemblies, like-for-like, requires testing and validation prior to being integrated into the manufacturing process. The average time to find an alternative for medium complexity parts for production is reported to range from **6 to 12 months**.
- **High complexity** parts are complex sub-assembly parts and have a significant impact on the performance of the companies' products. These also have a critical role in the overall safety of the products. These parts need to go through extensive validation for performance and/or compliances, according to varying regulations, before the appropriate files can be updated and the proper competent authorities or regulatory bodies can be notified prior to the purchase of parts for validation. The average time that it would take to find an alternative for high complexity parts for production is up to 1 year of additional testing. Where the exemption directly impacts the performance of that component (e.g., a centrifuge rotor) the evaluation of the replacement could take **3 to 5 years**.

12.3. Critical review

12.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds (cf. section 4.2 on page 51). None of these entries are, however, relevant for the use of lead in the scope of the exemption 15-series in EEE of cat. 9 IMCI.

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

12.3.2. Substitution and elimination of the restricted substance

Transfer of cat. 9 IMCI from the scope of exemption 15 to exemption 15(a).

In the last review of exemptions 15 and 15(a) conducted by (Deubzer et al. 2022), the applicants had proposed transferring cat. 8, 9 and 11 from exemption 15 into the scope of exemption 15(a). TMC were asked whether they agree that the current wording of exemption 15(a) covers the applications of lead in flip chip packages (FCPs) for use in cat. 9 IMCI.

(TMC 2023c) did not agree and explain that exemption III-15 permits lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip-chip packages and is currently in force for cat. 9 IMCI. Alternatives have entered the market in recent designs and a change to 15(a) restricting Pb-containing solder by die and node size has occurred. However, there are still a significant number of suppliers that have not investigated or implemented these changes.

Considering that exemption 15(a) was introduced in 2016, it is remarkable that suppliers should not even be informed about these changes. Technically, the applicants' answer is implausible. The current wording of exemption 15(a) represents the technical status of lead-free FCPs at the time of the last review conducted by (Gensch et al. 2016), predating the review by (Deubzer et al. 2022). The current wording was proposed by the applicants in 2015 including manufacturers of such FCPs. To the consultants' best knowledge from previous reviews, FCPs with nodes of less than 90 nm were from the time of introduction designed to be assembled with lead-free solders, i.e. they cannot be assembled with lead-containing solders. It can be assumed that the same applies to the other types of FCPs in the scope of the two other sub-clauses of exemption 15(a).

The applicant did not provide any information that would have given reasons to disprove the above statement. TMC was requested to provide examples of lead-containing FCPs which their members use, and which would not be covered by exemption 15(a).

*(TMC 2024) answered that the submitted SEA document provides a detailed description of the TMC products, whereas the product portfolios are widely diversified, with TMC members each having typically **2,000 to 3,000 products** currently made available on the EEA market. These are highly complex, sophisticated electronic instruments, which can have between **2,000 and 40,000 parts** and therefore rely on a vast supply chain involving **tens of thousands of suppliers and hundreds of thousands of items**. The Annex of the SEA document contains further details concerning the product groups and equipment types that benefit from the current exemption III-15. Please also note that the product groups mentioned in the annex of the SEA document exemplify the types of products concerned, but **do not** represent an exhaustive list of each and every category 9 industrial product currently benefiting from exemption III-15.*

Given the complexity of category 9 industrial test and measurement instruments and the vast supply chain as well as the short deadline to respond to this follow-up question (1

*week), it is **impossible** for TMC members to confirm with the necessary due diligence and certainty that the proposed continuation of only exemption III-15(a)[40] covers all applications currently benefiting from exemption III-15.*

As regards the obsolete parts where TMC members consume last-time-buy inventory for the remaining life of the product - the typical active life of TMC products is 10 years (i.e. being placed on the market) - it is impossible to reach out to the supplier and get a confirmation, as the supplier would not provide this information for obsolete parts.

Without this information from the supply chain, it is not possible to definitively state the definition for exemption III-15(a) covers all applicable uses in the components used to produce test and measurement equipment benefitting from Exemption III-15 today.

*In addition, TMC would like to highlight again that members acknowledge that there are suitable alternatives available to substitute lead in solders for **new** components in newly designed instruments. However, while exemption III-15 will be designed out over time as new lead-free components become available, a continuation of exemption 15 for category 9 industrial test and measurement instruments is still warranted as these lead-free components **cannot be used for existing T&M products**. Given the typical active lifetime of 10 years of T&M instruments as well as the greater inventory of older parts used for the repair of products currently placed on the market, a discontinuation of exemption III-15 for category 9 products would counter the logic of an increased circular economy and create avoidable EEE waste.*

*As detailed in the SEA, the total monetized impact of a non-renewal is estimated in the range of **309 million EUR and 442 million EUR**.*

*Lastly, we would like to highlight again that after reviewing the current state of the evolution of technology for the cat. 9 industrial measurement and control instruments, TMC members have difficulty in understanding how the narrowing down of the scope of exemption III-15 as suggested by the consultants will lead to greater protection of human health and the environment compared to the wording in its current form. This holds especially true when considering that cat. 9 industrial test and measurement instrument contribute to only a **fraction of 1%** of the total annual quantities of RoHS restricted substance (please refer to the SEA document for details). The recommended scope reduction would only lead to significant unnecessary burden for stakeholders without commensurate environmental and/or human health benefits.*

In conclusion, TMC maintains that a renewal of exemption III-15 in its current wording is warranted according to article 5 of the RoHS Directive.

The above reply repeats non-technical statements that have been expressed in the renewal request and in the SEA. The applicants do not answer the technical question nor can the answer be found in the SEA of (EPPA 2023). They cannot provide a single example of a FCP used by TMC members that would not be covered by exemption 15(a).

[40] **TMC:** *In a previous questionnaire sent to TMC members by the consultants, it was suggested that only exemption III-15(a) would be recommended to continue beyond the initial expiry date of 21 July 2021 by an "x" number of years, whereas x could range between 0 – 7 years. Although this information is not mentioned in this document, it is assumed that the consultants refer to the possibility of extending exemption III-15(a) by a maximum of 7 years as opposed to also continuing exemption III-15 in its current wording beyond the expiry date of 21 July 2024 for cat. 9 IMCI.*

The consultants therefore conclude that the applicant has no technical arguments against the inclusion of cat. 9 IMCI into the scope of exemption 15(a).

Open questions from the previous review by (Deubzer et al. 2022)

The below core questions remained open in the previous review of exemptions 15 and 15(a) so that (Deubzer et al. 2022) recommended the expiry of exemption 15 and exemption 15(a). The applicant was therefore requested to answer these open questions:

- First clause of exemption 15(a)
  Flip chip packages (FCPs) with technology nodes larger than 90 nm are still placed on the EEA market in new EEE. These older FCP models cannot be redesigned to enable the use of lead-free solders but smaller node lead-free FCPs have been available since 2007. Cat. 9 IMCI will have been in the scope of the RoHS Directive 2011/65/EU since 2011, i.e. for 13 years, when exemption 15 will expire in 2024. Please explain why FCPs with technology nodes larger than 90 nm are still required in cat. 9 IMCI for another 7 years until 2031 in the presence of lead-free alternatives since 2007, and 20 years after cat. 9 IMCI were adopted to the scope of the RoHS Directive.

- Second clause of exemption 15(a)
  The applicants claim that the use of lead is scientifically and technically impracticable for FCPs with dies of 300 mm^2 or more, independently from the technology nodes. The review process revealed that larger die size FCPs (single dies and stacked) with smaller technology nodes can be produced with lead-free solders. The applicants did not provide information as to which die size (> 300 mm^2) and technology nodes FCPs can be produced with lead-free solders.

- Third clause of exemption 15(a)
  The review of exemption 15/15(a) by (Gensch et al. 2016) showed that using plastic/organic interposers instead of silicon interposers enables lead-free soldering of stacked die FCPs with interposers of 300 mm^2 and more. In the last review by Deubzer et al. (2022), applicants stated that the usability of plastics instead of silicon interposers has its limits and, among others, depends on the number of connections between adjacent dies in the FCP. The applicants failed, however, to explain the conditions and limitations for the use of organic interposers, or why these conditions are not adequate to restrict the exemption scope. The actual scientific and technical practicability of lead-free soldering in FCPs with large (≥ 300 mm^2) interposers remained unclear.

- Please explain the conditions – or sets of conditions – that require the use of silicon interposers for interposer sizes ≥ 300 mm^2 instead of organic interposers. Please also take into account whether and how far the chiplet technology and/or the use of silicon bridges instead of silicon interposers enable the use of lead-free solders in such FCPs.

When asked to provide insights into these open questions, (TMC 2024) repeat earlier statements about suitable substitutes that can be used in newly designed instruments, and that they will design out over time exemption 15 as new lead-free components become available. Additionally, given the long lifetime of T&M instruments as well as the greater inventory of older parts used for the repair of products currently placed on the market, a

discontinuation of exemption 15 for category 9 products would counter the logic of an increased circular economy and create avoidable EEE waste.

(TMC 2024) state to have further outlined in the submission documents that components which benefit from exemption 15 typically do not have form-fit-function drop-in replacements that are either lead-free or can benefit from exemption 15(a). Older product designs utilizing exemption 15 components would therefore need to be redesigned to match new component parameters, including a revised layout for PCB. Such changes require product-by-product projects to manage the change, including verification of each product against published performance specifications.

Taking additionally into account the socio-economic consequences of a nonrenewal of exemption III-15, which is monetised in the range of 309 million and 442 million EUR , TMC considers that a renewal of exemption III-15 is warranted in accordance with RoHS art. 5(1)(a).

The above reply repeats non-technical statements that have been expressed in the renewal request and in the SEA. Neither does it answer the technical questions nor can the answer be found in the SEA of (EPPA 2023). Adding to this, TMC still speak about using lead-free FCPs once they become available, ignoring that (Gensch et al. 2016) and (Deubzer et al. 2022) found such alternatives to have been available since 2007, for more than 15 years already, at least for the FCPs in the scope of the first sub-clause of exemption 15(a). TMC do not provide any technical argument as to why the exemption has still been used in new cat. 9 IMCI placed on the European Economic Area market, and why this exemption should be renewed for another 7 years to allow the continued use of such FCPs.

The consultants conclude that the question why FCPs covered by that sub-clause are still used in cat. 9 IMCI as well as the status of lead-free soldering in FCPs addressed in subclauses 2) and 3) of exemption 15(a) remain unclear like in the previous review by (Deubzer et al. 2022)

12.3.3. Environmental, health, safety and socioeconomic impacts

TMC state that cat. 9 IMCI contribute to the Waste Electrical and Electronic Equipment (WEEE) stream only around 0.2 % by weight of EU WEEE so that the environmental impact of cat. 9 IMCI is negligible. They also state that there is no exposure of humans and the environment to lead contained in FCPs during manufacturing and use of cat. 9 IMCI.

The current RoHS Directive does not define any thresholds for use of restricted substances or contributions to the overall waste generation for which Art. 5(1)(a) would justify granting an exemption if these thresholds are not exceeded. Exemptions are to be granted in line with Art. 5(1)(a) if – next to “REACH-compliance” - any of its three sub-clauses (cf. section 12.3.4 on page 229) is fulfilled.

TMC address environmental, health and safety impacts but do not claim that the third sub-clause of Art. 5(1)(a) would be applicable, which would require a more detailed and life-cycle-oriented assessment. For example, potential impacts on workers by exposure in the waste treatment and at the end of life of devices in general would have to be considered, as well as impacts arising in the mining and refining of lead.

(EPPA 2023) quantify the economic impacts of a non-renewal of the exemption with 309 million EUR to 442 million EUR, which they summarise from business impacts on cat. 9

IMCI manufacturers, impacts on the wider economy and socioeconomic impacts cause by unemployment. The individual contributions of each of these types of impacts are marked as confidential and are not publicly available. Even though not explicitly stated, the data for the SEA seem to have been collected from TMC member companies which, according to (EPPA 2023), cover 70 % of the EEA market.

The consultants base their recommendation on the result of the technical assessment in the light of the three sub-clauses of Art. 5(1)(a). If the exemption will not be granted on this ground, the consultants cannot exclude that adverse impacts described by TMC/EPPA (cf. section 12.2.2 on page 221) arise. The consultants consider beyond their mandate any judgement as to which degree of socioeconomic impact would justify granting an exemption on socioeconomic grounds in the case that none of the three sub-clauses of Art. 5(1)(a) is fulfilled. [41]

12.3.4. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria[42] is fulfilled:

11) 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**;

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

13) 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.

(TMC 2023a) request the 7 year renewal of exemption 15 claiming that this exemption is required to allow the continued placing on the market of cat. 9 IMCI. In the previous review of exemptions 15 and 15(a), (Deubzer et al. 2022) recommended not to renew these exemptions. The applicants failed to provide evidence as to how far substitution or elimination of lead are scientifically and technically practicable in applications within the scope of the current exemption III-15(a).

TMC could not provide this information either but put forward their complex supply chain on which they rely to obtain such information, and which their suppliers do not have available. In the consultants' understanding, applicants are responsible to organise the expertise required to substantiate exemption renewal requests with the required expertise, and to be able to answer technical questions adequately. The critical review shows that TMC could not answer technical questions adequately. RoHS compliance and the related efforts are the responsibility of EEE producers, not of the supply chain.

(Deubzer et al. 2022) presented a fallback option for the case that the COM decide to renew the exemption (cf. Table 12-3 on page 218) which implies the renewal of exemption III-15

[41] Art. 5(1)(a) stipulates that any of the three sub-class must be *fulfilled*, and that decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV *shall take into account* the socioeconomic impact of substitution.

[42] Differently from Art. 5(1)(a) in the RoHS Directive, the criteria are numbered so that they can be addressed in the below text.

as the currently still valid exemption III-15(a) for cat. 9 IMCI. TMC reject adopting this approach insisting on the 7 year renewal of exemption 15 as requested and claiming that exemption 15(a) would not cover all applications of lead in the scope of exemption 15(a). Upon request, TMC could, however, not provide any specific example of lead-containing FCPs used in cat. 9 IMCI which exemption 15(a) would not cover. Technically, TMC's claim is not plausible either because FCPs that are not in scope of the current exemption 15(a) in the consultants understanding were designed to be assembled with lead-free solders.

In the light of the above situation, the consultants recommend adopting the recommendation of (Deubzer et al. 2022) and not to renew exemption III-15 for cat. 9 IMCI.

The consultants cannot exclude that adverse socioeconomic impacts described by the applicant (cf. section 12.2.3 on page 222) arise at least to some degree if the exemption is not renewed for cat. 9 IMCI.

12.4. Recommendation

In the light of the information made available by the applicant, the consultants propose adopting the recommendation of (Deubzer et al. 2022) in the previous review of exemptions 15 and 15(a), which was not to renew the exemptions. The applicants did not answer technical questions, including those that had remained open in the previous review, and which resulted in the above recommendation not to renew the exemption. In the consultants' understanding, recommending the exemption to be granted would infringe Art. 5(1)(a) in the absence of clear evidence to which degree the substitution of lead in FCPs is still scientifically and technically impracticable.

The consultants cannot exclude that adverse socioeconomic impacts described by the applicant may arise if the exemption is not renewed for cat. 9 IMCI. The consultants consider beyond their mandate any judgement as to which degree of socioeconomic impact would justify granting an exemption on socioeconomic grounds if none of the three sub-clauses of Art. 5(1)(a) is fulfilled.

If the COM decides to renew the exemption, the consultants recommend adopting the wording and scopes proposed by (Deubzer et al. 2022) for this case:

No.	Exemption	Scope and dates of applicability
15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	Applies to categories 8, 9 and 11. Expires on 21 July 2024 [if applicable: date of publication in Official Journal] + 12 or 18 months for categories 8, 9 and 11
15(a)	Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the following criteria applies: - a semiconductor technology node of 90 nm or larger;	Applies to category 9 industrial monitoring and control instruments from [date of expiry of exemption 15 + 1 day] on

	- a single die of 300 mm^2 or larger in any semi-conductor technology node; - stacked die packages with die of 300 mm^2or larger, or silicon interposers of 300 mm^2 or larger.	Expires on [DATE] for category 9 industrial monitoring and control instruments

The COM may consider a short-term expiry date for the above renewed exemption 15(a) defined by the time required to prepare and timely submit renewal requests.

Applicant's feedback on the recommendation

(TMC 2024a) do not agree to the recommendation refering to the statements in their application documents and pointing out that Article 5(1)(a) of the RoHS Directive requires that decisions on granting exemptions need to consider the socioeconomic impact of substitution.

The consultants are confident that they considered all relevant arguments made available by applicants and stakeholders during the review, and that the arguments have been evaluated taking into account the requirements of Art. 5(1)(a) and the mandate commissioned by the COM for the review of this exemption.

12.5. References

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TMC (2024): Answers to questionnaire 2 sent by Tobias Steinbrecher, EPPA, to Dr. Otmar Deubzer. RoHS Pack 27 (RoHS 29).

TMC (2024a): Feedback on the recommendation for renewal of exemption III-15 sent by Tobias Steinbrecher, EPPA, to Dr. Otmar Deubzer. RoHS Pack 27 (RoHS 29).

Zangl et al. (2010): Adaptation to scientific and technical progress of Annex II to Directive Adaptation Directive2000/53/EC (ELV) and of the Annex to Directive 2002/95/EC (RoHS). Final report - revised version. Final Report. In cooperation with Stéphanie Zangl, Markus Blepp, Carl-Otto Gensch, Ran Liu, Katja Moch [Öko-Institut e.V.] und Otmar Deubzer, Deubzer, Otmar [Fraunhofer IZM]. Öko-Institut e. V. und Fraunhofer IZM. Freiburg (Adaptation to scientific and technical progress of Directive 2000/53/EC and 2002/96/EC; ELV and RoHS exemption review, RoHS IV, ELV II). Retrieved from http://elv.exemptions.oeko.info/fileadmin/user_upload/Consultation_2014_1/Ex_3_2010_Review_Final_report_ELV_RoHS_28_07_2010.pdf; or https://circabc.europa.eu/sd/d/a4bca0a9-b6de-401d-beff-6d15bf423915/Corr_Final%20report_ELV_RoHS_28_07_2010.pdf.

13. Exemption 18(b) of Annex III: Lead in fluorescent powder of discharge lamps

The below Table 13-1 shows the wording, scope and expiry dates of the exemption.

Table 13-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
III-18(b)	Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi2O5:Pb)	Applies to categories 1 to 11. Expires on - 21 July 2021 for categories 1-7 and 10. - 21 July 2021 for category 8 other than in vitro diagnostic medical devices and category 9 other than industrial monitoring and control instruments. - 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.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

BSP	Barium silicate phosphor doped with lead, also known as BaSi2O5:Pb
Cat.	Category, referring to the categories of EEE specified in Annex I of the current RoHS Directive
Ce doped	Cerium-doped
COM	European Commission
CFL	Compact Fluorescent Lamp
EEE	Electrical and electronic equipment
HID	High-intensity discharge lamp
Hg	Mercury
IMCI	Industrial monitoring and control instrument

Lead-free	Not containing lead in the applications in scope of the exemption to be reviewed
LED	Light-emitting diode
OLED	Organic light-emitting diode
SEA	Socioeconomic analysis
UV	Ultraviolet
UVA	Ultraviolet A
UVB	Ultraviolet B
WPE	Wall Plug Efficiencies
YPO	Yttrium orthophosphate

13.1. Background and technical information

On 13 January 2023, (LightingEurope 2023a), an industry consortium (Umbrella Project), applied for renewal of the exemption III-18(b) for the maximum validity period of 5 years for cat. 11. Exemption III-18(b) expires on 21 July 2024 for cat. 9 IMCI, and for cat. 11.

Table 13-2: Requested exemption renewal

No.	*Requested exemption*	*Requested scope and dates of applicability*
III-18(b)	*Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi2O5:Pb)*	*Applies to category 11 and expires on 21 July 2029 (= 2024 + 5 years)*

The European Sunlight Association (ESA 2022) and NARVA Lichtquellen GmbH & Co (NARVA 2022) support LightingEurope's request. No contributions were received during the public consultation.

13.1.1. History of the exemption

The exemption was reviewed by (Baron et al. 2022). *LightingEurope (LE) with the support of the European Sunlight Association (ESA) and based on additional information provided by Mallinckrodt Pharmaceuticals c/o Therakos, Inc. submitted a request for the renewal of the following three exemptions:*

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

- *Annex III, 18(b)-I: "Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP when used in medical phototherapy equipment."*
- *Annex IV, 34: "Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi2O5:Pb) phosphors."*

According to (Baron et al. 2022), in this renewal application, the applicants requested that the three applications should be combined into a single exemption. The aim was to avoid ambiguity or repetition in the renewal application. (Baron et al. 2022) identified a preference for merging the medical applications covered by Annex III 18(b)-I and Annex IV Ex. 34 on the one hand and keeping Annex III 18(b) separate on the other. It was the applicant's intention that the scope of the exemptions should not be changed. In 2020 the renewal was requested for EEE categories 5, 8 and 9 with a maximum possible validity period.

Following the renewal requests submitted in January 2020, (Baron et al. 2022) reviewed the exemption and recommended its renewal as listed in Table 13-3. (Baron et al. 2022) did not review the exemption for cat. 11 as it was not requested by the applicant.

Table 13-3: Renewal of current exemption 18(b) recommended by (Baron et al. 2022)

Exemption formulation	Duration
	Expires on:
18(b) Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi2O5:Pb)	— 21 July 2026 for categories 5, 8 and 9; — 21 July 2023 for category 8 in vitro diagnostic medical devices; — 21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.
New item: 18(b)-II: Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps containing phosphors such as BSP (BaSi2O5:Pb) when used in medical phototherapy equipment, incl. extracorporeal photopheresis lamps	— 21 July 2026 for categories 5, 8 and 9

Source: (Baron et al. 2022).

13.1.2. Focus of the review

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status January 2024). On 13 January 2023, (LightingEurope 2023a) applied for the renewal of the current exemption 18(b) for cat. 11 since it will expire on 21 July 2024.

In the light of this situation, the COM tasked the consultants to assess in their review of the exemption renewal request at hand whether and how far the recommendation of (Baron et al. 2022) can be adopted to cat. 11 in line with Art. 5(1)(a). A re-evaluation of the previous review by (Baron et al. 2022) is not intended. The consultants will rely on the critical review conducted by (Baron et al. 2022) and on the resulting conclusions and recommendation unless the renewal request or stakeholder contributions give reasons to reassess the state of science and technology.

13.1.3. Summary of the requested exemption

According to (LightingEurope 2023a) exemption 18(b) covers indoor sun tanning discharge lamps containing lead as an activator in the fluorescent powder. These lamps are produced in T12, T8 and T5 diameters and CFL (compact fluorescent lamp) configurations. The phosphors contained in these lamps are manufactured from the same components but can vary in spectral discharge across the UVA and UVB spectrum by the specified proportional phosphor mix. The lamps, and equipment they are installed in, are governed by EU regulations concerning the allowable output of ultraviolet radiation permitted within a determined exposure time. The EU regulates tanning equipment and the installed lamps which are marked by a specific "X, Y" code system for the erythemally-weighed UV radiation in accordance with EN standard 61228 Ed.2 (2008-01). The lamps are installed in various commercial and residential indoor tanning equipment. This can be in the form of a sun tanning bed or booth or a tabletop appliance for facial tanning. The abovementioned EN standard forms the basis of lamp marking and is mandatory. It clearly limits room for substitution by lead-free phosphors.

(LightingEurope 2023a) state that in the past months, since (Baron et al. 2022) have been in contact with LightingEurope to request clarifications and further input, no new developments have taken place. In addition, during the past 2 years, the suntanning industry was heavily impacted by Covid-19 restrictions, with salons being some of the first establishments to be closed down.

13.1.4. Technical description of the exemption and use of the restricted substance

Discharge lamps for the purpose of (sun) tanning and for medical purposes (photo-therapy and extracorporeal photopheresis (ECP) contain BaSi2O5:Pb (BSP) as a phosphor (activator) to produce UV radiation of dedicated wave lengths. An (inorganic) phosphor is a doped (here Pb) pigment that emits electromagnetic radiation – in this case UV (290nm-400nm) – after being stimulated – also through UV radiation (254 nm). The lead is required to activate the barium silicate phosphor to be able to fluoresce in the designated wavelength. Pb-doped barium silicate phosphor is used in over 95 % of the indoor low-pressure mercury vapour fluorescent lamps[43] (Baron et al. 2022).

According to (LightingEurope 2023a) this exemption covers indoor sun tanning discharge lamps containing lead as activator in the fluorescent powder. The lamps produce UVA and

[43] *Low-pressure mercury vapor fluorescent lamps and neon lights based on cold cathode fluorescent lamp (CCFL), e.g. for advertisement, are different types of fluorescent lamps and should not be confused. (Baron et al. 2022*)

UVB in predetermined dosages and ratios for the purpose of producing artificial sunlight. The lamps are installed in tanning equipment which are calibrated for the use of specific lamp types and they are marked in accordance with EU regulations for tanning lamps and equipment. Brochures and data about these lamps can be seen in several websites, e.g.:

- *Lighttech http://www.light-sources.com/tanning/tanning-lamp-products*
- *Cosmedico: https://www.cosmedico.de/en/products/*
- *iSOLde: https://www.isoldelicht.de/en/isolde-tanning-lamps/*

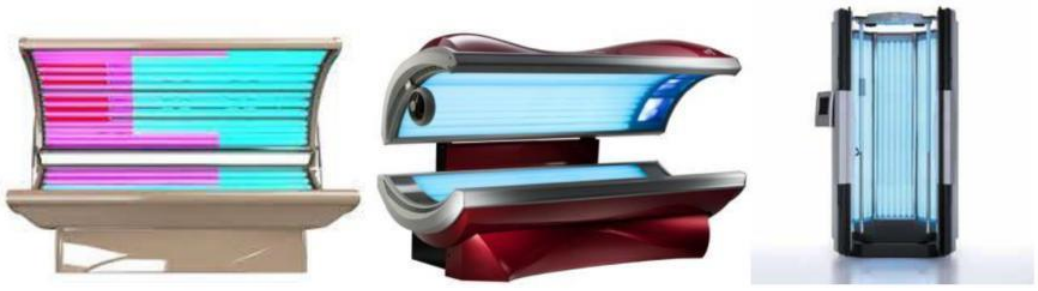
The lamps and equipment are governed by EU regulations concerning the allowable output of ultraviolet radiation permitted within a determined exposure time. The EU regulates tanning equipment and the installed lamps which are marked by a specific "X, Y" code system. For example, see, IEC 606335-2-27 and EN standard 61228 Ed.2 (2008-01). The lamps are installed in various commercial and residential indoor tanning equipment which can be in the form of a tanning bed or booth or a tabletop appliance for facial tanning.

The typical lifetime of these lamps ranges from 600 to 1000 hours with a session or usage time that ranges approximately from 5-30 minutes.

These lamps are not used for the production of visible light so general lighting efficacy standards do not apply. UV output efficacy (UVA radiation out vs electrical power in) is typically between 15 % and 25 %, but the real measure is with what power the desired effect is reached. This is governed by the equipment, lamp type, lamp power, UV output measured by standardized means, user skin type and other such factors.

Indoor sun tanning lamps are light sources that produce ultraviolet light in the regions of the UVA and UVB spectrum. Their intent is to produce artificial sunlight to replicate sunlight exposure for the human body (similar to that as produced by the sun) yet applied in calculated doses per European regulations. It is estimated that over 90 % of indoor tanning lamps produced and used throughout Europe are manufactured with BSP (BaSi2O5 :Pb) phosphors containing 1 % or less lead as an activator. There is no feasible alternative for this phosphor that will yield the same or similar results and has undergone the extensive European and US regulatory testing associated with the application of the tanning lamps using these phosphors. Almost 100 % of the tanning lamps using these phosphors are produced in the EU. Below (Figure 13-1) are three examples of typical indoor suntanning equipment. Left and centre photos are tanning beds and right photo is a tanning booth.

Figure 13-1: Examples of indoor tanning equipment



Source: (LightingEurope 2023a)

(LightingEurope 2023a) state that the market demand for tanning lamps will remain stable in the coming years.

Further details as to the technical background of lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP are described in (Baron et al. 2022).

13.1.5. Amount(s) of restricted substance(s) used under the exemption

According to (LightingEurope 2023a) the phosphor coating represents the homogenous material used in the fluorescent lamps with respect to this exemption. The lead content of the BSP phosphor is less than 1 % of the total phosphor weight and there is no published data available for the quantity of tanning lamps entering the EU.

However, based on market estimations of (LightingEurope 2023a) the lead content of tanning lamps is limited to 180.5 kg of lead total per year entering the EU[44]. This amount is approximately 10 % less in the BSP phosphor and taking into account the decrease in available market, compared to the amount in the 2015 exemption renewal request.

13.2. Justification of the requested exemption

13.2.1. Substitution and Elimination of the restricted substance

(LightingEurope 2023a) state that in the use of lead according to exemption III-18(b) there is no substitution for lead available and that no new developments have taken place since the last contact with (Baron et al. 2022). Therefore, please refer to the descriptions of (Baron et al. 2022) for more details regarding substitution and elimination.

In summary, (LightingEurope 2023a) state that the only potential alternative material, Ce doped YPO phosphor, does not fulfil all the necessary criteria.

In their renewal request (LightingEurope 2023a) also make clear that in principle, other technologies can be evaluated for eliminating fluorescent technology for tanning. For example, LED, OLED, HID, and incandescent or halogen technology. However, for any new technology the replacement market (replacing lamps in existing fixtures) and the market for new equipment using the new technology need to be addressed. The criteria to determine whether a new technology can replace existing fluorescent technology using BSP (and Hg) in existing equipment are:

- *Lamp specification must be the same with regard to UVA and UVB output and spectral power distribution*
- *Safety*
- *Compatibility (Electrical and mechanical specification)*
- *Reliability*

[44] This estimated lead quantity now excludes the UK market. LightingEurope 2023a.

- *Tanning result*
- *Compliance with CE regulations (X/Y coding system for tanning lamps according to EN 60335-2-27)*
- *No (negative) side effects*
- *Effective treatment results for phototherapy patients (e.g. clearance rates for psoriasis, effective chemotherapy, etc.)*
- *Economic feasibility (cost of replacement technology)*

For new equipment similar criteria apply as above.

13.2.2. Environmental, health, safety and socioeconomic impacts

Environmental impacts

According to (LightingEurope 2023a) information on the environmental impacts of lead usage in the scope of this exemption is not available as no alternate phosphor types are available that will yield the same result nor have undergone the regulatory testing of the EU or US. There are no statistical data available specific to the Life Cycle Analysis of the tanning and medical lamps represented in this exemption request, however due to the relatively low market quantities for special lighting, the total environmental impact is expected to be limited. Research conducted about fluorescent lamps for general lighting applications does not specifically equate to these specialty lamps as they are not designed to produce visible light. Efficacies, expressing the amount of visible light in Lumen per Watt, are normally related to e.g. fluorescent lamps for general lighting, and do not apply to tanning lamps. Cradle to grave estimates for the production of the components and the finished lamps in this exemption request are similar to those of general lighting fluorescent lamps.

(LightingEurope 2023a) refer to the fact however that the use of lead as an activator of the phosphor in these lamps allows the transmission of the specific wavelengths of light to be emitted in such a fashion to be the most effective form for its purpose, which is not achievable with other phosphor types or other technologies. Therefore, efficacies of any alternate product types would not be an adequate comparison.

The potential substitution or replacement to other wavelengths or ultraviolet dosages would require revalidation of all existing installed equipment in the EU market or could result in the elimination of such equipment, causing great hardship to the small business owners of tanning salons throughout the EU. These current lamp types have been tested, studied and regulated in the EU and changes to these products would require a duplication of the clinical testing which has been compiled over years of study and regulation. It is further noted that the overall lead content of such lamps, as in general lighting, has been reduced in the past five years to the less than 0.1 % lead content, to allow for recycled glass in the glass envelope of the lamp.

Additionally, the sun tanning lamps are collected and sent without dismantling for recycling. (LightingEurope 2023a) state that sun tanning lamps are in the scope of EU Directives 2002/96/EC - WEEE and 2012/19/EU - WEEE Recast. Take back systems are in place in all EU Member States: end users and most commercial customers can bring back the lamps

free of charge. Sun tanning lamps are collected separately from general household waste and separately from other WEEE waste. A dedicated recycling process exists for lamps.

European lamp manufacturing companies have founded Collection & Recycling Organizations in the EU Member-States, represented by EucoLight, with the objective to organize the collection and recycling of gas discharge lamps. The goal is to comply with present and probable future EU legislation and meet or exceed national targets.

According to (LightingEurope 2023a), the following channels have been established in the respective member states providing countrywide coverage:

- *Direct collection from large end users and professional installers: Containers have been made available, ad hoc or permanently, and will be collected upon notification by the end user that the container is full.*
- *Collection through distribution: Wholesalers and Retailers place collection means at their premises respectively in their shops. Collection is done upon notification.*
- *Collection through municipalities: Where the infrastructure allows collection, means are placed at municipality depots.*

Socio-economic impacts

(LightingEurope 2023a) state that is expected that even if UVA LEDs become available with feasible specifications, tanning equipment may become much more expensive. It will therefore become an economically unattractive solution and this can have a significant impact on the application.

The possibility of lead-free technology for these lamps is not feasible for replacement lamps in existing equipment due to the scientific and clinical evaluations that would need to be carried out on every type of tanning equipment in the field. This would place an economic burden on small business owners, such as tanning salons and dermatologists, and in the worst case could lead to the closure of many businesses.

It is conceivable that new equipment could be converted to non-lead phosphors. However, over 90 % - and it is estimated that it could be as high as 99 % - of the tanning phosphors are lead activated. There are no alternative non-lead activated phosphors available today that provide the same or equivalent spectral radiation.

If the exemption is not renewed, the indoor tanning industry in Europe will cease to exist as there are no reliable substitutes. LightingEurope members estimate that almost 100 % of these lamps used in Europe are manufactured in Europe by fluorescent lamp companies. It is estimated that

- *almost 100 % of the indoor tanning equipment sold in Europe is manufactured in Europe.*
- *almost 100 % of the tanning lamps sold as aftermarket lamps are sold by manufacturers or distributors located in Europe.*
- *over 90 % of the tanning lamps used in the US are manufactured in Europe.*
- *over 75 % of the tanning equipment sold in the United States is made in Europe.*

13.2.3. Stakeholder contributions

During the public consultation phase no contributions were received. Like already mentioned, the European Sunlight Association (ESA 2022) and NARVA Lichtquellen GmbH & Co (NARVA 2022) support LightingEurope's request and their letter of support were provided together with the renewal request.

The European Sunlight Association, acting on behalf of the European indoor tanning industry, are endorsing LightingEurope's application to renew exemption III-18(b) for cat. 11. (ESA 2022) highlight the importance of this exemption, noting that despite previous efforts to find technological alternatives, there have been no significant developments providing comparable substitutes. They emphasize that the lamps containing lead are integral components of tanning equipment and that there are currently no suitable replacements available or expected in the near future.

(ESA 2022) point out that any potential alternative would not only require changes in lamp technology but also adjustments in control gear, such as power supplies, which could have significant economic implications for both manufacturers and small, independent business owners operating tanning salons. They highlight the substantial contribution of the indoor tanning industry to the economy, including a turnover of approximately 2.1 billion Euros annually, and stress the potential socio-economic impacts if the exemptions were not renewed.

13.2.4. Roadmap towards substitution or elimination of the restricted substance

(LightingEurope 2023a) state that given the market size and in combination with strict regulations, efforts to substitute BSP containing lamps are extremely limited (to non-existent). No plans are made to replace Pb with Ce as earlier tests were unsuccessful and no new insights have been created.

Regarding LEDs, other UVA applications are available in LEDs but tanning development has been limited. At this moment it is not possible to predict if and when UVA LED based equipment will become feasible, however the tests and approval process would take a very long period. Therefore, (LightingEurope 2023a) request a renewal for the maximum validity period.

In their letter of support (NARVA 2022) discuss different possible lead-free alternatives: CE-doped YPO, high-pressure lamps and LEDs. However, they summarize that none of these technologies can substitute or eliminate the UV lamps with lead-containing BSP phosphor.

13.3. Critical review

13.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds (cf. section 4.2 on page 51). None of these entries are, however, relevant for the use of lead in the scope of exemption III-18(b).

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

13.3.2. Substitution and elimination of the restricted substance

Following the approach to assess whether the recommendation of (Baron et al. 2022) can be adopted to cat. 11 in the scope of the exemption renewal request, it is worthwhile realising also the reasons for their recommendation.

(LightingEurope 2023a) tested the substitution of lead in barium silicate phosphor with cerium (Ce) doped yttrium phosphate phosphor (YPO). The results indicate that it is not feasible due to high UVA and UVB output variance. Limited phosphor options hinder finding alternatives, and switching to other phosphors may emit harmful radiation. LED technology, though available, isn't optimal for required wavelengths. (Baron et al. 2022) concluded that Ce-doped YPO isn't feasible, LED approaches are inadequate, and lead reduction is not chemically possible. Renewal applications should detail progress, but the current one lacks substantial updates.

In (LightingEurope 2023a) state that it is estimated that over 90 % of indoor tanning lamps produced and used throughout Europe are manufactured with BSP (BaSi2O5 :Pb) phosphors containing 1 % or less lead as an activator.

The consultants therefore wanted to understand why the remaining 10 % of the lamps mentioned do not contain BSP phosphors.

(LightingEurope 2023b) state that there is no suntanning equipment that does not contain a lead activated phosphor lamp, as its specific UVB spectrum is needed to initiate the pigmentation process by melanin synthesis. There is one very specific type of suntanning equipment on the market, which is supplied in extremely small quantities, that in order to boost the pigmentation effect, has added pure UVA lamps besides the lead activated phosphor lamps. This is a pure UVA lamp with 368 nm wavelength emission peak whose phosphor does not contain a lead activator.

The above aligns with the information provided for the last review of the exemption by (Baron et al. 2022). *For tanning applications, no test results are available yet regarding the effectiveness in reaching the desired effect in a comparative study between equipment using fluorescent lamps and equipment using LEDs. For most of the applications tests are not done yet as no LEDs were available. Hence data on the effectiveness is not available.* (Baron et al. 2022) *concluded that substitution or elimination of lead is scientifically and*

technically not practicable in the applications in the scope of the exemption and therefore recommended the renewal of exemption 18(b) for categories 5, 8 other than in vitro diagnostic medical devices and 9 other than industrial monitoring and control instruments.

In the light of the submitted renewal requests and additional information, **the consultants see no reasons to diverge from the above recommendation of (Baron et al. 2022)** and the below approach.

(Baron et al. 2022) envisage to review the exemptions 18(b) and 18(b)-II in parallel in the future. In case a substitute was found for one of both uses of lead, it is highly probable that this substitute could be implemented in both applications. Thus, (Baron et al. 2022) recommend to ***align all named categories in terms of the validity period****. Also, this will be more pragmatic for market surveillance and will with time lower the administrative burden of stakeholders and the European Commission with regards to renewed exemption requests for the coexisting exemptions.*

13.3.3. Environmental, health, safety and socioeconomic impacts

The applicant submitted information as to environment, health and safety impacts which is reflected in section 13.2.2 on page 239. According to (Baron et al. 2022) information on environmental, health, and safety impacts is limited due to technically infeasible substitutes.

13.3.4. Categorisation of suntanning equipment

According to (LightingEurope 2023a) suntanning lamps are used in suntanning equipment. It is, however, not completely clear how to classify suntanning equipment and consequently LightingEurope see that the classification can differ. According to (LightingEurope 2023b) manufacturers are not sure whether to exclusively focus on the suntanning lamps and assign them to category 5 (lighting equipment) or whether the focus should be on the equipment itself (e.g., sunbeds) which includes lighting functionalities. Due to this uncertain situation, the application for category 11 (other EEE) was made for reasons of legal certainty, to ensure that certain suntanning equipment types do not end up being unintentionally excluded. (LightingEurope 2023a) regards the decision of the European Commission to avoid the separation in categories in the decisions for the exemptions 1-4 of Annex III from February 2022 as very helpful. (LightingEurope 2023a) state that a separation of this exemption in different categories is not helpful as a clear and legally certain classification is not available. The named application is specifically "sun tanning", and LightingEurope do not have information that there are possibilities of uses in products falling in other categories.

Overall, the argumentation appears reasonable given the complexities and uncertainties involved in classifying suntanning equipment within the regulatory framework. By seeking legal certainty and referencing relevant decisions, LightingEurope present a plausible rationale for their approach. As the categorisation of EEE is in the responsibility of the producers, the consultants follow the applicant’s reasoning.

13.3.5. Summary and 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.*

(LightingEurope 2023a) request a 5-year renewal of exemption III-18(b) with its current wording for cat. 11 until 21 July 2029. The consultants recommend adopting the result of the previous review of this exemption by (Baron et al. 2022) - which included cat. 5, 8 and 9 - for cat. 11. Following the recommendation of (Baron et al. 2022)the renewal of the exemption for category 11 until 2026 can be justified by Art. 5(1)(a). (LightingEurope 2023b) rejected the alignment of the expiry dates for cat.11. They argued that applying in this timeframe (18 months before the exemption expires in 2026) would not allow time for new developments in the industry to be reported in the exemption application.

The consultants agree that an expiry in 2026 would actually conflict with the 18 months period prior expiry of the exemption for renewal requests. Therefore the consultants recommend an alignment following the approach proposed by (Baron et al. 2022) but to extend the exemption until 21 July 2026 for all categories of EEE in scope of the exemption to allow sufficient time for renewal applications.

13.4. Recommendation

The consultants conclude that the recommendation of (Baron et al. 2022) can be adopted for cat. 11. The substitution and elimination of lead in the scope of exemption III-18(b) are scientifically and technically still impracticable so that, in line with (Baron et al. 2022), granting the exemption would be in line with Art. 5(1)(a).

As to the validity period, (Baron et al. 2022) *recommend a parallel future review of exemptions 18(b) and the new item 18(b)(II) since a substitute found for one of both uses of lead is highly probable to be a substitute for both applications. Aligning validity periods is beneficial for efficiency and reduced administrative burden on stakeholders and the European Commission regarding exemption requests.*

The consultants recommend the below wording and scope for the renewed exemption.

No.	Exemption	Scope and dates of applicability
III-18(b)	Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP ($BaSi_2O_5$:Pb)	Applies to categories 1 to 11 Expires on - 21 July 2021 for categories 1 to 4, 6, 7, 8 medical devices other than in vitro diagnostic medical devices, 9 monitoring and control instruments other than industrial monitoring and control instruments, and 10. - 21 July 2023 for category 8 in vitro diagnostic medical devices - 21 July 2024 for industrial monitoring and control instruments - 21 July 2026 for categories 5, 8 other than in vitro diagnostic medical devices, 9 other than industrial monitoring and control instruments, **and cat. 11.**

It is recommended that the COM allows sufficient time to remain between the official publication of the COM decision and the expiry date so that renewal requests can be submitted no later than 18 months prior to the exemption expiry.

Applicants' feedback on the recommendations

(LightingEurope 2024) have no further comments regarding the above recommendation.

13.5. References

Baron et al. (2022): RoHS Pack 24. Study to assess requests for renewal of seven (-7-) exemptions 18(b), 18(b)-I, 24, 29, 32 and 34 of Annex III and exemption 34 of Annex IV of Directive 2011/65/EU (Pack 24) – Final Report. In cooperation with Yifaat Baron, Carl-Otto Gensch, Andreas Köhler, Ran Liu, Clara Loew, Katja Moch, Öko-Institut. Retrieved from https://data.europa.eu/doi/10.2779/123658.

ESA (2022): ESA - Support Letter, EU RoHS Application to Extend Exemption III-18(b). RoHS Pack 27. Retrieved from https://rohs.biois.eu/ESA%20Letter_RoHS%20Exemption%2018(b)%20cat%2011_6.12.2022.pdf, Last updated 26.02.2024.

EUROMOT (2024): Answers to recommendation sent via e-mail by Maitheya Riva, RINA, to Alexandra Morozov, Fraunhofer IZM. RoHS Pack 27 (RoHS 29).

LightingEurope (2023a): Request for renewal of exemption III-18(b). RoHS Pack 27. Retrieved from https://rohs.biois.eu/LE_RoHS_Exemptions_18b_Cat.11_20230112_FINAL.pdf, Last updated 26.02.2024.

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from https://rohs.biois.eu/Ex_III-18b_LE_Questionnaire-1_Clarification.pdf, Last updated 26.02.2024.

LightingEurope (2024): Answers to recommendation sent via e-mail by Sophia Emke, LightingEurope, to Alexandra Morozov, Fraunhofer IZM. RoHS Pack 27 (RoHS 29).

NARVA (2022): NARVA - Support Letter, EU RoHS Application to Extend Exemption III-18(b). RoHS Pack 27. Retrieved from https://rohs.biois.eu/NARVA_Supportletter%20RoHS%20exemption%2018b%20Cat.%2011_4.1.2023.pdf, Last updated 26.02.2024.

14. Exemption 34 of Annex III: Lead in trimmer potentiometers

The below Table 14-1 shows the wording, scope and expiry dates of the exemption.

Table 14-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
III-34	Lead in cermet-based trimmer potentiometer elements	Applies to categories 1 to 11. 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, - 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.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

Cat.	Category, referring to the categories of EEE specified in Annex I of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instrument
Lead-free	Not containing lead in the applications in scope of the exemption to be reviewed
SEA	Socioeconomic analysis
TP	Cermet-based trimmer potentiometer

14.1. Background and technical information

On 20 January 2023, (TMC) requested the renewal of the above exemption for cat. 9 industrial monitoring and control instruments (IMCI) with the wording, scope and validity period shown in the below table.

Table 14-2: Requested exemption renewal

No.	Requested exemption	Requested scope and dates of applicability
III-34	*Lead in cermet-based trimmer potentiometer elements*	*Applies to category 9 industrial monitoring and control instruments.* *Expires on 21 July 2031 (= 2024 +7 years) for category 9 industrial monitoring and control instruments.*

(EPPA 2023) submitted a socioeconomic analysis (SEA) along with their renewal request. (MTE 2023) contributed to the stakeholder consultation stating their support for the exemption renewal requests submitted by the 'Umbrella Project' in 2020 (Pack 24 review) for the exemption, including for category 8 medical technology uses.

14.1.1. History of the exemption

The exemption was reviewed once in 2007. The applicant requested this exemption claiming that exemptions 5 and 7 listed in the annex of directive 2002/95/EC (RoHS 1), as they were formulated in 2006/2007, did not cover the use of lead in these cermet-based trimmer potentiometers:

- No. 5: Lead in glass of cathode ray tubes, electronic components and fluorescent tubes;
- No. 7: Lead in electronic ceramic parts (e.g. piezoelectronic devices).

The manufacturer said that this resistive layer in the cermet-based trimmer potentiometer is a homogeneous material, as it can be mechanically separated from the ceramic base. This homogeneous material, the thick film layer containing the lead, is neither a glass nor a ceramic material and thus would not be covered by the above exemptions. As a consequence, exemption 34 was adopted to the annex of RoHS 1 with its current wording:

"Lead in cermet-based trimmer potentiometer elements"

Exemption 34 was transferred to Annex III of RoHS 2 with an expiry date in July 2016.

To avoid confusion about the scopes of exemptions 5 and 7, and to make sure these exemptions actually cover those uses of lead where it cannot be substituted or eliminated, the consultants aspired to improve exemptions 5 and 7, and to align them with the exemption wording of parallel exemptions within the ELV Directive as far as possible.

Exemption 11 of annex II in directive 2000/53/EC (ELV Directive), the equivalent to exemption 7(c)-I of RoHS Annex III, was reviewed in 2007/2008. The stakeholders decided

that the wording in the ELV Directive covers applications like lead in cermet-based trimmer potentiometers.

In the subsequent review of RoHS exemption 7c in 2008/2009, it was therefore decided to adopt the wording of ELV exemption 11 with slight adaptations resulting in the current wording of RoHS exemption 7(c)(I). This wording integrated the scopes of exemptions 5 and 7, and in principle the use of lead in trimmer potentiometers in the scope of exemption 34. Nevertheless, the exemption was decided to be maintained after the review of exemption 34 by (Gensch et al. 2016) to avoid confusion in industry as to whether the use of lead in trimmer potentiometers would still be allowed. To avoid overlaps, the scope of exemption 34 was excluded from the scope of exemption 7(c)(I).

Following renewal requests submitted in January 2020, (Baron et al. 2022) reviewed the exemption. The renewal requests included cat. 9 IMCI, which was hence included as well into the renewal of exemption 34 proposed by (Baron et al. 2022).

Table 14-3: Renewal of the current exemption 34 recommended by (Baron et al. 2022)

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

Source: (Baron et al. 2022)

14.1.2. Focus of the review of this renewal request

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status January 2024). (TMC 2023a) therefore applied for the renewal of the current exemption 34 for cat. 9 IMCI since it was earmarked for expiry on 21 July 2024 for this subcategory of cat. 9 EEE. The exemption thus became due for review even though the recommendation for the renewal of exemption 34 of (Baron et al. 2022) included cat. 9 IMCI.

In the light of this situation, the COM tasked the consultants to assess in their review of the exemption renewal request at hand whether and how far the recommendation of (Baron et al. 2022) can be adopted to cat. 9 IMCI in line with Art. 5(1)(a). A re-evaluation of the previous review by (Baron et al. 2022) is not intended. The consultants will rely on the critical review conducted by (Baron et al. 2022) and on the resulting conclusions and recommendation unless the renewal request or stakeholder contributions give reasons to reassess the state of science and technology.

14.1.3. Summary of the requested exemption

(TMC 2023a) explain that the cermet potentiometer is typically used to calibrate a specific measurement or control parameter so that the final product can meet that exacting measurement resolution or output control parameter that the application requires. Thick film is a resistive and conductive film greater than 0.0001 inches thick resulting from firing a paste or ink that has been deposited on a ceramic substrate. The lead oxide (PbO) within

the glass substrate with the resistive ink allows the thick film to be fired at lower temperatures. This makes the resultant cermet to have the thermal characteristics and resistive value stability of the ceramic material and enable the electric resistance of the material to remain stable under changing temperatures.

Of the alternates investigated, most were eliminated either because they were also toxic or had a melting point too high for current substrate materials and the manufacturing processes employed. Only Sodium Bismuth Titanate has the potential to be used but would require further investigation. Bismuth Oxide is another alternate though the toxicity needs to be assessed to see if it would be a regrettable substitution. However, in both cases TMC currently have not identified any alternates cermet resistor that employ these materials and are commercially available. A thorough Socio-Economic Analysis was conducted in addition to the technical assessment and attached to this submission, further illustrating the negative socio-economic impacts a non-renewal of exemption 34 would have at this stage. Overall, the analysis concludes that the total impact of non-renewal of this exemption is monetized in the range of 0.3 billion EUR and 1 billion EUR (public range; conservative lower bound estimate).

14.1.4. Technical description of the exemption and use of the restricted substance

(EPPA 2023) explain that a cermet potentiometer is typically used to calibrate a specific measurement or control parameter so that the final product can meet that exacting measurement resolution or output control parameter that the application requires.

Figure 14-1: Examples of trimmer potentiometers

Source: (EPPA 2023)

Whenever there is a critical measurement that can vary from production unit to production unit (because of component tolerances) then precise calibration adjustment is required to each product during the manufacturing process. Once calibrated in the factory, that setting must remain stable during storage, transport and use for the installed life of the product, only checked during annual calibration or the preventative maintenance program for the product in question. For further technical details see (Baron et al. 2022) and (EPPA 2023).

(TMC 2023a) highlight that cat. 9 IMCI are very different from low mix, high-volume consumer products which are frequently re-designed to follow consumer trends and are placed on the market for a limited duration. Cat. 9 IMCI are high mix, low volume products and their producers portfolios of thousands of highly complex instruments. Each instrument is designed for high reliability and serviceability to support long useful lifespans and are made available on the market for at least a decade. These instruments are designed:

- *exclusively for professional and industrial use;*
- *to meet high performance requirements in critical applications;*

- *to last up to 40 years.*

Redesign is not frequent and happens every seven years on average as compared to every 1.5 years or less for consumer products. Once cat. 9 IMCI are placed onto the market, they are typically accompanied with a long-term customer support arrangement to maintain reliability and calibration.

Product portfolios are widely diversified, with TMC members each having typically 2,000 to 3,000 products currently made available on the market. These are highly complex, sophisticated electronic instruments, each having many necessary options and accessories. Each instrument can have a minimum of 2,000 and up to 40,000 parts; requiring a vast supply chain involving tens of thousands of suppliers and hundreds of thousands of items.

According to (EPPA 2023), the physical function of lead in the components that are utilised by cat. 9 IMCI are like those outlined in the previous exemption renewal request that was reviewed by (Baron et al. 2022). Cermet potentiometers (CPT) that contain lead have the following characteristics:

- *Long lifetime, typically up to 50,000 rotation cycles (they are usually rated at 25,000 cycles)*
- *Low temperature coefficient (TC), which is a measurement of the resistance change relative to ambient temperature change and is expressed as parts per million (PPM) per degree centigrade change, or as a percentage. The TC for a typical Cermet potentiometer is 150 ppm/°C which is lower than other types of potentiometer*
- *High level of heat dissipation*
- *Wide operating temperature range, -55 °C to +125 °C*
- *Higher wattage rating, e.g. 3 watts*
- *Low reactance at high maximum frequency*
- *Good resolution (resolution is the smallest possible change in resistance ratio)*
- *Low electrical noise when resistance is adjusted*
- *Small size enabling use in high density microelectronic circuits*
- *Preliminary tests with lead-free inks seem to show that a lubricant shall be necessary*
- *Even with a lubricant, the same performance will not be reached with all ohmic values*

(EPPA 2023) indicate the below example types of cat. 9 IMCI that use CPTs:

- *Relative Humidity sensors*
- *Power supplies*
- *Dosimetry Readers*
- *Temperature controller modules*
- *Sample Prep Liquid Chromatography*

- *Liquid Chromatography / Mass Spectrometry*
- *CO_2 Incubators*
- *Environmental Chambers*
- *Minimum Inhibitory Concentration (MIC) Lab test automation*
- *Spectroscopy Equipment*
- *Electron Microscopes*

14.1.5. Amount(s) of restricted substance(s) used under the exemption

Based on the full material disclosures displayed in Table 14-4, (EPPA 2023) conclude that trimmer potentiometers contain lead specifically as PbO within the glass matrix of the conductor (the potentiometer sweep arm) and the resistor itself which represent only 0.14 % of the mass of the potentiometer.

Table 14-4: Full material disclosure for the most common cermet trim pot family used

Model 89LF BOM-style material declaration. BI Technologies Corporation 8/16/2010

No content here is banned per E.U. R.o.H.S.. Average mass of 89LF trimmer is 1.2 grams each. Prepared by Eric Arnold (714) 447-2565

Weights above 1 milligram rounded to the nearest mg. Values less than 1 milligram given in scientific notation.

Sub-component	Material	% of total mass	Substance name	CAS #	Substance Weight (grams)	Special classification
Housing	PBT blend	33.0%	PBT	26062-94-2	0.303	
			Fiberglass	65997-17-3	0.081	
			SbO	1309-64-4	0.020	Fire retardant
Shaft	Brass	28.8%	Cu	7440-50-8	0.217	
			Zn	7440-66-6	0.125	
			Pb in brass	7439-92-1	0.011	Pb in copper alloy (RoHS exempt)
Slider block	PBT blend	2.1%	PBT	009002-84-0	0.019	
			Fiberglass	65997-17-3	0.006	
			PTFE	009002-84-0	0.001	
Contact	Cu alloy wire	0.13%	Cu	7440-50-8	8.43E-04	
			Zn	7440-66-6	4.14E-04	
			Ni	7440-02-0	2.76E-04	
	Nickel alloy bar	0.08%	Cu	7440-50-8	5.00E-07	
			Ni	7440-02-0	8.46E-04	
			C	7440-44-0	6.00E-07	
			Mn	7439-96-5	2.50E-06	
			Fe	7439-89-6	1.50E-04	
			S	7704-34-9	5.00E-07	
			Si	7440-21-3	5.00E-08	
Terminals	Cu wire	4.9%	Cu	7440-50-8	0.060	
	Sn plating	0.002%	Sn	7440-31-5	1.73E-05	
Potting	Epoxy	11.0%	SiO2, amorphous	7631-86-9	0.007	
			modified aliphatic polyamine	trade secret	0.027	
			hydantoin epoxy resin	15336-62-0	0.007	
			epichlorohydrin / polyglycol epoxy resin	26142-30-3	0.007	
			epichlorohydrin/bisphenol A epoxy resin	unknown	0.081	BPA
			cycloaliphatic epoxy resin	2386-87-0	0.007	
Substrate	Alumina	19.8%	Al2O3	1344-28-1	0.233	
			SiO2, amorphous	7631-86-9	2.42E-03	
			TiO2	13463-67-7	1.21E-03	
			FeO2	1345-25-1	0.001	
			MnO2	1313-13-9	0.002	
			MgO	1309-48-4	0.001	
			CaO	1305-78-8	0.001	
Conductor	AgPd thick film	0.05%	Al2O3	1344-28-1	4.34E-06	
			SiO2, amorphous	7631-86-9	1.90E-05	
			TiO2	13463-67-7	4.34E-06	
			PbO	1317-36-8	2.59E-05	RoHS exemption 34
			ZnO	1314-13-2	4.71E-06	
			B2O3	1303-86-2	1.60E-06	
			ZrO2	1314-23-4	3.84E-07	
			BaO	1304-28-5	4.93E-06	
			Ag	7440-22-4	5.17E-04	
			Pd	7440-05-3	5.76E-05	
Resistor	Ruthenate thick film	0.09%	Al2O3	1344-28-1	1.47E-05	
			SiO2, amorphous	7631-86-9	1.24E-04	
			TiO2	13463-67-7	1.47E-05	
			MnO2	1313-13-9	6.66E-06	
			PbO	1317-36-8	3.24E-04	RoHS exemption 34
			ZnO	1314-13-2	3.54E-05	
			B2O3	1303-86-2	4.14E-05	
			ZrO2	1314-23-4	9.94E-06	
			BaO	1304-28-5	1.66E-05	
			Ag	7440-22-4	4.00E-05	
			Pd	7440-05-3	5.10E-05	
			Steatite	14807-96-6	2.22E-06	
			Bi2Ru2O6	unknown	5.00E-05	
			Pb2Ru2O6+x	unknown	3.55E-04	RoHS exemption 34
			RuO2	12036-10-1	2.33E-05	

Source: (EPPA 2023)

According to (EPPA 2023), out of a total mass of 1.2 g per cermet potentiometer, the PbO totals 0.7 mg. The types of products using the exemption are typically cap expenditure purchases and represent less than 3,000 products sold into the EU:

(0.377 mg + 0.324 mg + 0.0259 mg) * 3,000 ≈ 0.73 mg * 3,000 ≈ 2.2 g

*(EPPA 2023) conclude that the total PbO import is less than **10 g** per year for Cat 9 IMCI.*

The main lead-containing substance is actually the ruthenium-containing one, followed by the lead-oxide. The lead content in both these substances is thus less than 2.2 g. *According to (TMC 2023a), the above figures are based on their members' feedbacks.* The actual figures may thus actually be higher.

Based on the information provided, it is plausible to assume that maximum 10 g of lead are placed on the EU market every year under the exemption 34 with cat. 9 IMCI.

14.2. Justification of the requested exemption

14.2.1. Substitution and Elimination of the restricted substance

(EPPA 2023) state that only Sodium Bismuth Titanate has the potential to be used but would require further investigation. Bismuth Oxide is another alternate though the toxicity needs to be assessed to see if it would be a regrettable substitution. However, in both cases they currently have not identified any alternate cermet resistors that employ these materials and are commercially available. According to (TMC 2023a), the qualification of potential lead-free trimmer potentiometers would require five to seven years to ensure their reliability in the cat. 9 IMCI. More details about substitution and elimination efforts are provided by (TMC; EPPA 2023).

14.2.2. Environmental, health, safety and socioeconomic impacts

(EPPA 2023) identify in their SEA the main potential negative consequences that the EU society at large would face in the framework of the potential restriction of non-renewal of Annex III, exemption 34, lead in cermet-based trimmer potentiometer elements. The results are based on a survey focused on the EU test and measurement equipment industry, with market share coverage of approximately 70 % of the EU market. It therefore provided sufficiently reliable data for a representative extrapolation of the EU market.

In the opinion of (EPPA 2023), overall, the results of the SEA demonstrate the safe use of lead in cermet-based trimmer potentiometer elements and can reasonably justify the renewal of this exemption, on the grounds that a broad restriction would have disproportionate negative impacts on society when compared with the risk to human health, animal health or the environment.

(EPPA 2023) monetise the total impact of a non-renewal of this exemption in the range of 0.3 billion EUR and 1 billion EUR (conservative estimates in net losses, potential gains for suppliers of other components have been already taken into account), consisting of economic impacts (EBIT loss) on test and measurement industrial type products' manufacturers, substitution costs for test and measurement industrial type products' manufacturers, and social impacts (i.e., unemployment in the EU-27). In terms of business and market impacts, a non-renewal would constraint most of the companies currently supplying RoHS-based test and measurement industrial products to cease production and business activities of all products that include lead.

14.2.3. Roadmap towards substitution or elimination of the restricted substance

Following (TMC 2023a), their members have pointed out that they principally rely on their component suppliers to find alternatives since most of the exemptions used in their products are not produced on-site by the company but bought off-the-shelf from suppliers. Therefore, meeting with suppliers to understand their (potential) alternatives, getting samples, measuring, and testing is the typical process to evaluate the suitability of potential alternatives which can take up to 4 years, as reported by the companies. The process would then be followed by the validation of the potential suitable alternatives accompanied by testing done by the manufacturers by the finished cat. 9 IMCI with the validation of the functionality and performance being their responsibility as well. However, the companies noted the impacts deriving from their suppliers as, depending on the complexity, there can be little to significant time and resources needed to validate alternatives.

The companies reported that the validation period alone would take a minimum of 6 months and up to a year after the delivery of suitable alternatives per product. It is significant to note that this validation period would only apply if the component were a fit, form, and function drop-in replacement. If any design changes to the exemption-free part of the product would be required to accommodate for the alternative, a validation period would be required for each redesigned product that used to utilize the component that relied on the exemption. Moreover, the validation would lead to the organizations incurring additional expenses. These include labour costs and costs arising from potential product resubmission requirements for testing to various notified bodies to ensure that substitution does not create any electrical and functional safety concerns.

If a new substance free part is available, this part must be qualified for use by performing a variety of tasks, as described above. Due to the complexity and diversity of the applications, this must be done individually by each company for each product group. This process would divert resources from other projects and increase the cost to ensure continued availability of these products. This validation and testing process varies according to part complexity and impact upon the final product design; which can be categorised as low, medium, and high:

- *Low complexity parts are the off-the-shelf components or hardware parts that do not have a substantial performance impact. Replacement can be done based on supplier information, assuming a form/fit/function compliance, with standard manufacturing, testing, and validation processes. Based on process timescales reported by a T&M coalition company, the average time that it can take for these parts to be replaced ranges from 3 to 6 months.*
- *Medium complexity parts are more complex sub-assembly electronic parts, such as small motors, which need additional validation for their performance. These parts are often commercial assemblies that are generally available to the electronic industry, and are utilised by the Test & Measurement coalition companies. Replacement of these assemblies, like-for-like, requires testing and validation prior to being integrated into the manufacturing process. The average time to find an alternative for medium complexity parts for production is reported to range from 6 to 12 months.*
- *High Complexity parts are the complex sub-assemblies or parts that have a significant impact on performance of the company's products or play a critical role*

in overall safety of the products. These parts need to go through extensive validation for performance and/or compliances for varying regulations before the appropriate files can be updated and the proper competent authorities or regulatory bodies can be notified prior to purchase of parts for validation. The average time that it would take to find an alternative for high complexity parts for production is up to 1 year for additional testing. Where the exemption directly impacts the performance of that component (e.g., a centrifuge rotor) the evaluation of the replacement could take from 3 to 5 years.

Taking everything into consideration, (TMC 2023a) claim the substitution process to take a minimum of 5 to 7 years.

14.2.4. Stakeholder contributions

(MTE 2023) contributed the "MedTech Europe recommendation for the extension of RoHS lead exemptions for medical technologies in the scope of category 8" and "[…] would like to reiterate its support for the exemption renewal requests submitted by the 'Umbrella Project' in 20204 for the abovementioned exemptions, including for the category 8 medical technology uses."

(MTE 2023) submitted the same contribution to support several other renewal requests. It is of generic nature, and the arguments focus on cat. 8, for which the renewal of exemption 34 was not requested and which is therefore not addressed in this review.

14.3. Critical review

14.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds. None of these entries are, however, relevant for the use of lead in the scope of exemption III-34 in EEE of cat. 9 IMCI (cf. section 4.2 on page 51).

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

14.3.2. Substitution and elimination of the restricted substance

Following the approach to assess whether the recommendation of (Baron et al. 2022) can be adopted to cat. 9 IMCI in the light of TMC's exemption renewal request, it is worthwhile realizing also the reasons for their recommendation.

(Baron et al. 2022) recommend to renew the exemption since "[…] it appears that no suitable substitutes for lead-based cermet materials are available to date that meet all of the performance characteristics of lead-based thick-film materials for resistive cermets. This finding supports the first criterion: it is still scientifically or technically impractical to replace lead in cermet materials that are used in frequent operated variable resistors. However, as it is not likely that most trimmer potentiometers will be operated frequently enough to affect their reliability during their service life, the consultant concludes that the second criterion "reliability" applies only for a subset of trimmer potentiometers, notably those that are designed for frequent use. The exemption is only needed for lead-based resistive materials in cermet-based potentiometers, in particular for application purposes that involve frequent operation cycles. […] The technical specification of lead-containing cermet-based trimmers […], in particular the wide operating temperature range (-55 °C to +125 °C) […] as well as the higher wattage rating allows the use of leaded trimmers for EEE applications that operate at high temperatures or have strong heat generation due to their wattage. However, for most trimmer applications, it is unlikely that high wattage and high temperature stability would be required. […] The consultant understands that a specification of the use conditions or for the type of equipment could be a way forward to narrow down the scope of the exemption in the future. […] (Baron et al. 2022) further argue that not all trimmer potentiometers may require service lives of up to 50 000 revolutions. Lead-free substitutes for cermet-based trimmers could at least be used for some applications e.g. that are intended for infrequent operation and installation in low-power EEE. This possibility to narrow down the scope of the exemption should be followed up by e.g. supply chain surveys by the industry."

As to the validity period of the renewed exemption 34, *(Baron et al. 2022) conclude that "[…] the exemption should be renewed only for a short period in order to point out to the industry that the information has to be updated and that active support in phasing out the exemption is expected. As for the categories, it was already noted that category 9 industrial monitoring and control instruments, and for category 11, Ex. 34 is anyway valid until 21 July 2024. The short duration for the renewal until 21 July 2024 allows to set one common expiry date. The earlier expiry date for category 8 in vitro diagnostic medical devices, where Ex. 34 expires 21 July 2023, is also recommended to be aligned with the other EEE categories. This common expiry date is recommended together with a request from industry to prepare technical information for a future review should the exemption renewal be necessary. This includes the provision of technical details as to the different applications addressed under this exemption and specify possibilities to narrow down the scope of the exemption. "*

The consultants asked the applicant whether they agree to the adoption of the recommendation (cf. *Table 14-3* on page 249) of (Baron et al. 2022), which only deviates from the current exemption 34 in its 2024 expiry date for all categories of EEE. (JBCE et al. 2023) reiterated "[…] *that all submitted renewal applications, including the renewal application for RoHS exemption III-34, request the renewal of the exemption […] with the subsequent maximum renewal period of 7 years. […] The only available alternative to the Thick-Film (Cermet) potentiometer was a Polymer Thick-Film (PTF) device. A PTF device could approach the electrical characteristics required (though inferior) but the environmental*

characteristics were significantly different – humidity tolerance was an order of magnitude worse off (± 10 %). This would render a PTF device unusable in a significant portion of cat. 9 Industrial products with examples provided within the renewal submission. […] At this time, no such alternative film technology exists and are commercially available unless the consultants are aware of a technology that did not come up in our worldwide search. […] When a lead-free substitution becomes available, the substitution process would take a minimum of 5-7 years […]. Hence, the full 7-year extension is requested, with the expectation of a further renewal request after that to accommodate that substitution process if a suitable alternative were to become available during the next renewal period. To renew with any other time period would make no practical sense at this time.

TMC base their opposition on the lack of lead-free alternatives and, if such alternatives were available, the time required for their qualification to enable their reliable use in cat. 9 EEE. (Baron et al. 2022) in principle share this view as to the availability of lead-free alternatives, however, only for frequently used potentiometers installed in high power EEE. For others, they see opportunities for substitution to narrow down the exemption scope if the corresponding technical details are collected along the supply chain and provided in the applications for the next renewal of exemption 34 which they therefore recommend to expire on 21 July 2024 already for all categories. *(EPPA 2023) explain that some trimmer potentiometers are used to once calibrate an IMCI in the factory, after which the calibration is checked during annual calibration.* These trimmer potentiometers could thus be candidates for which (Baron et al. 2022) see opportunities for substitution or elimination of lead.

To facilitate the approach of (Baron et al. 2022), exemption 34 should therefore be renewed as proposed by (Baron et al. 2022), i.e. renewal with its current wording for all categories of EEE, and expiry[45] on 21 July 2024 for all categories of EEE including cat. 8 and 9 with all their subcategories. Since this does not imply any changes in the exemption scope compared to the currently valid exemption 34, nor is its final expiry intended. The applicant's arguments as to the non-availability of lead-free trimmer potentiometers are obsolete from the technical point of view. Further on, the renewal request[46] of the Umbrella Project from 15 January 2020 for the renewal of exemption 34 (review by (Baron et al. 2022) included cat. 9 IMCI as well. TMC could have contributed to the related stakeholder consultation at that time to bring in their members' perspective.

The COM had made clear in earlier reviews that exemption requests require category specific evidence in line with Art. 5(1)(a) and in case of absence there is no justification to grant deviating exemptions for specific categories.

Also worthwhile to note is that not all manufacturers of cat. 9 IMCI are members of TMC. Further on, the TMC request did not find specific support of other cat. 9 IMCI manufacturers during the stakeholder consultation for this current review where they could have expressed objections against the adoption of the recommendation of (Baron et al. 2022).

[45] This implies the assumption that the COM would leave sufficient time between the official publication of the decision as to the renewal of the exemption in the Official Journal to allow renewal request to be submitted no later than 18 months prior to the expiry of the renewed exemption.

[46] Cf. https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_24/Exemptions/34/34_Exemption_Request__15012020_final.pdf

14.3.3. Environmental, health, safety and socioeconomic impacts

(EPPA 2023) describe severe socioeconomic, health and safety consequences if exemption 34 is not renewed for cat. 9 IMCI. The consultants cannot exclude that the revocation of the exemption could have adverse socioeconomic impacts. The consultants do, however, not recommend revocating the exemption, or restricting its scope so that cat. 9 IMCI would be excluded from the scope of the future exemption so that no adverse environmental or socioeconomic impacts can be expected to arise.

14.3.4. Summary and 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.*

TMC request the 7 year renewal of exemption III-34 with its current wording for cat. 9 IMCI until 21 July 2031. Following their mandate for this exemption, the consultants assessed whether the result of the previous review of this exemption by (Baron et al. 2022) - which included cat. 9 IMCI - can be adopted for cat. 9 IMCI in the light of the applicant at hand.

The applicant objects the adoption of the renewal of this exemption recommended[47] by (Baron et al. 2022) with its current wording but an expiry on 21 July 2024 for all categories of EEE. They argue that no lead-free alternatives are available, and once they are available, five to seven years are required for their qualification to ensure their reliable functioning in cat. 9 IMCI.

(Baron et al. 2022) see possibilities to narrow the scope of the exemption in a next review for all categories of EEE including cat. 9 IMCI and therefore recommend the 2024 expiry to verify and reflect this potential in a restricted exemption scope. The current review confirmed this potential for cat. 9 IMCI. The consultants therefore recommend adopting the exemption proposed by (Baron et al. 2022) to support the approach targeting the restriction of the exemption scope in 2024 for all categories of EEE. No additional evidence for cat.9 IMCI was provided that would require to deviate from the wording recommended in 2022, which also included cat. 9 IMCI.

The COM should grant sufficient time beyond the official publication of the COM decision as to the renewal of exemption 34 and the expiry date of the exemption to allow time for the preparation and timely submission of renewal requests less than 18 months prior to the expiry of the exemption.

[47] Cf. Table 14-3 on page 6

Stakeholders applying for the renewal of exemption III-34 should take account of the intentions expressed by (Baron et al. 2022) whether and how far the exemption could be restricted to devices in which the trimmer potentiometers are seldomly used and low voltages are applied.

14.4. Recommendation

The consultants recommend maintaining the exemption renewal proposed by (Baron et al. 2022) which includes cat. 9 IMCI. (Baron et al. 2022) identified a potential to narrow the scope of the exemption and recommend the renewal of the current exemption III-34 with the same wording and scope until 21 July 2024 for all categories of EEE including cat. 9 IMCI.

The aligned exemption expiry shall enable a harmonized renewal of exemption 34 for all categories of EEE with a new scope that verifies the potential for a restriction of the scope identified by (Baron et al. 2022). (Baron et al. 2022) want the industry to collect information for the next renewal request as to the use of lead-free cermet-based trimmer potentiometers in less demanding applications, i.e. those where they are used less frequently in particular in EEE with lower power.

If the COM decides to follow the approach of (Baron et al. 2022), the below wording is recommended for the renewed exemption III-34:

No.	Exemption	Scope and dates of applicability
III-34	Lead in cermet-based trimmer potentiometer elements	Applies to categories 1 to 11. Expires on 21 July 2024 for categories 1 to 11.

The consultants recommend that the COM ensures sufficient time between the offical publication of the decision and the expiry date to allow timely submissions of renewal requests 18 months prior to the exemption expiry.

Applicant's feedback on the recommendation

(TMC 2024) do not agree to the recommended expiry date stating that the information provided has not been fully considered and none of their arguments have been taken into account in the consultants' recommendation in line with Art. 5(1)(a).

The consultants are confident that they considered all relevant arguments made available by the applicants and stakeholders during the review and that the arguments have been evaluated in line with the mandate commissioned by the COM for the review of this exemption.

14.5. References

Baron et al. (2022): RoHS Pack 24. Study to assess requests for renewal of seven (-7-) exemptions 18(b), 18(b)-I, 24, 29, 32 and 34 of Annex III and exemption 34 of Annex IV of Directive 2011/65/EU (Pack 24) – Final Report. In cooperation with Yifaat Baron, Carl-Otto Gensch, Andreas

Köhler, Ran Liu, Clara Loew, Katja Moch, Öko-Institut. Retrieved from https://data.europa.eu/doi/10.2779/123658.

EPPA (2023): Socioeconomic analysis of the impacts of non-renewal of Lead (Pb) exemption for test & measurement industrial type products (Category 9) Exemption 34 – Annex III. RoHS Pack 27. Retrieved from https://rohs.biois.eu/TMC_SEA_Exemption_34_2023_PUBLIC_VERSION.pdf.

Gensch et al. (2016): Assistance to the Commission on Technological, Socio-Economic and Cost - Benefit Assessment Related to Exemptions from the Substance Restrictions in Electrical and Electronic Equipment - Study to assess renewal requests for 29 RoHS 2 Annex III exemptions. RoHS 14. In cooperation with Carl-Otto Gensch, Yifaat Baron, Markus Blepp, Katja Moch, Susanne Moritz, Oeko-Institut und Dr. Deubzer, Otmar, Fraunhofer Institut Zuverlässigkeit und Mikrointegration IZM (Adaptation to Scientific and Technical Progress of Annexes III and IV of Directive 2011/65/EU, RoHS XIV). Retrieved from https://circabc.europa.eu/sd/a/eda9d68b-6ac9-4fb9-8667-5e561d8c957e/RoHS-Pack_9_Final_Full_report_Lamps_Alloys_Solders_June2016.pdf.

MTE (2023): MedTech Europe recommendation for the extension of RoHS lead exemptions for medical technologies in the scope of category 8. Support for the exemption renewal requests submitted by the ‘Umbrella Project’ in 2020 for the abovementioned exemptions, including for category 8 medical technology uses. Retrieved from https://rohs.biois.eu/MTE.pdf.

TMC (2023a): Request for renewal of exemption IV-34. RoHS Pack 27. Retrieved from https://rohs.biois.eu/RoHS_Application_Form_34.pdf.

TMC (2023b): Answers to questionnaire 1 (clarification questionnaire) sent by Tobias Steinbrecher, EPPA, to Dr. Otmar Deubzer via e-mail. RoHS Pack 27. Retrieved from https://rohs.biois.eu/Ex_III-34_TMC_Questionnaire-1_Clarification.pdf.

TMC (2024): Feedback on the recommendation, sent by Tobias Steinbrecher, EPPA, to Dr. Otmar Deubzer via e-mail. RoHS Pack 27.

15. Exemption 42 of Annex III: Lead in bearings and bushes

The below Table 15-1 shows the wording, scope and expiry dates of the exemption.

Table 15-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
III-42	Lead in bearings and bushes of diesel or gaseous fuel-powered internal combustion engines applied in non-road professional use equipment: - with engine total displacement ≥ 15 litres; or - with engine total displacement < 15 litres and the engine is designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds; or regular maintenance is typically performed in a harsh and dirty outdoor environment, such as mining, construction, and agriculture applications	Applies to category 11. Expires on 21 July 2024.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

Cat.	Category, referring to the categories of EEE specified in Annex I of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
EU	European Union
EUROMOT	European Association of Internal Combustion Engine Manufacturers
IMCI	Industrial monitoring and control instrument

Lead-free	Not containing lead in the applications in scope of the exemption to be reviewed
Pb	Lead
PFAS	Perfluoroalkyl and Polyfluoroalkyl Substances
SEA	Socioeconomic analysis

15.1. Background and technical information

On 20 January 2023, (EUROMOT 2023a) requested the renewal of the exemption III-42 for cat. 11 with the wording, scope and validity period shown in the below table.

Table 15-2: Requested exemption renewal

No.	*Requested exemption*	*Requested scope and dates of applicability*
III-42	*Lead in bearings and bushes of diesel or gaseous fuel-powered internal combustion engines applied in non-road professional use equipment:* • *with engine total displacement ≥ 15 litres;* *or* • *with engine total displacement < 15 litres and the engine is designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds; or regular maintenance is typically performed in a harsh and dirty outdoor environment, such as mining, construction, and agriculture applications*	*Applies to category 11.* *Expires on 21 July 2029 (2024 + 5 years).*

The request is supported by the (National Association of Manufacturers 2023).

15.1.1. History of the exemption

(Gensch et al. 2016) reviewed the exemption request of EUROMOT and recommended to grant the exemption in its current wording for 5 years with the validity starting in 2019 and expiry on 21 July 2024. The European Commission (COM) followed the recommendation. After a renewal request of (EUROMOT 2023a), the exemption has become due for review.

15.1.2. Summary of the requested exemption

According to (EUROMOT 2023a) lead as an overlay coatings and alloying element is used in a number of bushings and bearings in specific non-road professional use engines. The engines which require the use of lead are ones which have:

- *engine total displacement ≥ 15 litres to compensate for slight misalignments that often occur in extreme high load operations,*
- *engine total displacement < 15 litres and requires a quick (<10sec) signal to start to achieve good reliability as lead acts as the initial lubricant, or*
- *requires maintenance in harsh and dirty environments where contaminants can be introduced to the system.*

Lead provides seizure resistance, resistance to damage, conformability, embeddability, fatigue strength, flexibility, chemical resistance, impact of manufacturing tolerances and tolerance to cold temperature and limited lubrication during start-up.

The development and qualification of lead-free alternatives is underway by bearing and engine manufacturers, however additional time is required to test and qualify potential alternatives. The testing of bushings and bearings can be characterised by the following key steps, each of which brings increased confidence that a solution can be deployed as a viable alternative:

1. *Laboratory tests of bearings to determine if they meet required performance criteria*
2. *Engine trials with new bearings*
3. *Field trials with finished equipment containing engines that have new bearings that are being tested.*

However, it is essential that all steps are undertaken as failures have been identified in the last stage of testing. There is no internationally accepted standard test regime to test bushings and bearings, so each company has developed their own methodology with the most difficult to achieve performance parameters usually being tested first.

Lead-free alternatives, relying upon alternative alloy compositions or polymer overlays (which for some rely upon Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) substances) are starting to show initial signs of suitable performance when tested by bearing manufacturers. The activities undertaken by bearing manufacturers are starting to identify potential alternatives which looks to offer similar key technical characteristics. However, other bearing manufacturers are still in the processes of developing bearings which can offer the same performance as lead-based bearings.

Engine manufacturers in both their current engine designs and new designs are testing potential lead-free alternatives, with the types of testing they undertake being reflective of their own in-service applications. Currently, all testing undertaken by engine manufacturers identifies the lead-free alternative which they tested having significant loss of technical performance in at least one critical parameter. As such, none yet have been determined to be a viable alternative.

Two different engine manufacturers have trialled using lead-free bearings, as testing indicated lead-free alternative in these specific applications, they might have suitable performance. In both cases, however, engine failure was observed. This underlines the importance of testing.

Given current lead-free alternatives still cannot offer the same performance as lead-containing bushings and bearings, this exemption is therefore requested on the basis of the inferior reliability of lead-free substitutes.

15.1.3. Technical description of the exemption and use of the restricted substance

(EUROMOT 2023a) points out that the exemption III-42 for cat. 11 is relevant for bearings and bushes in internal combustion engines designed for professional use, with either:

14) *a large engine size (≥15L),*
15) *highly demanding applications (where signal to start and full load is <10 sec), and/or*
16) *or is exposed to harsh and dirty environment during maintenance.*
17) *Examples of applications of each of these criteria are as follows:*
18) *Emergency generators, fire pumps and uninterruptable power system (UPS) installations*
19) *Drills, compressors, rock crushers, irrigation pumps, fire pumps, mine trucks, tub grinders, excavator, screeners, wheel loader, skid steer loader and generators installed temporarily on site. Such applications are used in a number of different industries including mining, agriculture, and construction.*

Consumer equipment with small engine sizes do not have the same technological and reliability demands, so are not proposed to be included in the scope of this exemption.

Due to the scope of the RoHS Directive, "forms of transport", "professional non-road mobile machinery" and "stationary industrial tools or fixed installations" are excluded from the scope of the Directive. As discussed in the previous exemption request, this significantly impacts the types of internal combustion engines which are in scope of the Directive's requirements. The key differentiator for many of these applications is whether they are designed to be stationary when in use.

It is worthwhile noting the possible overlap of this exemption with exemption 6c of Annex III of the Directive, for lead in copper alloys, as bearings and bushings produced from copper alloys with up to 4% lead are also used in professional use non-road equipment engines. It is understood that all such applications are to be covered by exemption 6c as long as this exemption is renewed.

Highly demanding applications

Applications which require the 10 second signal-to-start have many key features which make it a highly demanding application:

- *Applications, such as emergency back-up power, will sit for extended periods of time without being exercised and only started for planned maintenance or an actual power outage. During the latter one of these, power is required to be restored within 10 seconds.*
- *The signal to start requirement is in all weather conditions and can be in situations where ambient temperature is below -4oC, which causes oil to be more viscous and so will move much slower than at higher temperatures and may not reach reciprocating components for minutes, compared to seconds in less harsh conditions.*

It is during this period, where it is only the lubricity of lead in the bearings that enables the engine to move without seizing and with minimal wear to internal components. To enable the quicker flow of oil at lower temperatures, engines are designed with a filtration bypass

system to avoid the added restriction of the oil filters and enable faster flow to the reciprocating components. This of course allows for particles of any size to be circulated throughout the engine that can cause damage, until such time as the oil is warmed to the appropriate temperature and the filtration loop is again enabled.

- *For engines designed for fast start-up applications, lead is necessary to achieve good reliability.*

Harsh and Dirty:

The terminology of harsh and dirty, is once again requested to be included in the scope of the exemption. The inclusion of terminology is important given that many applications require engines to be located in 'harsh and dirty' environments for significant lengths of time, for example in quarries or construction sites, where providing a sufficiently clean environment such that particles will not be introduced to the engine, especially during maintenance, is impossible. Debris may be introduced during service and maintenance procedures or from the environment that the engine operates in.

It is recognised that whenever a term is included in an exemption, to allow for the consistent determination across Member States and companies, it is always preferred that such terminology is accompanied by a quantitative definition. Efforts have been expended in the intervening timeframe since exemption 42 was granted to try to better define the terms, however a consolidated quantitative wording was unable to be defined due to the complex and interplaying factors of what is deemed as acceptable.

There are multiple permissible values of determining 'dirty' which depend on multiple interdependent factors including particle size and distribution, number of particles, particle hardness and engine specific parameters. There are manufacturers' cleanliness standards, which define a permissible particle load for differing types of components, as well as a maximum permissible particle size are outlined. However, these standards vary between companies, both in terms of what are defined as critical parameters and quantitative values listed, with indicative examples listed below:

- *Company A: 'clean' is defined as parts which are exposed to particles of <850µm debris particle size only.*
- *Company B: Maximum particle size allowed is 80-100µm based upon clearances and tolerances. The maximum size may be less for abrasive particles, which can key on to bearing surfaces.*
- *Company C: Maximum permissible particle size for a metallic crankshaft is 120µm for mineral particles and 600µm for metallic particles, with a maximum of 1 mineral particle per 1000cm^2 surface in the 80 to 120µm range and 10 metallic particles per 100cm2 surface in the 400 to 600µm range.*
- *Company D: Maximum particle size 500µm.*

The disparity in the values listed by each company reflect the different engine specific parameters (e.g., design, intended use, etc.) which affect the impact of particles including clearances, tolerances, and wear. It is important to note that these standards relate to 'components ready for shipment', rather than parts which are operating in engines in such an environment. As such it is not possible to extrapolate the values listed in these standards to produce a permissible level for whole engines in the field a due to the large numbers of variables that affect engine reliability.

Indications can be seen in some of the companies' standards that critical parameters sometimes require tighter control, however in an operational environment these increase in their complexity, as well as introducing other critical parameters. As an example, the type of particle has a large impact on the bearing or bushing's ability to withstand its introduction, with the hardness and abrasiveness of particles playing a critical role. Dry sand particles compared to moist clay particles have very different impacts on acceptability and listing all potential contaminants in equipment utilising the exemption that are expected to experience would be impossible. Another consideration is the number of particles per cubic meter of air, which to date only one company standard has been identified that gives a permissible number of particles, with most EUROMOT members stating that this is not a measured parameter in real environments.

An indicative estimate provided by a EUROMOT member is no more than 2 grams of particulates ingested through an air intake system, but this is not a transferable parameter as this will also depend on other variables such as engine size and the fact that contamination may also be introduced through handling during maintenance and service, i.e., that it cannot always be attributed to the quality of air in which equipment is operated or serviced.

Harsh can be described in a qualitative way, such as a description provided by an engine manufacturer below, but a quantitative description for particle, size, number, and hardness is impossible to bound in a straightforward way as they are interdependent.

'A harsh environment is one where dirt and debris particles, that contain abrasive particles, are present and will / may accumulate on machinery (powered by reciprocating engines) or engines, tools used to service engines and technicians / mechanics clothing or person, and / or environment where the dirt, debris and contaminants, including abrasive particles, are airborne in the environment such that contaminates will be present in the proximity of the engine at times of service or maintenance.

In these environments the dirt and debris, including abrasive particles, can enter the engine at times or moments of service or maintenance when internal passages or surfaces of the engine are exposed to the environment.'

For example, a few small very hard particles may be similarly damaging as a larger number of larger, softer particles. Hence, it has not been possible for the industry to define boundaries for all three variables under all real field conditions.

According to (EUROMOT 2023a) the lead has the function as a coating or alloying element to produce a tribological interface for bushings and bearings, to provide the required performance and reliability which include seizure resistance, resistance to damage, conformability, embeddability, fatigue strength, flexibility, chemical resistance, impact of manufacturing tolerances and tolerance to cold temperature and limited lubrication during start-up.

Various lead alloys are used as bearings or as layers of bearing surfaces. Lead bushings and bearings, including the following which is provided as a non-exhaustive list[48]:

[48] Note that there are sometimes differences in naming convention of certain bushings and bearings depending on the company in question and location, where possible alternative naming has been indicated.

- *Main bearings,*
- *Con rod (crankshaft) bearings,*
- *Piston pin bushings,*
- *Camshaft bushings,*
- *Cam follower roller pins,*
- *Thrust (camshaft and crankshaft) bearings,*
- *Gear box (gear train) bearings and bushings,*
- *Turbocharger bearings and bushings,*
- *Idler gear bearing and bushings (gear box bearing),*
- *Oil pump bearing and bushings, and*
- *Valve train (rocker arm) bearing and bushings.*

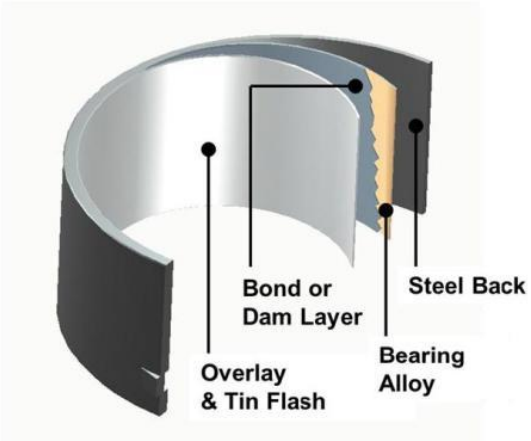
(EUROMOT 2023a) state that lead is used in bushings and bearings, which are mechanical elements providing movement relative to another element with minimum power loss. Bushings are technically identical to a bearing except that they are a single independent one-part device whereas bearings are mostly made of two or more materials or components.

Lead is used as a thin coating (up to 90% lead) to provide a tribological interface between two moving parts which helps to prevent seizure and it can absorb debris which might otherwise cause engine failure. Lead is also used as an alloying element (up to 20% lead), often as a layer below the thin lead-rich coating, which provides conformability to help the bearing to compensate for slight misalignments that often occur following service or extreme high load operations. Lead would typically comprise between 1 and 3% of a complete leaded bearing (based on total part weight). Lead from all these components would typically comprise less than 0.025% of a complete engine.

There are multiple types of bearings and bushes, as outlined by Section 4 to 6, which come in a variety of shapes, designs, and sizes, all of which are required to have a combination of important properties to provide the required performance and reliability for the intended conditions of use and lifetime. The specific requirements for each specific property depend on multiple variables including engine capacity, conditions of use, conditions during rebuild and servicing, rotation velocity, loading, etc.

Bearings may be constructed in three layers as shown in Figure 15-1, with the steel back providing rigidity, the bearing alloy generally consisting, typically of copper or aluminium plus lead alloys and the thin overlayer that provides anti-friction properties through a high lead content (even when oil lubricant is absent). A bond or dam layer may be deposited between the overlay and the bearing alloy to prevent migration of metals from one layer into another.

Figure 15-1: Tri-metal bearing



Source: (EUROMOT 2023a)

Lead overlay compositions vary depending on the application and bearing in question, with indicative examples provided in Table 15-3. The lining material can then either be a copper or aluminium alloy, with lead contained up to 25% of the alloy depending on the alloy used.

Table 15-3 Examples of lead overlay compositions

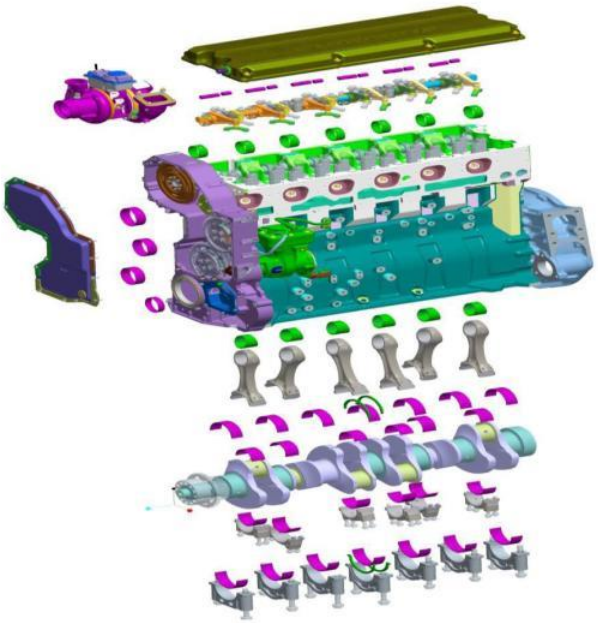
Lead (Pb), %	Tin (Sn), %	Copper (Cu), %	Indium (In), %	Alumina (Al2O3), %
90	-	-	10	-
88	10	2	-	-
88	10	-	-	2
87	10	3	-	-
85	10	5	-	-
82	9	-	9	-
80	18	2	-	-
78	14	8	-	-
75.5	12.5	2	10	-

Source: (EUROMOT 2023a)

Engine bearings are designed to operate in a hydrodynamic lubrication regime with a lubricant film layer between two moving surfaces, but during starting and stopping, speed and load changes, these two surfaces may not be fully separated by a lubricant film. As such bearings may operate in boundary and mixed lubrication regimes, meaning that the bearing may need to operate with insufficient oil and so require the lead to also provide lubrication. Under these conditions, the contacting material surfaces as well as the engine oils containing additives play an important role in determining the friction and wear. Lubricant starvation can easily lead to metal to-metal contact, without a suitable surface on the bearing this can cause high wear of the bearing surfaces due to severe ploughing, and wear debris can initiate seizure failure.

Each engine contains many different designs of bearings, an indicative example engine is shown in Figure 15-2.

Figure 15-2: Parts of a typical internal combustion engine with bearings and bushes shown in pink and green



Source: (EUROMOT 2023a)

Engines also contain bushings that are made from one leaded alloy and are usually in the shape of hollow cylinders. These can be made of copper alloys that contain lead where the lead acts as a dry lubricant. Some contain <4% lead and so would be in scope of exemption III-6c but at some need to contain >4% lead to provide sufficient dry lubricity.

According to (EUROMOT 2023a) the particular characteristics and functions of the lead in the scope of this exemption request that require its use are the following.

Bearings and bushes are required to have many important properties to provide the required performance and reliability for the intended conditions of use and lifetime, which are described below. Usually, a combination of essential properties is required by each bearing or bushing. The specific requirements for each specific bearing or busing depends on one or more of many variables including engine capacity, conditions of use, conditions during rebuild and servicing, rotation velocity, loading, etc. but can be generally described as a combination of the following.

***Seizure resistance** is the ability of the bearing material to resist physical joining (metal to metal bonding), which is important as it provides a measure of the bearings ability to survive momentary contact with the counter surface when there is not enough oil film to fully separate the two surfaces. This in combination with resistance to damage is an important characteristic of bearings covered by the exemption. Seizure usually occurs due to the heat generated, and resultant high temperature, by high friction forces that occur when lubrication fails. All bearings experience some metal-to-metal contact, however under certain circumstances seizure resistance is especially important. One such example is when the bearing experiences cold start and/or oil starvation which are often experienced in applications where the time between signal to start and full load is required to be less than 10 seconds as the lubrication oil drains away. Another factor where high seizure resistance is especially important is when high roughness of the bearing or shaft surfaces is caused by dirt particles being introduced to bushings and bearings. Without the ability to resist*

seizure, the heat generated at the surface of the bearings can cause the metal surfaces to melt and then seize, resulting in catastrophic failure of the engine.

***Conformability** is the ability of the bearing material to accommodate misalignments in the geometry of the bearing, without which bearings can experience excessive wear and high specific loading. Misalignment is most notable after when the engine is new or after a rebuild and conformability is essential to compensate for this. This is critical at start-up of all engines in scope of the exemption request, as the metal surfaces are likely to have little or no lubrication. For larger sized engines, small variations in the dimensions of bushings and bearings are more common, which can result in misalignment of parts. Lead's soft properties provides the desired conformability, allowing the bearing to conform to the variation when there is metal to metal contact, allowing the engine to function correctly, which is especially important during the wear in period of a new or reconditioned engine. Poor conformability of the bearing material can result in excessive wear, premature failure of the bearing and catastrophic failure of the engine.*

***Embeddability** is the ability of the bearing material to entrap and trap within the surface layer small foreign particles, such as dirt, engine wear debris, dust, and other abrasive residuals, allowing the continued function of the part. Poor embeddability of a bearing material causes accelerated wear and allows particles to produce scratches on the bearing surfaces, which significantly reduces the lifetime of the engine, and may also lead to seizure. Lead has low affinity for iron that allows it to accept debris in a way that minimises shaft damage and manages energy dissipation in the system to avoid the debris accelerating progressive damage.*

Although embeddability is an important characteristic of any bearing, as soot and debris are inherent to the operation of all internal combustion engines, the applications and end-uses in scope of this exemption require regular maintenance activities performed in a harsh and dirty outdoor environment and also to operate in such an environment so that these engines need to be able to function with much more dirt that those engines that can be maintained in clean workshops. This characteristic cannot be overstated in its importance. In such environments the ability to limit dirt ingress is often impossible as there is often significant amount of fine dust within the environment which is therefore expected to enter the engine.

In addition to environmental considerations, embeddability is still an important factor during the running-in of an engine as metal shards or 'chips' can be introduced as part of the normal manufacturing processes.

***Fatigue strength** is the maximum value of cycling stress that the bearing can withstand after an infinite number of cycles. Cycling stresses applied to the bearings are the result of the combustion and inertia forces developed in the internal combustion engines.*

In addition to the key performance behaviours outlined above, the following are also important:

- *Flexibility of the coatings.*
- *Chemical resistance to resist chemical attack of oxidized and impure lubricant.*
- *Tolerance to cold temperature and limited lubrication during start-up.*
- *Low yield strength.*
- *Thermal conductivity.*

- *Load Capacity. A measure of the maximum hydrodynamic pressure which a material can be expected to endure. Important for some types of engines, as high loads can cause misalignment which lead based bearings can more easily accommodate.*
- *Ability to withstand some manufacturing tolerances.*

15.1.4. Amount(s) of restricted substance(s) used under the exemption

(EUROMOT 2023a) state that the lead content is between 20 and 90%, depending on application, with higher values attributable to overlay coatings and the lower values as an alloying element.

According to (EUROMOT 2023a) the amount of lead used for products in scope of the RoHS Directive varies depending upon bearing and engine design, as well as the engine displacement (larger engines would typically utilise more lead due to larger component size).

The previous exemption renewal request (EUROMOT 2015) outlined a methodology for calculating the lead placed on the market from this exemption, which has been utilised in this calculation. Much of the previous information which underpins the calculation has been utilised, with the annual genset sales in the EU recalculated based on information from Association of Equipment Manufacturers (AEM) in terms of percentage change of sales. The assumption that non-genset applications add 25% of numbers sold has been used and the data following data taken from the renewal as it is deemed to still be relevant:

- *Average engine mass*
- *Average lead content from bearings*
- *Percentage of units in scope of RoHS for each power band*

The calculation in Figure 15-3 indicates that 1.73 tonnes of lead is placed on the EU market due to bearings of new engines that are in scope of this exemption renewal request. It should be noted that professional engines can have new bearings which are installed during the service life of the engine, but this calculation does not account for any spares use.

Figure 15-3: Calculation of amount of lead in bearings used in engines in scope of this exemption request

Power Band (kVA)	Average engine mass, kg	Average lead content from bearings (% by total engine mass)	Annual genset sales in EU market 2015	% Change in sales from AEM data	Annual genset sales in EU market 2021	Annual engine sales in EU market, add 25% for other applications	Percent in Scope of RoHS Units in Scope	Engine mass in scope, kg	Annual Lead quantity into EU market, kg
7.5-250	447	0.0008%	50241	97%	98975	123718	100%	55302153	442.4
251-750	1020	0.0200%	8453	0%	8453	10566	47%	5065460	1013.1
751-2000	4506	0.0200%	2410	-21%	1904	2380	5%	536186	107.2
2000+	7500	0.0200%	667	270%	1801	2251	5%	844172	168.8

Source: (EUROMOT 2023a)

15.2. Justification of the requested exemption

15.2.1. Substitution and Elimination of the restricted substance

(EUROMOT 2023a, 2023b) claim that since they submitted the original exemption request (EUROMOT 2015) for lead in bearings, manufacturers of bearings and of engines have carried out research into lead-free substitutes, however so far without success.

To identify if lead-free bearings can be considered as an alternative, they have to undergo multiple stages of testing, involving both bearing and engine suppliers to replicate the environments they will likely see during their operations. Testing involves at least three stages:

1. *Laboratory tests of bearings to determine if they meet required performance criteria*
2. *Engine trials with new bearings*
3. *Field trials with finished equipment containing engines that have new bearings that are being tested.*

As explained in EUROMOT's original exemption request (EUROMOT 2015), bearings that appear to meet performance requirements often fail when used in engines, especially during field trials.

For less challenging environments, such as in road vehicles (e.g., private cars), lead-free bearings are able to be used, however the on-going testing undertaken for applications covered by this exemption request indicate that lead-free alternative are not suitable at this time due to decreased reliability and inferior performance.

EUROMOT (EUROMOT 2023a, 2023b) outline the activities that have been undertaken to identify alternatives, however, to date no alternative has been identified with either the required technical performance to support products covered by this exemption request, or their long-term reliability was found to be very poor with many premature failures. Testing is being undertaken on a continual basis with other lead-free alternatives when they become available. More time is needed for these to be developed and the necessary testing undertaken with the aim that they give reliable performance comparable to current materials. Furthermore, It is important to note that some of the polymer alternatives rely upon Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) substances which could be impacted by the upcoming REACH restriction The detailed descriptions of the tests undertaken can be found in (EUROMOT 2023a, 2023b).

According to (EUROMOT 2023b) multiple alternatives have been investigated by EUROMOT members since the last exemption application as possible alternatives for lead in bearings. The following materials have been investigated:

- *Copper alloy,*
- *SnAl bearing,*
- *Lead free brome bearing (with and without Bi addition),*
- *Lead free multi-layer materials,*
- *Multi-layer materials with additional coatings,*

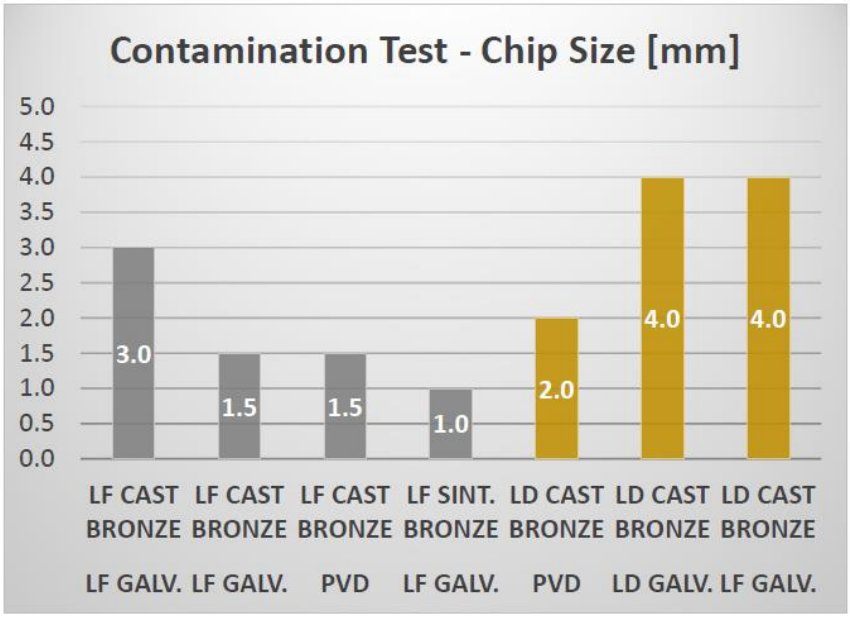
- *Polymer coated bearings consisting of PFAS materials, (currently under evaluation for Restriction under REACH).*
- *Aluminium bushes*

(EUROMOT 2023a, 2023b) provide examples of the tests carried out by two manufacturers which are representative for a significant proportion of the bearing market. The following overlay materials were further tested by these two bearing manufacturers since the last exemption request in 2015:

- *Lead ($PbSn_{10}In_{14} + Al_2O_3$)*
- *Lead-free 1 (Sn)*
- *Lead-free 2 (PAI; Al (10-15) PTFE (5-7) Silane 5)*
- *Lead-free 3 (PAI 45%; MoS_2 55%)*
- *Lead-free 4 (PAI; MoS_2 44%; graphite 23%)*
- *Lead-free 4 (Bi)*

The testing included chip contamination tests (see Figure 15-4, Figure 15-5), where the ability to resist seizure is tested via the introduction of chips of different sizes, dynamic seizure tests and stress testing. The chip contamination testing showed that lead-containing bearings outperformed most lead-free alternatives. It was only in late 2021 that one potential alternative (LF sintered bronze | LF Galv.) was identified as showing comparable performance to lead-containing alternatives. It is important to note that although comparable attributes are starting to be identified, this has only been as a result of significant development by bearing manufacturers, which needs to be taken forward by engine manufacturers for testing.

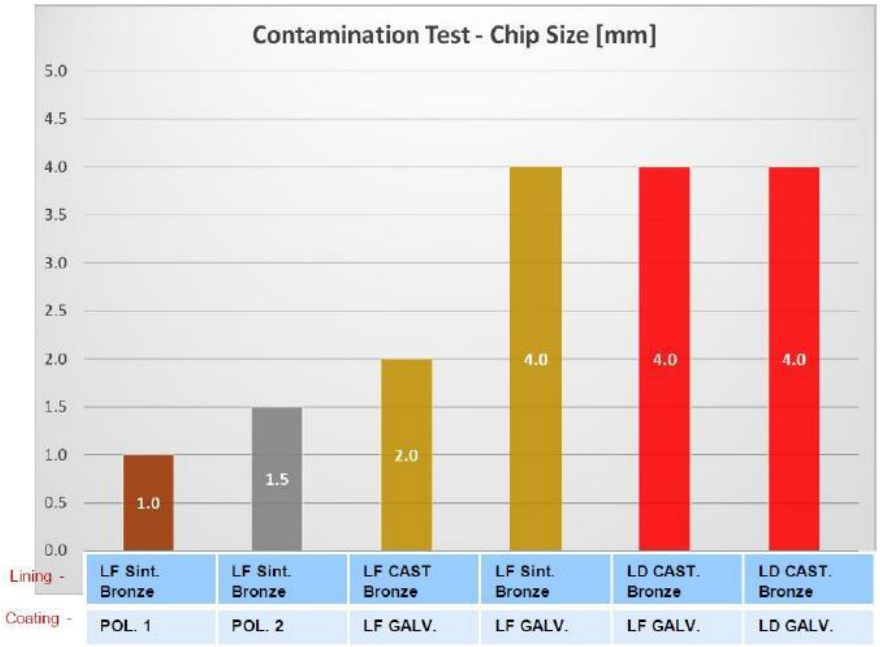
Figure 15-4: Copper bearing chip resistance testing (1)



Source: (EUROMOT 2023a)

LF: Lead-free LD: leaded Galv.: Galvanized coating
PVD: PVD Sputter coating (Part 2)

Figure 15-5: Copper bearing chip resistance testing (2)



Source: (EUROMOT 2023a)

LF: Lead-free LD: leaded Galv:. Galvanized coating
POL: Polymer spray coat (Part 2)

In addition to the contamination test, (EUROMOT 2023a) state that this bearing manufacturer carried out dynamic seizure testing, stress testing, cap shift testing and bearing debris testing. (EUROMOT 2023a) conclude that currently no tested alternative offers the same performance as the lead bearing.

The second manufacturer mentioned in (EUROMOT 2023a) conducted a bearing debris testing with the following materials:

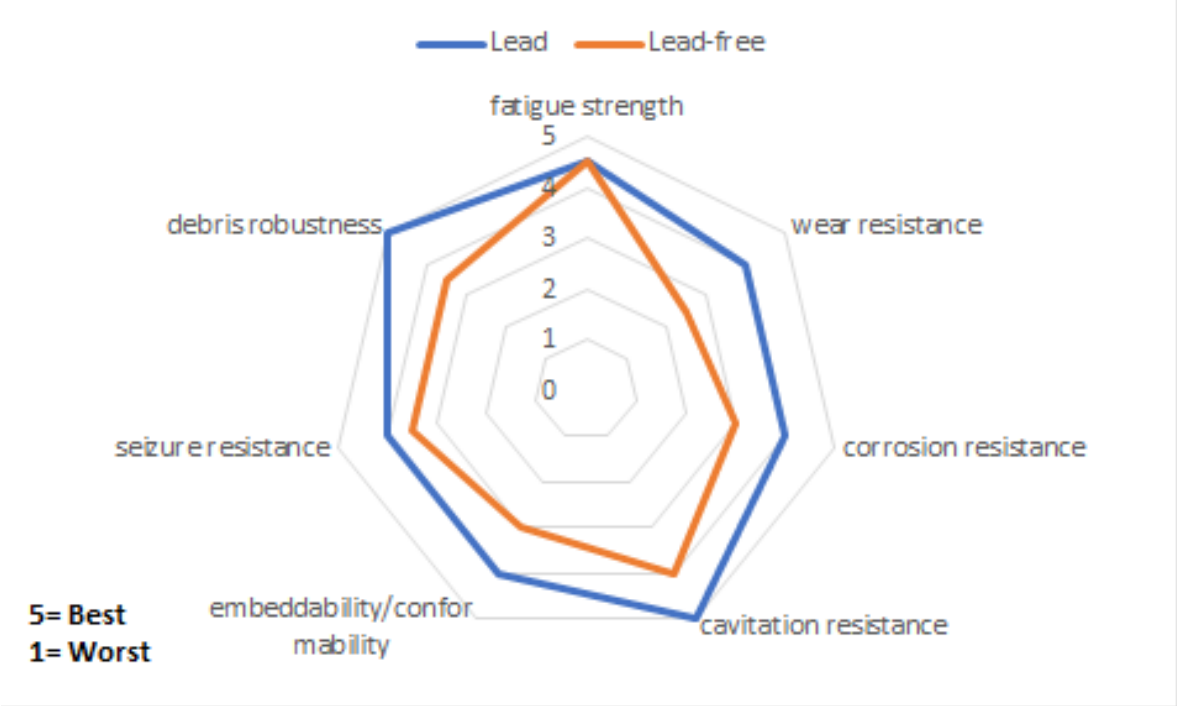
1) *Pb base overlay/Copper base alloy*
2) *Pb base overlay/Aluminium base alloy*
3) *Pb free overlay/Copper base PB free alloy*
4) *PVD (sputter)/Copper base alloy*
5) *Polymer overlay/Aluminium base alloy*

According to (EUROMOT 2023a) the material 2 (Pb-based) was considered by the manufacturer to be the best performer due to the value and consistency of the average number to failure. Material 5 (Pb-free) gave results superior to both 1 and 3. However, the variability in the results of material 5 is greater, which was considered unacceptable, and Material 1 (Pb based) and Material 3 (Pb free) had similar performance. As Material 3 has an equivalent debris tolerance to one of the conventional Pb-based materials (Material 1), it is at a stage where engine manufacturers could test it in their applications to determine its suitability.

Furthermore, (EUROMOT 2023a) describes test undertaken by an engine manufacturer. In those tests 2 lead-free bearings were tested. The conclusion reached by this manufacturer was that this was due to the hardness and higher resistance to conformance in the bearing contact area (a bearing with lead is more relenting) of the lead-free bearing. Once lead bearings were used no further failures were observed due to this issue. This issue is especially important to stationary engines, such as power generators, due to their sensitivity during the dry start phase and if lead-free bearings had to be used it should be expected that there would be a significant increase in the failure rate in such applications.

Another manufacturer is currently comparing the most promising lead-free alternative bearing to the current lead bearing, as outlined in Figure 15-6. This compares seven performance parameters necessary for their applications for leaded bearings and the most promising lead-free substitute tested by this manufacturer to date.

Figure 15-6: Comparative testing of leaded bearing to lead-free alternative



Source: (EUROMOT 2023a)

It can be seen that although the lead-free alternative shows higher performance for some of the tested characteristics, namely cavitation resistance and corrosion resistance, leaded bearings still outperform the tested alternative on the other attributes (wear resistance, embeddability/conformability, seizure resistance and debris robustness). Given the operational environment of the products in scope of this exemption, decreased performance of any of these attributes poses a real risk to causing engine failure. Work to understand the extent to which failures would be experienced on this manufacturer's engines due to the decreased performance is being undertaken, along with investigating if the bearings can be developed further to reduce the decrease in performance.

The tests from two other engine manufacturers are described in (EUROMOT 2023a). Du to engine failure the performance of the lead-free alloys was also insufficient in these tests.

The detailed descriptions of the tests carried out, as well as the conclusions can be found in (EUROMOT 2023a, 2023b). Furthermore, the logistical challenges associated with

conducting maintenance in remote or inaccessible locations, such as mines or disaster sites were also addressed. (EUROMOT 2023b) underlined the critical need for on-site maintenance to ensure the continued operation of essential equipment, emphasizing the impracticality of transporting heavy machinery to workshops, which would not be a harsh and dirty environment for servicing.

15.2.2. Environmental, health, safety and socioeconomic impacts

According to (EUROMOT 2023a), in the commercial internal combustion engine sector there is effectively a closed-loop system for the recycling of mixed metal components generated during the remanufacturing process and at end of life. End-of-life bearings have a positive metal value, whereas landfilling has a cost, so almost 100% of bearings are collected and recycled, although not always by the original engine manufacturer. Closed loops are in effect industry-wide, as it is not possible for bearing or engine manufacturers to guarantee the take-back of their own bearings for recycling, but the metals are recovered through traditional metal recycling processes that take place within the EU and are reused, although not necessarily in bearings. Therefore, there is no closed loop as defined in Article 4.5 of RoHS.

15.2.3. Roadmap towards substitution or elimination of the restricted substance

EUROMOT (EUROMOT 2023a, 2023b) claims that due to the operational environment and an expected service for up to and beyond 20 years, material testing and development activities necessarily take many years to complete to ensure long term reliability.

(EUROMOT 2023a) outlines the activities that have been undertaken to identify alternatives, however, as explained above, to date no alternative has been identified with either the required technical performance to support products covered by this exemption request, or their long-term reliability was found to be very poor with many premature failures. Testing is being undertaken on a continual basis with other lead-free alternatives when they become available. More time is needed for these to be developed and the necessary testing undertaken with the aim that they give reliable performance comparable to current materials.

After laboratory tests, extensive "on-engine" and field testing must be executed to evaluate the reliability and durability of the substitute material. This testing needs to be undertaken by each engine manufacturer to ensure the testing reflects the demands of their application and the tolerances that are inherently in-built into each system. The reliability of the system then needs to be proven with an estimated 500,000+ cumulative hours of testing to understand if the alternative is equal to that of current leaded bearings / bushings.

Even then, as evidenced by failures where lead-free alternatives have been incorporated into current manufacturing, real world conditions are impossible to fully replicate with testing.

(EUROMOT 2023a) provided the qualification requirements which can be seen in Table 15-4. It provides an estimation on the expected timeframes for the development of an alternative, it is important to note that the following are based on the concept that each test

will 'pass' first time. If any further development is required to resolve technical issues the timeframes outlined would be much longer.

Table 15-4: Qualification requirements

Stage	Requirement	Indicative Timeframe
1. Search for alternative lining and overlay alloys	Has been underway for many years, with some showing initial signs of suitable performance. However, not all manufacturers are able to demonstrate this and therefore defining a completion date is not possible	Unknown
2. Evaluation in bearings	Solution/design development	1-2 years
3. Evaluation of lead-free bearings in engine assemblies	For some manufacturers industrialization of the solution is required	6 months
4. Engine redesign	Some alternatives may not be a drop-in replacement and affect the overall engine design.	Up to a year
5. Evaluation of lead-free engines in the field	Can begin this phase only when bench testing of engines with lead-free bearings shows that these are reliable, and performance and emissions are not adversely affected	2 years
Total	**5 years once a solution is developed by bearing suppliers**	

Source: (EUROMOT 2023a)

Internal combustion engines are required to comply with emission legislation. As changing a bearing material may affect emissions and so compliance must be confirmed before a new design can be placed on the market. The EU, USA, Canada, China, Japan, and many other countries all have their own specific emissions legislation, with for global approvals this also needs to be considered. This will require between 1-3 years depending on the engine manufacturer, which for the majority of engine manufacturers will be in addition to the above timescale.

15.2.4. Stakeholder contributions

The request is supported by the National Association of Manufacturers (National Association of Manufacturers 2023). During the public consultation five contributions (DEUTZ 2023; EGMF 2023; EMA 2023; JCB 2023; Volvo Penta 2023) were received. Those consisted entirely of letters of support expressing general support for all requests by EUROMOT during the Pack 27 reviews. None of the above-mentioned stakeholders has provided any technical arguments, and the questions in the consultation questionnaire have not been answered.

15.3. Critical review

15.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds. None of these entries are, however, relevant for the use of lead in the scope of exemption III-42 (cf. section 4.2 on page 51 for details).

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

15.3.2. Substitution and elimination of the restricted substance

Generally, lead-free overlay coatings and alloying elements are used in bearings and bushes. *(EUROMOT 2023a, 2023b) state that these cannot be used for the applications within the scope of exemption III-42 because lead-free alternatives do not have the properties required in a harsh and dirty environment.*

The operation, maintenance and repair of cat. 11 EEE in harsh and dirty environments as a core obstacle to the substitution of lead was already discussed in the previous review of the exemption by (Gensch et al. 2016). The applicants plausibly describe that maintenance and repair of the EEE in the scope of the exemption is impracticable since they are operated in remote or inaccessible locations, such as mines or disaster sites.

Since the last exemption request in 2015, *(EUROMOT 2023a, 2023b) can demonstrate significant efforts to explore alternative materials and evaluate their suitability for different applications. EUROMOT members tested many lead-free bearings from various manufacturers in engines covered by this exemption request. The results consistently demonstrate unacceptable performance and reliability (cf. section* 15.2.1*).*

Overall, the provided information suggests that substitution and elimination of lead is scientifically and technically still impracticable.

15.3.3. Wording of the exemption

The consultants investigated whether the exemption scope can be narrowed or at least be specified and proposed the following amendment of the wording: “Lead as an overlay coating and alloying element in bearings and bushes […]”.

(EUROMOT 2023b) suggest to keep the current wording, as the suggested change aims at accommodating instances in which the two applications are used separately. (EUROMOT 2023b) state that the wording may create misunderstanding on the substances covered by the exemption as lead is used as an alloying element as well and not in its pure form. A change of the wording to “Lead as an overlay coating and alloying element” might be misunderstood as applicable only to the use of 100% lead concentration in overlay coatings.

The consultants thereupon proposed a new wording: “Lead (up to 90 %) in overlay coatings of tribological interfaces and lead (up to 20 %) in layers below the overlay coating compensating misalignments in bearings and bushes […]”.

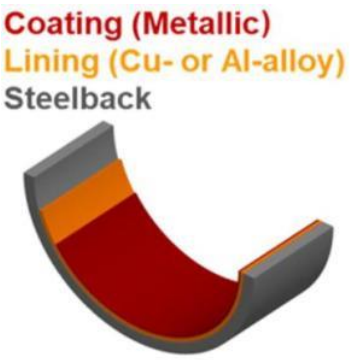
However, (EUROMOT 2024a) raised two concerning aspects with the suggested new wording:

- *The enforceability of the new wording,*
- *The concentrations identified to be used in bearings and bushing liners and overlay coatings.*

(EUROMOT 2024a) state that implementation of the proposed exemption would create confusion as there is no standard test to assess misalignment and it would be overlooking other technical parameters that are of equal importance for safe operation and reliability. Lead-containing coatings and layers are not used solely to compensate for misalignments but it is fundamental to ensure seizure resistance, resistance to damage, conformability, embeddability, fatigue strength, flexibility, chemical resistance, impact of manufacturing tolerances and tolerance to cold temperature and limited lubrication during start-up.

Moreover, the definition of a tribological interface is of difficult understanding as it is not uniquely defined by a standard or a regulation, this characteristic can only be assessed by destructive testing techniques that would require the sectioning of a bearing to assess compliance. This would introduce challenges to the implementation of the Directive as the tribological interface cannot be tested in a non-destructive way by Member States assessing conformity.

Figure 15-7: Example of structure of a multilayer bearing.



Source: (EUROMOT 2024a)

Considering the example of bearing structure highlighted in Figure 15-7, the following layers are identifiable:

- Steelback, the thickest layer without lead.
- Lining, composed of a lead containing alloy (up to 33 % Pb).
- Overlay coating, which is a galvanised layer on the lining that can contains lead up to 95 %.

Further investigation on the concentration of lead in overlay coatings have highlighted that specification generally allow Pb up to ~95% as per ISO 4383 (2012). Below Figure 15-8 of ISO 4383 shows various specifications for overlay coatings.

Figure 15-8: Specifications of overlay coating according to ISO 4383 (2012)

Chemical element	Chemical composition Mass fraction, %		
	$PdSn_{10}Cu_2$	$PbSn_{10}$	$PdIn_7$
Pb	Remainder	Remainder	Remainder
Sn	8 to 12	8 to 12	-
Cu	1 to 3	-	-
In	-	-	5 to 10
Total others	0.5	0.5	0.5

Source: (EUROMOT 2024a)

The lining material can either be a copper or aluminium alloy, with lead contained up to 33 % depending on the alloy used. Moreover, lead-containing alloying materials generally allow Pb up to 33% as per ISO 4383. Below Figure 15-9 shows various lead based copper alloy specifications for bearings.

Figure 15-9: Specifications of layer below overlay coating compositions according to ISO 4383:201(E)

Chemical element	Chemical composition Mass fraction, %				
	$CuPb_{10}Sn_{10}$[a]	$CuPb_{17}Sn_5$	$CuPb_{24}Sn_4$	$CuPb_{24}Sn$	$CuPb_{30}$
	G-cast P-sintered	G-cast	G-cast P-sintered	G-cast P-sintered	P-sintered
Components					
Cu	Remainder	Remainder	Remainder	Remainder	Remainder
Pb	9 to 11	14 to 20	19 to 27	19 to 27	26 to 33
Sn	9 to 11	4 to 6	3 to 4.5	0.6 to 2	0.5
Impurity					
Zn	<0.5	<0.5	<0.5	<0.5	<0.5
P	<0.1	<0.1	<0.1	<0.1	<0.1
Fe	<0.7	<0.7	<0.7	<0.7	<0.7
Ni	<0.5	<0.5	<0.5	<0.5	<0.5
Sb	<0.5	<0.5	<0.5	<0.5	<0.5
Total others	0.5	0.5	0.5	0.5	0.5
[a] the chemical composition of this alloy differs from that of the solid multilayer thick-walled plain bearing in accordance with ISO 4382-1.					

Source: (EUROMOT 2024a)

In light of the considerations discussed in the previous point, (EUROMOT 2024a) suggested the following wording: "Lead in overlay coating up to 95% and/or lead in lining up to 33% of bearings and bushes […]"

Based on the proposal of (EUROMOT 2024a), the consultants developed the following adjusted wording: "Up to 95 % of lead in overlay coatings and/or up to 33 % of lead in linings of bearings and bushes […]".

15.3.4. Environmental, health, safety and socioeconomic impacts

Although the consequences of not extending the exemption are not explicitly mentioned in (EUROMOT 2023a, 2023b, 2024a), the consultants understand that this would have a significant impact on the applications mentioned. This is evident from the test results for lead-free alternatives described in section 15.2.1. For example, emergency generators, fire pumps and uninterruptable power system installations could no longer be placed on the market due to performance and reliability concerns. For this reason, the consultants conclude that the revocation of the exemption could have adverse socioeconomic impacts.

According to (EUROMOT 2023a) all bushings and bearings are subsequently recycled. Additionally, professional engines at end of life are recycled as steel scrap and lead is recovered in the EU by steel recycling processes. The number of engines and quantity of lead are not recorded consistently in the EU, so a calculation on quantities is difficult, especially as the engines reaching their end of life currently are over 30 years old. In a stable market, the quantity of lead used in new engines will be similar to the amount reaching the end of life. The amount of lead in end-of-life bearings and bushings that are recycled is the amount used in new engines minus lead lost due to wear.

The amount of lead lost due to wear is expected to be very low, but unable to be calculated. However, it is important to note that any lead lost due to wear would be collected in the engine oil system and therefore not released into the environment.

It is worthwhile noting that bearings are not intended to be replaced during the lifetime of the engine, and as such only an extremely small number of bearings are used as spare parts.

15.3.5. Summary and 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.*

(EUROMOT 2023a) request a 5-year renewal of exemption III-42 with its current wording for cat. 11 until 21 July 2029. (EUROMOT 2023a, 2023b) argue that no lead-free alternatives are available, and once they are available, minimum five years are required for their qualification to ensure their reliable functioning in cat. 11.

The main obstacle for the substitution of lead in the applications in the scope of exemption 42 is the requirement of servicing, maintenance and repair in the field, i.e. in the harsh and dirty environments in which the machines are operated, instead of performing these operations in workshops. The research and development efforts of (EUROMOT 2023a, 2023b, 2024a) since the last review by (Gensch et al. 2016) did not yet yield viable lead-free solutions.

The consultants conclude from the provided evidence that substitution or elimination of lead are scientifically and technically still impracticable so that granting an exemption could be justified based on the criteria outlined in Article 5(1)(a).

In cooperation with the applicant, the use of lead in the bearings and bushes was specified and integrated into the exemption scope.

15.4. Recommendation

The consultants recommend renewing the exemption. Substitution or elimination of lead are scientifically and technically not yet practicable so that granting the exemption would be in line with the requirements of Art. 5(1)(a). Since the practicability of substitution or elimination is not foreseeable within the next five years, the applicant’s request for a five-year renewal could be followed.

If the COM decides to renew the exemption, the below wording is recommended:

No.	Exemption	Scope and dates of applicability
III-42(a)	Up to 95 % of lead in overlay coatings and/or up to 33 % of lead in linings of bearings and bushes of diesel or gaseous fuel-powered internal combustion engines applied in non-road professional use equipment: - with engine total displacement ≥ 15 litres; or - with engine total displacement < 15 litres and the engine is designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds; or regular maintenance is typically performed in a harsh and dirty outdoor environment, such as mining, construction, and agriculture applications	Applies to category 11 from [date of publication of COM decision + 12 months + 1 day] on Expires on 21 July 2029.

Applicants' feedback on the recommendations

(EUROMOT 2024b) state that they agree with the recommendations for the above exemption and have no additional comments to provide.

15.5. References

DEUTZ (2023): Consultation response by DEUTZ AG for the exemption request III-42. RoHS Pack27. Retrieved from https://rohs.biois.eu/DEUTZ.pdf, Last updated 26.02.2024.

EGMF (2023): Consultation response by European Garden Machinery Industry Federation for the exemption request III-42. RoHS Pack27. Retrieved from https://rohs.biois.eu/EMA.pdf, Last updated 26.02.2024.

EMA (2023): Consultation response by Truck and Engine Manufacturers Association for the exemption request III-42. RoHS Pack27. Retrieved from https://rohs.biois.eu/EMA.pdf, Last updated 26.02.2024.

EUROMOT (2015): Request for renewal of exemption III-42. RoHS Pack 11. Retrieved from https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_11/Request_2016-1/RoHS_Lead_Bearings_Exemption_Request_Form_EUROMOT_2015-07-27.pdf, Last updated 26.02.2024.

EUROMOT (2023a): Request for renewal of exemption III-42. RoHS Pack 27. Retrieved from https://rohs.biois.eu/RoHS_V_Application_Form-ex42-EUROMOT-LeadBearings.pdf, Last updated 26.02.2024.

EUROMOT (2023b): Answers to questionnaire 1 (clarification questionnaire) sent via e-mail by Maitheya Riva, RINA, to Alexandra Morozov. RoHS Pack 27. Retrieved from https://rohs.biois.eu/Ex_III-42_EUROMOT_Questionnaire-1_Clarification_Answer.pdf, Last updated 26.02.2024.

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JCB (2023): Consultation response by JCB Power Systems LTD for the exemption request III-42. RoHS Pack27. Retrieved from https://rohs.biois.eu/JCB_support_EUROMOT.pdf, Last updated 26.02.2024.

National Association of Manufacturers (2023): NAM - Support Letter, EU RoHS Application to Extend Exemption III-42, Last updated 26.02.2024.

Volvo Penta (2023): Consultation response by Volvo Penta for the exemption request III-42. RoHS Pack27. Retrieved from https://rohs.biois.eu/Volvo_Penta.pdf, Last updated 26.02.2024.

16. Exemption 44 of Annex III: Lead in solder in engines

The below Table 16-1 shows the wording, scope and expiry dates of the exemption.

Table 16-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
III-44	Lead in solder of sensors, actuators, and engine control units of combustion engines within the scope of Regulation (EU) 2016/1628 of the European Parliament and of the Council ([49]), installed in equipment used at fixed positions while in operation which is designed for professionals, but also used by non-professional users	Applies to category 11 and expires on 21 July 2024.

Declaration

In the sections preceding the "Critical review", the phrasings and wordings of applicants' and stakeholders' explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

BGA	Ball grid array (a specific surface-mount chip package used for integrated circuits)
Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
COM	European Commission
ECM	Engine control module (synonymous to ECU)
ECU	Engine control unit (synonymous to ECM)
EEE	Electrical and electronic equipment
ELV	End-of-life vehicles (Directive 2000/53/EC)

[49] Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53).

OEM	Original equipment manufacturer
PCB	Printed circuit board
RoHS 1	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	Directive 2011/65/EU, current RoHS Directive

16.1. Background and technical information

On 20 January 2022, (EUROMOT 2023a) requested the renewal of the exemption displayed in Table 16-2 for EEE of category (cat.) 11.

Table 16-2: Wording and scope of the requested exemption

No.	*Requested Exemption*	*Requested scope and dates of applicability*
III-44	*Lead in solder of engine control units of combustion engines, installed in equipment used at fixed positions while in operation which is designed for professionals, but also used by non-professional users*	*Applies to category 11; expires on 21 January 2027*

Stakeholder contributions were submitted by (JCB 2023), (DEUTZ 2023), (Volvo Penta 2023), (EMA 2023), (Cummins 2023) and (EGMF 2023).

16.1.1. History of the exemption

Exemption III-44 was first requested by EUROMOT in June 2017 and was evaluated by (Gensch et al. 2019) resulting in the current wording of the exemption displayed in Table 16-1.

(EUROMOT 2023a) applied for the renewal of the current exemption 13(a) for cat. 11 since it was earmarked for expiry on 21 July 2024 for this subcategory of cat. 9 EEE.

16.1.2. Summary of the requested exemption and stakeholder contributions

Summary of the requested exemption (applicants)

"Lead is used in solder to make electrical connections to components in engine control units (ECUs). Work has been undertaken since the last exemption renewal to qualify lead-free solder in sensor and actuators, which were previously in scope of the exemption. However, more time is necessary to undertake the qualification of lead-free solder in ECUs.

ECUs are generally mounted on the engine block and as such experience a harsh operational environment which includes severe vibration and temperature fluctuations from -40ºC to 105ºC or greater for prolonged periods of time. Lead containing solder is known to provide resistance to failures due to thermal cycling, vibration and shock, does not form

whiskers which could cause short circuits, while still having a low but sharp melting point such that it can be applied to PCB's without damaging any components.

Manufacturers designing new ECUs, are designed with lead-free solder. However legacy ECUs requires testing and usually also circuit redesign and component substitutions to ensure that the ECUs will be reliable for many decades in demanding environments. EUROMOT members produce equipment designed to voluntary consensus safety standards and subject to third party certifications, customer requirements, and regulatory testing obligations. Changes to the solder can affect function, performance, or safety and as such must undergo extensive testing to ensure it meets internal quality benchmarks, design specifications, and regulatory requirements.

The type of ECU, engine and end-use equipment determines the types of tests that are required, with each manufacturer requiring their own testing regime. Testing is underway by EUROMOT members, but additional time is required for these to be completed." (EUROMOT 2023a)

Summary of the stakeholder contributions

JCB is a British multinational manufacturer of equipment for construction, agriculture, waste handling, and demolition. JCB design and manufacture internal combustion engines that are used in a variety of applications and are an active member of EUROMOT. JCB support the exemption request and urge the extension for a full five years. This continued exemption is critical to support European businesses that form an essential arm of the supply chain, and European distributors and consumers, by allowing the necessary time to extend the reliability and sustainability of their products. (JCB 2023)

DEUTZ AG is a publicly traded company and one of the world's leading manufacturers of innovative drive systems. Its core competencies are the development, production, distribution, and servicing of drive solutions in the power range up to 620 kW for off-highway applications. Their current portfolio extends from diesel, gas, and hydrogen engines to hybrid and all-electric drives. DEUTZ drives are used in a wide range of applications including construction equipment, agricultural machinery, material handling equipment such as forklift trucks and lifting platforms, commercial vehicles, rail vehicles, and boats used for private and commercial purposes. DEUTZ supports the exemption renewal request of EUROMOT and states that it is critical for European manufacturers and to support businesses and consumers and to continue to improve the reliability and sustainability of their products. (DEUTZ 2023)

Volvo Group manufactures trucks, buses, construction equipment, and power solutions for industrial and marine applications. Volvo Penta is the part of Volvo Group that manufactures engines and drivelines for off highway applications and power generation, as well as propulsion solutions, drivelines, user interfaces and support for marine applications. Volvo Penta supports the application for a renewal of the exemption for a full five years. The continued exemption is critical to European manufacturers and to support businesses and consumers and to continue to improve the reliability and sustainability of their products. (Volvo Penta 2023)

EMA, the Truck and Engine Manufacturers Association, represents worldwide manufacturers of internal combustion engines and on-highway medium and heavy-duty vehicles. EMA member companies design and manufacture internal combustion engines that are used in a wide variety of applications, including trucks and buses, farm, construction

and industrial equipment, marine vessels, locomotives, lawn, garden and utility equipment, and electric generators and other stationary applications. EMA support the application for renewal of this exemption for a full five years. The continued exemption is critical to European manufacturers and to support businesses and consumers and to continue to improve the reliability and sustainability of their products. (EMA 2023)

Cummins designs, manufactures, distributes and services diesel and natural gas engines and powertrain-related component products, including filtration, aftertreatment, turbochargers, fuel systems, controls systems, air handling systems, transmissions, electric power generation systems, batteries, and electrified power systems. They continue to make investments in critical future technologies and products to meet future emission requirements around the world and improve fuel economy performance of diesel and natural gas-powered engines and related components as well as development activities around fully electric, hybrid and hydrogen power solutions and hydrogen production. Cummins support the application for renewal of this exemption for a full five years. The continued exemption is critical to European manufacturers and to support businesses and consumers and to continue to improve the reliability and sustainability of their products. (Cummins 2023)

EGMF, the European Garden Machinery Industry Federation, is the largest representative of the outdoor power equipment industry in Europe since 1977. EGMF support EUROMOT's application for the renewal of this exemption. Ensuring the continuation of these exemptions is crucial for European manufacturers as it would support businesses and consumers and improve the reliability and sustainability of their products.

16.1.3. Technical description of the exemption and use of the restricted substance

Types of EEE for which the exemption renewal request is relevant

According to (EUROMOT 2023a), the scope of this exemption is electrical control components of NRMM engine systems that are not excluded from the scope of the RoHS Directive. Due to the scope of the RoHS Directive, "forms of transport", "professional non-road mobile machinery" and "stationary industrial tools or fixed installations" are excluded from the scope of the Directive. EUROMOT explain that this significantly impacts the types of internal combustion engines which are in scope of the Directive's requirements. The key differentiator for many of these applications is whether they are designed to be stationary when in use.

(EUROMOT 2023a) provide the following, non-comprehensive examples NRMM, adding that some are clearly not in scope of RoHS:

- *Construction, agricultural and forestry equipment such as bulldozers, truck-type loaders, diesel engine powered compressors, hydraulic excavators, mobile welders, fork-lift trucks, cranes, aerial lifts, drilling machines, screeners, conveyors, utility tractors, turf-care equipment, rock crushers, wheel loaders, crawler tractors, crawler loaders, road maintenance equipment, and*
- *Fluid pumps (including pumps such as irrigation pumps, fire pumps),*
- *Trailer mounted equipment, and*

- *Generator sets (including emergency generators, and uninterruptable power system (UPS) installations)*

(EUROMOT 2023a) note that some engines utilizing this exemption are also in scope of the 'NRMM Emissions Directive', i.e. Regulation 2016/1628/EC, which defines 'non-road mobile machinery different from the RoHS Directive [cf. section 16.1.1on page 287, the consultants]*: "'non-road mobile machinery' means any mobile machine, transportable equipment or vehicle with or without bodywork or wheels, not intended for the transport of passengers or goods on roads, and includes machinery installed on the chassis of vehicles intended for the transport of passengers or goods on roads".*[50]

(EUROMOT 2023a) explain that due to the different definitions, although 'professional NRMM' is excluded from the scope of RoHS, the NRMM Emissions Directive definition of non-road mobile machinery does not include in its definition the differentiation of professional or consumer equipment.

(EUROMOT 2023a) clarify that their exemption renewal request does not refer to engines intended solely for consumer use. However, this equipment is also used in engines designed for types of equipment that are excluded from the scope of the RoHS Directive.

Function of lead in this exemption

Regarding the function of lead in this particular application, (EUROMOT 2023a) state that lead is a constituent of solder alloy used to make electrical connections to components in Engine Control Units (ECUs). (EUROMOT 2023a) indicate that lead is used in tin/lead alloy and tin/lead/silver alloy for solder used in ECUs.

Material or component in which lead is used

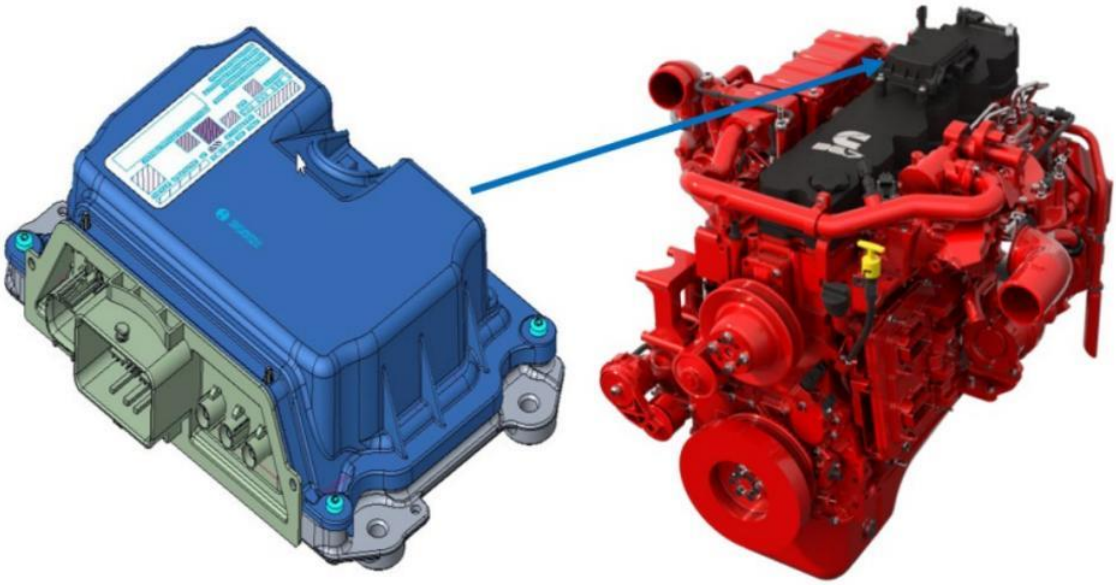
(EUROMOT 2023a) explain that exemption 44 of Annex III of the RoHS Directive originally included lead in solders used for sensors, actuators and ECUs. However, as was indicated in EUROMOT's original exemption request, manufacturers have been able to substitute lead in solders used for sensors and actuators but its use in ECUs is still necessary as substation has not yet been possible for all designs.

(EUROMOT 2023a) further state that solders are used in the electrical circuitry of engine control units (ECU) which monitor and control a number of actuators and sensors that are integral to the engine system to ensure the optimal performance of the engine.

(EUROMOT 2023a) provided two figures to illustrate ECUs and their location on the engine block, reproduced in Figure 16-1 and Figure 16-2.

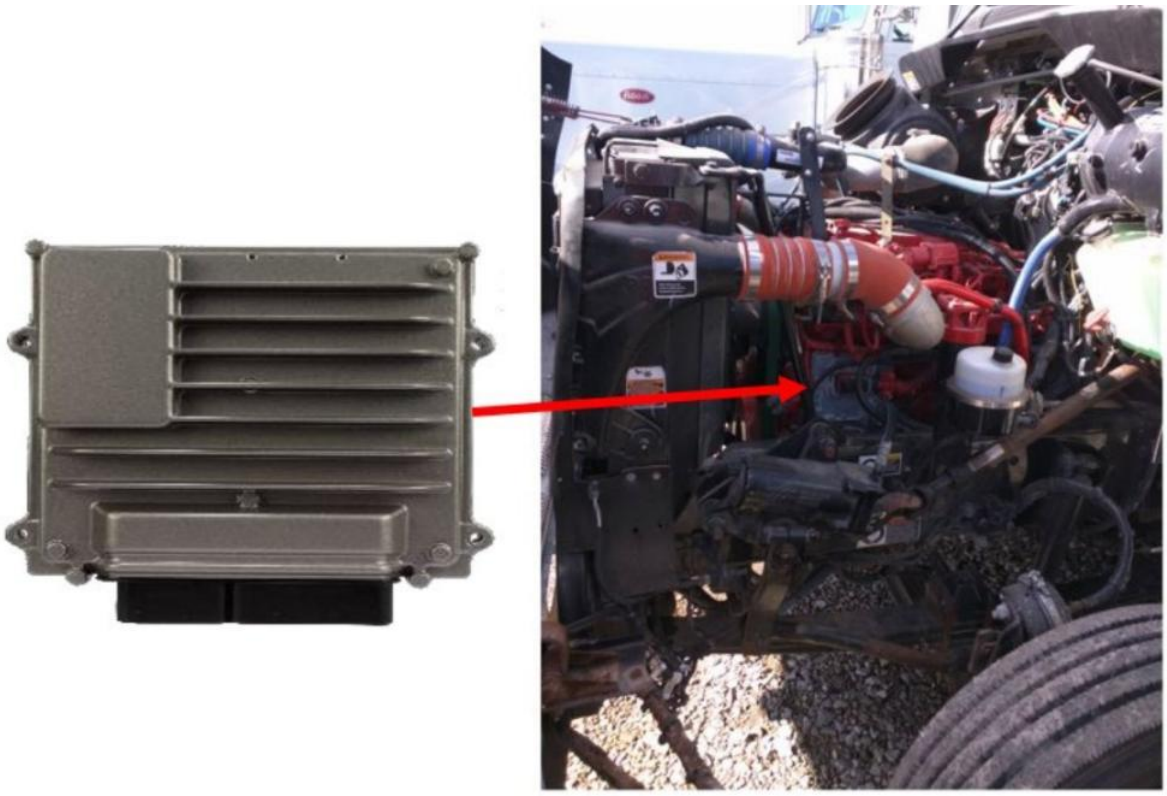
[50] Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive

Figure 16-1: Example ECU CAD diagram and its location on the engine block



Source: (EUROMOT 2023a)

Figure 16-2: Example ECU and its location in service



Source: (EUROMOT 2023a)

Comparing the applications in scope of this exemption renewal request, (EUROMOT 2023a) state that manufacturers of engines in scope of this exemption and their supply chains share many similarities with the automotive and aerospace industries. These manufacturers' sectors sell complex products comprised of thousands of parts and components, sourced from supply chains which overlap with the automotive and aerospace industries. However, applications served by this exemption are characterised by longer

lifecycles, higher costs, larger number of parts, higher variability and lower volume of products, and end-use applications which operate in harsh and dangerous environments demanding extreme reliability.

Regarding the functions of ECUs, (EUROMOT 2023a) explain that they monitor values, such as voltage or current, from numerous sensors within the engine bay, interprets the data using multidimensional performance maps, and adjusts the engine's actuators to control the engine's performance. The ECU ensures that sufficient fuel and air is used by the engine to ensure that it provides sufficient power for the application, without providing too much power and stressing the engine unnecessarily. It also ensures that the mixture of fuel to air is correct such that the combustion minimises emissions and fuel consumption, while still providing sufficient power.

As such, ECUs control parameters such as:

- *Air-fuel ratio based on the readings of sensors such as the oxygen sensors, the throttle position sensor, air flow sensor and engine coolant temperature sensor to determine if additional fuel should be added to the cylinders*
- *Idle speed based on readings of the crankshaft position sensor to determine revolutions per minute (RPM) and therefore controlling the idle speed by the ECU controlling throttle stop or an idle air bypass control stepper motor.*
- *Variable valve timing by controlling the time in the engine cycle at which the valves open, with valves usually being opened sooner at higher speeds to increase the flow of air into the cylinder, increasing power and fuel economy.*

Further, according to (EUROMOT 2023a), ECU's monitor many inputs which include:

- *Camshaft position sensor*
- *Knock sensor*
- *Vehicle speed sensor*
- *Crank shaft sensor*
- *Throttle position sensor*
- *Coolant temperature sensor*
- *Exhaust gas recirculation sensor*
- *Manifold absolute pressure sensor*
- *Heated oxygen sensor*
- *Mass air flow sensor*

Regarding the production and design of ECUs, (EUROMOT 2023a) explain that they can contain one or more printed circuit boards as part of their design and are manufactured both by engine manufactures in-house as well as by specific suppliers in the supply chain of engine manufacturers. Vehicle manufacturers dictate the systems' technical tailoring. The systems' technical tailoring differs not only from one manufacture to the other, but also from one model to the other of the same manufacturer. There is no industry standard to qualify lead free solder in these types of applications, but rather each vehicle manufacturer has

their own sequence and testing regime which is informed by the technical needs resulting from individual model design and operating environment. There are also certain end use applications, such as generators which require application specific testing such as testing to certain municipal codes or other regulatory requirements which can add additional requirements.

Further, according to (EUROMOT 2023a), manufacturers of equipment that contain engines determine where ECUs are located, but frequently the most appropriate location is attached to the engine block. The rationale for mounting the ECUs directly on engine blocks include:

- *Good electrical earth connections are essential and guaranteed when the ECU is mounted on the engine block. Without earthing, the signals that are sent from sensors and to actuators may cause damage to components or the ECU will malfunction.*
- *Avoidance of electromagnetic interference that would be detrimental to the operation of the sensitive control circuits within the ECU.*
- *The vibration profile and impacts are already well understood for the engine. Attaching ECUs to engines means that these will experience the same well understood levels of vibration and range of frequencies and so can be designed and tested to be reliable under these conditions.*

Discussing the challenges arising from the operational environment, (EUROMOT 2023a) state that ECUs are generally designed with vibration damping elements wherever possible to limit the vibration and shock experienced by the ECU. However, heat shielding is not possible as the ECM [engine control module, used synonymous with ECU in this document] *is subjected to heat from the engine and surrounding heat sources such as the exhaust system. Any heat shielding would be ineffective since temperatures of the component and surrounding environment would reach equilibrium.*

(EUROMOT 2023a) claim that the only other way of reducing the challenges of the operational environment is to consider remote mounting of the ECU (e.g., away of the engine block). For some applications this is not possible as the engine block is the only location which is capable for mounting the ECU. For others, the challenges in designing a wiring harness with additional cable length to reach more distant locations may introduce challenges with electromagnetic interference capability and other electrically or mechanically related failure modes. It is important to note that the wiring harness diameter ranges typically between 2.5 to 6 cm, which due to its physical size is not very flexible and has around one hundred separate wires connecting the ECM to the engine and sensors. Therefore, any additional length of the harness takes up additional space in the end-product's engine compartment, such as a genset enclosure space, which cannot always be accommodated due to the design of the equipment. There will also be additional weight that can also increase fuel consumption if the engine is also used to move the equipment.

When the ECM is mounted on the engine, variation in harness installation is minimised since the ECM mounts in only one place. If remote mounting is considered, then the harness would 10 have to accommodate multiple installation configurations, assuming that the Original Equipment Manufacturer (OEM) can mount the ECM in a suitable location. For ECU manufacturers which are not in-house to end equipment suppliers there is limited influence which could be exerted on OEM installation procedures and location. As such, this can introduce factors such as the risk of improper installation, potential damage to the ECM and harness during shipment.

(EUROMOT 2023a) provide a table that outlines the types of conditions experienced by applications covered by this exemption, compared to passenger road vehicles in scope of the End-of-Life (ELV) Directive, reproduced in Table 16-3.

Table 16-3: Operational environment of applications covered by this exemption compared to passenger vehicles

Parameter	Environment experienced by devices covered under this exemption	Environment experienced by passenger vehicles
Vibration as Root Square Mean (RSM) values	*Engines are designed with withstand up to 12g*	*There are no clear vibration level passenger vehicles are qualified to, as research is focused on the continual reduction of vibration. However, the value is expected to be less than 12g and the timeframes under which the engine operates under these conditions is expected to be orders of magnitude less.*[51]
Temperature of ECU	*95-105ºC or greater (At 12 g RMS)*	*It is expected that similar temperatures are experienced, but the timeframes which the engine operated under these conditions is expected to be orders of magnitude less.*[51]
Fuel	*Diesel, natural gas, or petrol. Some diesel engines are also dosed with diesel exhaust fluid to reduce exhausts NOx emissions.*	*Petrol or diesel.*
Duty Cycle[52]	*Based on testing requirements for NRMM: 30 - 70%*	*On average EU passenger vehicles only travel 11,300 km per year*[53]*, with some estimates stating cars are only used on average 4% of the time.*[54]
Proportion of time at full load	*Up to 100% (commonly required for generators) which*	*When the car is in use it is estimated that only an extremely*

[51] Based on 2021 Eurostat data the EU average distance travelled per person per day is 8.2km, given that most urban roads have a speed limit of 50km/h this results in an average travel time of less than 10 minutes per day: File:Average distance per person per day (kilometres) v3.png - Statistics Explained (europa.eu)

[52] Fraction of one period in which a signal or system is active

[53] EU Sectoral Profile – Transport 2020 transport-eu.pdf (odyssee-mure.eu)

[54] Based on UK usage General facts and figures about roads and road use (racfoundation.org)

	has a large impact on operating temperature and vibration level.	*small proportion is at full load and is estimated to be <5%.*[55]
ATEX compliance[56]	*Can be required depending on application.*	*Not required.*
Environment	*Used within harsh and dirty environments. Can be exposed to corrosive chemicals when used in factories, oil refineries etc, or in areas with high humidity or exposed to saltwater spray. Large temperature cycles are often experienced.*	*Exposed to water and saltwater spray and limited amounts of dust. However, ECUs tend to be only indirectly exposed to these so are only exposed to condensation and moderate temperature fluctuations.*

Source: (EUROMOT 2023a)

Characteristics and functions of lead that require its use

According to (EUROMOT 2023a), the electrical connections in the ECU are made using lead-containing solder to connect electronic components to the printed circuit board (PCB). Solder is also used to connect the ECU to wiring looms to ensure that measurements are accurate, and the often small signals are accurately transmitted to engine control units. The solder must maintain a low electrical resistance for the lifetime of the engine, and they must survive the hostile environmental conditions that will be experienced:

- *Resistance to failures due to thermal cycling, vibration, and shock all of which are defining features of applications supported by this exemption request- details provided below.*
- *Resistance to chemicals, high humidity, and corrosion due to salt laden atmospheres- details provided below.*
- *Able to withstand high temperatures for prolonged periods. Engines in scope of RoHS are used at fixed locations and so do not experience the air flow that moving vehicles experience. EUROMOT members estimate that the ECU could easily experience temperatures of 150ºC or greater for continual periods of many months for some applications.*
- *Must not form long whiskers that could cause short circuits*
- *Low meting point- such that the solder is able to be applied without causing damage to the PCB laminate or the components, but high enough not to melt or deform at the operating temperature of the ECU.*

[55] Based on emissions testing schemes, such as those outline in Figure 12, where the car is at its maximum velocity Road load determination of passenger cars - TNO-060-DTM-2012-02014.pdf (transportenvironment.org)

[56] Equipment and protective systems intended for use in potentially explosive atmospheres Directive (ATEX) 94/9/EC.

- *Sharp melting point- in order for the solder to be molten for as minimal a time as possible to reduce the formation of intermetallic phases which occur during this process and can introduce brittleness or unreliability to solder joints.*
- *High thermal conductivity in order to conduct heat away from powered components*

(EUROMOT 2023a) provide more details on some of these aspects as follows:

- *<u>Thermal Cycling:</u> Engines experience very large temperature fluctuations, with engines being used in temperatures as low as -40oC in the northern parts of Sweden or Finland and the temperatures of components including the ECU adjacent to the engine experiencing temperatures of up to 150oC. This wide temperature range can impose large stresses on solder bonds within the ECU. Components that get hot on the PCB, such as a system basis chip with lots of voltage regulators, often suffer with solder joint failure due to the thermal fatigue causing expansion and contraction.*
- *<u>Vibration and Shock:</u> Engines will vibrate for very long periods, and this can cause high frequency fatigue to solder bonds due to the repeated strain imposed. This is due to the fact that when the ECU is connected to a vibration load, the PCB assembly undergoes large bending and deformation, and large alternating stresses and strains are generated on the solder joints. The mechanical alternating stress between PCB board and solder joint will make the solder joint undergo cyclic tension and pressure, which may cause the generation, expansion, and extension of cracks. In addition, cracks may occur between semiconductor chips and solder joints. In addition to the vibration experienced during operation, although equipment with engines in scope of RoHS is used at fixed locations, it is moved between locations. This can be over very rough terrain such as in quarries and building sites and this can cause sudden shocks which impose very high g-forces on solder bonds (similar to dropping equipment onto a hard surface).*
- *<u>Chemical Resistance:</u> Equipment with engines is used in a wide variety of installations including chemical factories, oil refineries and marine environments where they are exposed to corrosive chemicals, high humidity, and high temperature, etc. These hostile conditions can accelerate corrosion of components and circuitry. The corrosion of lead-free solders, due to the inclusion of elements such as zinc, copper, silver and bismuth have higher corrosion susceptibility in corrosive environments9. The paper does highlight that some multielement solders, such as some tin-silver-copper combinations can offer higher chemical resistance than lead based solders in limited situations. However, under higher corrosion conditions (exposure to higher concentration to (NaCl) and higher temperatures the corrosion susceptibility increased. Considering the environments EUROMOT members product operate in, any potential susceptibility to corrosion could have severe consequences on the operability of their products.*
- *<u>Tin Whiskers:</u> Another potential failure mode is with exposed solderable coatings. This can occur because the solder wetting of component terminals and the pads on PCBs by lead-free solders is inferior to that of leaded solders so that areas of the terminals and the pads can remain uncoated by solder. When these terminals and pads are electroplated with tin metal (a common solderability preservative) and are exposed to corrosive or high humidity environments, they can be susceptible to the formation of tin whiskers that can cause short circuits. Tin whiskers are mainly an issue when low voltages are generated by a sensor which is connected to the ECU*

because a short circuit caused by a whisker will alter the output voltage so that the sensor transmits the wrong signal. Mitigation measures against whiskers are known and are used, but until these are implemented and thoroughly tested in realistic environmental conditions, the reliability will not be known. The areas that are not wetted by solder can also suffer from corrosion in corrosive atmospheres that can occur in factories, and this causes an open circuit failure.

(EUROMOT 2023a) add that the long-term reliability of equipment with engines relies on the reliability of all of the individual components and solder bonds. Only one of the solder bonds needs to fail to cause the engine to stop functioning correctly.

16.1.4. Amount(s) of restricted substance(s) used under the exemption

(EUROMOT 2023a) indicate the lead content in the solder alloy used to make electrical connections to components in ECUs to be 30 – 40 % by weight. Through application for which the exemption is requested, an estimated 1.66 kg of lead is placed on the EU market annually.

Providing more detail on their estimate, (EUROMOT 2023a) explain that the amount of lead in an ECU depends on the size and complexity of the ECU. Based on information from EUROMOT members, the amount of lead varies from 2.485 to 13.88 mg per unit, depending on the ECU and the application. In the previous exemption renewal request, an estimated 68,000 units were placed on the EU market annually which were in scope of RoHS, based on information provided by The Association of Equipment Manufacturers (AEM) which outlines the published worldwide market data representative of all power generation equipment regardless of manufacturer. Across the product category codes which are determined to be included in the scope of RoHS, there has been an average increase in sales of 76 % based on the growth between 2017 and 2021. As such, EUROMOT estimates that 119,680 units are placed on the EU market annually. Based on a worst-case estimate that 13.88 mg of lead is used for all ECUs, this results in 1.66 kg of lead being placed on the EU market.

The consultants note a sizable difference in the estimated amount of lead described above compared to amount estimated in the initial application for this exemption by (EUROMOT 2017), in which it was estimated that ECUs contained an average of 35 g of lead in solder, leading to an estimate of more than 2 tonnes of lead contained in the ECUs.

Requested to clarify this difference, (EUROMOT 2023b) state that the basis for the previous calculation has not been able to be identified, but considers that the following factors may have contributed to the difference:

- *It could be that the previous evaluation took into consideration the entirety of the weight of the solder point, rather than the actual content of lead (40%)*
- *The change in technologies and the push towards miniaturization of electronic components to achieve lighter and more versatile assemblies*

While the consultants do not consider the above two factors sufficient to explain for the difference between the amounts of lead estimated in the initial exemption and the current renewal request, the new estimate of lead in solder per ECU (14 mg) appears more plausible compared to the original estimate (35 g).

16.2. Justification of the requested exemption

16.2.1. Substitution and Elimination of the restricted substance

Substitution

(EUROMOT 2023a) argue that while lead-free solder is already used in the electronics industry and in type approved vehicles in scope of the ELV Directive, the environments which are experienced in these applications are not equivalent to those applications utilising this exemption as shown above in Table 16-3 (on page 294). Equipment using this exemption operates in some of the most demanding and severe environments over a product life cycle measured in decades, therefore specific testing replicating in-service conditions is essential.

Tin, silver, copper (SAC) solder alloys were first developed for consumer electronics but were found to have inferior thermal fatigue performance compared to tin/lead in automotive engine compartment conditions[57]. Research showed that adding one more element to SAC either gave an alloy with too high a melting temperature (so damaged components) or too low a maximum operating temperature for engine compartment applications.

Lead-free solder processes in general need around 25 to 30 Kelvin higher soldering temperatures than eutectic tin-lead, as most lead-free solders have higher melting points. The elevated soldering temperatures impose additional thermal stress on components on electronic circuit boards. Components therefore must be qualified for the elevated temperatures required for lead-free soldering processes. The higher soldering temperatures cause higher thermal stresses on the components, which may cause minor damages like micro-cracks or delamination of composite or interconnected materials.

The operational conditions of engines in scope of this exemption experience large thermal cycles with vibration (up to 12g) for prolonged periods of time, which is known to cause cracking in SAC alloys[58], a phenomenon termed high cycle fatigue.

Often research into lead free solders has given contradictory results in terms of its viability as an alternative. This variability was investigated by JGPP[59] which showed that susceptibility to failure depends on:

- *The solder alloy composition,*
- *G-force of the application: with lower g-forces having lower failure rates,*

[57] See figure 3 of "Lead-free for High-reliability, High-temperature Applications", H. Steen and B. Toleno, whitepaper-lf-high-reliability-high-temperature-applications.pdf (henkel-dam.com)

[58] High-Frequency Vibration Tests of Sn-Pb and Lead-Free Solder Joints, D Di Maio and C Hunt, NPL report MAT 2, August 2007, MAT2.pdf (npl.co.uk)

[59] T. Woodrow, JCAA/JG-PP Lead-free solder project: Vibration and Thermal Shock Tests", April 2006 JTR Executive Summary Draft July 30 2007.pdf (hlinstruments.com)

- *Position on circuit board (as this affects the g-force),*
- *Type of component: with ball grid array (BGA) being the most susceptible.*

Applications utilising this exemption often have a number of BGA's and experience high vibration requirements, and as a result, qualifying a lead-free alternative solder has proven to be very challenging. Automotive and solder alloy manufacturers collaborated to develop a novel six-component alloy containing tin, silver, copper, nickel, bismuth, and antimony (called InnoLot) that was deemed superior to the standard SAC alloys[60] for automotive applications. InnoLot has been used in some applications since 2008, but again the specific operational environment of engines utilising this exemption needs to be considered. Studies have been undertaken assessing InnoLot performance, with one study determining that InnoLot was slightly superior to SnPb at 30 MPa under low cycle fatigue conditions but inferior to SnPb at about 34 MPa and higher stress levels under high cycle fatigue[61]. Studies such as this highlight the need for testing reflective of the operational environment of the equipment, to ensure that lead-free alternatives are viable. It is important to note that testing to predict service lifetimes is unable to be accurately estimated from accelerated testing as the acceleration factors for tin/lead and lead-free solders are different. As such, testing new solders on ECUs to the operational environment is still on-going.

EUROMOT members produce equipment designed to voluntary consensus safety standards and subject to third party certifications, customer requirements, and regulatory testing obligations. Changes to materials and formulations which affect fit, function, performance, or safety must undergo extensive testing to ensure new designs meet internal quality benchmarks, design specifications, and regulatory requirements.

Over the intervening time period since EUROMOT originally requested the exemption that was granted as 44 of Annex III, engine manufacturers have undertaken considerable efforts to qualify lead-free solder in sensors and actuators, and now all that remains to be undertaken is the final stages of qualification of lead-free solder in all ECUs. When manufacturers design new ECUs, these are designed with the use of lead-free solders. However, simply replacing lead solder with lead-free solder in existing designs is usually impossible and risks early failures and so any change in materials requires extensive testing and usually also circuit redesign and component substitutions to ensure that the ECUs will be reliable for many decades in demanding environments. One challenge is that tin-lead BGAs are usually older designs often without lead-free equivalents and so new circuit designs are needed to accommodate alternative types of BGAs.

Other bonding methods

(EUROMOT 2023a) acknowledge that soldering is not the only bonding method and others pose potential alternative solutions in some scenarios. The following provides a brief summary of their suitability for use in ECUs:

- *Welding and brazing: Welding requires temperatures >1000ºC and brazing 450-500ºC both of which would degrade or destroy the PCB and many types of components on the PCB*

[60] ALPHA® Innolot Solder Preforms | MacDermid Alpha

[61] Barry08EngD.pdf (bham.ac.uk) Figures 4.46 and 4.50

- *Plug and socket connectors/crimp connectors: This is not suitable for surface mount component and through-hole components on PCBs. Connectors can also suffer from fretting failure when exposed to cyclic temperature changes or to vibration.*
- *Conductive adhesives: The contact resistance can increase over time due to the oxidation of the terminal surfaces. Many conductive adhesives also contain silver, which when exposed to hydrogen sulphide, which is common in many of the industrial environments where engine systems are use, forms insulating sulphides. There are also concerns over the long-term reliability of conductive adhesives, especially in high vibration environments, which can cause the delamination of the adhesive bonds.*

(EUROMOT 2023a) conclude that as such, lead-free solder is continued to be thought of as the most viable alternative to lead containing solder, with additional time required to complete the qualification necessary to use it.

Reliability of substitutes

According to (EUROMOT 2023a), when manufacturers have qualified lead-free solder, the following are some of the tests which engine manufacturers must undertake. The following list includes the type of testing undertaken to qualify lead-free solder for sensors and actuators which no longer require the exemption, to outline the amount of testing undertaken to date. The following tests are not intended to be an exhaustive list, as different manufacturers have different testing requirements, but rather indicate the number and variety of tests which have to be undertaken.

Besides a longer list of tests to which sensors and actuators need to be subjected, (EUROMOT 2023a) state that the following tests outline some of the requirements for ECUs:

- *Vibration Resonance Frequency*[±]
- *Component stress analysis*[±]
- *Thermal Analysis*[±] *including low and high temperatures operation and life tests, thermal shock*[±] *(500 cycles minimum) and temperature to failure*
- *Humidity and salt atmosphere testing*[±]
- *High pressure wash and chemical resistance testing*[±] *to ensure its durability*
- *Signal integrity- testing parameters such as signal overshoot, undershoot, rise and fall times, monotonic signal edges, jitter, droop, ringing, ground bounce, cross talk, reflection, power, and ground noise*
- *Combined Environment*[±]*: Same test as sensors but may use different vibration profile depending on the application of the ECU*
- *Electromagnetic compatibility testing such as conducted emissions and immunity testing, and radiated immunity testing*
- *Electrostatic Discharge Testing*
- *Tolerance to misconnections through the testing of parameters such as short circuits, power interruptions, over voltage*

(EUROMOT 2023a) remark that the tests identified by this symbol "±" potentially require duplication to evaluate the specific environments that each type of ECU operates within.

Lead-free soldered ECUs are expected to achieve a comparable lifetime and reliability as the lead-soldered ones, in order to be considered sufficiently reliable. Otherwise, the engine products' lifetime either becomes shorter or the ECUs must be repaired and exchanged, if this is at all possible, leading to greater waste and timeframes where the affected end-product is no longer available. Given the essential sectors some of these engines serve, such as emergency generators in hospitals, this can have wider society implications.

Lead-free ECUs are currently available on the market[62] but it is important to note that ECU qualification can only be undertaken as part of a single point application, considering a single system architecture or operational environment expected of the engine. Therefore, any qualification undertaken by one manufacture is not transferable to other models, types or operational environment served. This is due to the fact that the above listed testing needs to qualify the ECU to the expected operational environment of the engine and therefore even though lead-free applications have been available on the market for some applications, not all manufacturers can use them.

16.2.2. Environmental, health, safety, and socioeconomic impacts

(EUROMOT 2023a) point out that if this exemption is not renewed for ECUs, many types of end-products will not be available in the EU. These may affect institutions that need emergency generators such as hospitals, it could also affect construction, mining, etc. Employment by engine and end-product manufacturers would also be affected if products cannot be placed on the EU market. Due to uncertainties over the scope of the RoHS NRMM exemption and extreme difficulty with costing the impacts from equipment unavailability, it is not possible to quantify socio-economic impacts. (EUROMOT 2023a) further highlight that some applications utilising this exemption are safety relevant and may cause accidents in case of failure. (EUROMOT 2024a) added that due to the varied and essential functions such equipment support to other sectors the unavailability of those devices could cause a much larger effect to downstream users in terms of availability of products and services. (EUROMOT 2023a) do not claim that environmental impacts or health impacts would occur if this exemption were not renewed beyond the above statements.

[62] Electronic Control Units: Diesel Engine ECU - Transtron and Control Unit : Hitachi Astemo Americas, Inc. (hitachi-automotive.us)

16.2.3. Roadmap towards substitution or elimination of the restricted substance

(EUROMOT 2023a) claim that engine manufacturers and their supply chain have been undertaking a considerable effort to qualify lead-free solder in sensor and actuators, and efforts are continuing to qualify lead-free solder in ECUs.

(EUROMOT 2023a) note that depending on the manufacturer, different tests have been undertaken to date and for some tests different testing profiles have been used depending on the manufacturer. The differences in testing are as a consequence of the different operational conditions each engine is expected to experience in its operational life. The prioritisation of the tests is mostly based on a combination of key parameter testing and simpler tests being undertaken first. This allows for the confidence in the lead-free solution to be built as quickly as possible, and any critical technical differences identified as early as possible.

The following tests are provided as a small sample of the tests which engine manufacturers have undertaken to date to test lead-free solder in ECU's, with test results submitted in the confidential submission:

- *Critical temperature profile*
- *High and low temperature operating life*
- *Thermal shock testing*
- *Combined environment testing (vibration testing at high and low temperatures)*
- *Humidity testing*

According to (EUROMOT 2023a), the tests completed to date indicate the use of lead-free solder is promising, with additional time required for the full testing requirements to be undertaken.

(EUROMOT 2023a) remark that the global shortage of semi-conductors has had an impact on qualification timeframes for some manufacturers.

(EUROMOT 2023a) claim that the timescale for the re-design and validation of engine control units is a little uncertain as only some ECUs are designed in-house by engine manufactures. For other suppliers of ECUs, there is little or no incentive to develop lead-free versions specifically for the industrial equipment sector. This is due to the comparatively small market size of products covered by this exemption compared to the same types of ECUs used for heavy goods vehicles where there is no lead restriction. As such, the following timeline is mostly based on in-house redesign, and additional time would be required if other manufacturers are not able to undertake the same level of requalification activities in the same timescale.

(EUROMOT 2023a) provide the following table, stating that the timeframes are also made on the basis that all qualification stages are successful first time and manufacturers do not encounter dead ends during their assessments.

Table 16-4: Types of qualification activity required and timescales for lead solder substitution

Typical activities	*Timeline*
Procure prototype materials	*Up to 6 months is expected due to supply chain shortages of some components*
Testing of alternative of materials / components in laboratory testing	*2-5 years depending on complexity the ECU. Testing includes vibration and reliability testing which take at least 6 months for each test*
Durability test in engine	*1500 operating hours for each product*
Field test in machine	*Between 3 months to three years (For applications where long-term functionality is critical)*
Supplier approval (if required)	*Minimum 1 month*
Global approvals	*1-2 years*

Source: (EUROMOT 2023a)

According to (EUROMOT 2023a), the above table outlines the main steps manufacturers need to undertake, but as it can be seen there is significant variation in the timeframes for each stage depending on the types of ECU, engine and end-use equipment which determines the types of tests that are required in each stage. This varies between manufacturers (as their product portfolios are very different to each other), as well as the number of tests required at each stage. The number of tests therefore vary between manufacturers. Also, as the operational environment for different models of ECU/engine made by a single manufacturer are often very different, this often necessitates different testing regimes.

EUROMOT's members have already started the testing listed above in the table and currently estimate that a further five years from the date of this application is required to undertake the remaining testing to qualify lead-free solder in all ECU types.

(EUROMOT 2023a) describe three factors from the above table in more detail in the following.

Supply Chain Issues

The recent global shortage of electronics[63] limits has had a significant impact on global industries but is especially impacting the automotive sector. As such, this impacts the manufactures' ability to build prototype controllers for testing without impacting current production demand.

Field testing

[63] European Central Bank, 2021 bulletin The semiconductor shortage and its implication for euro area trade, production and prices (europa.eu)

Testing must also be conducted on actual diesel (or gas) engines to identify failure modes which can only be identified with loads and environmental conditions that are consistent with the entire reciprocating engine assembly working as a complete engine system and at locations where the engines are intended to be used (e.g., on farms, in quarries, etc.). Due to the complexity of the environment the equipment operate in EUROMOT members have found that this step is essential in qualification activities and has identified failures of potential alternatives only at this stage for other qualification activities[64].

Global Approvals

Some equipment in scope of this exemption, made by some manufactures, is also in scope of the NRMM Emissions Directive which sets requirements relating to gaseous and particulate pollutant emission limits, relating to carbon monoxide, hydrocarbons, nitrogen oxides (NOx) and particulates. There are also reliability requirements. These engines also need to gain type-approval by Member State competent authorities to certify that they meet the essential technical requirements of the legislation. As ECUs have the ability to control engine emissions, any change in design or supplier may require lengthy emissions testing and recertification, which takes as long as the testing needed for type approval of a new engine design.

Equipment manufacturers make their products available in more than just EU jurisdictions and normally undertake all global approvals before incorporating a change such as this due to the use of a single manufacturing line for all jurisdictions. Other jurisdictions impose additional obligations such as the US Environmental Protection Agency (EPA) requiring manufacturers to keep a list of parts which have impact to the emissions systems of engines[65]. It is the manufacturers responsibility to identify which components have the potential to impact emissions but given the functionality of the ECU this would be included on all engine manufactures affected parts list. Engine manufactures for any identified components must have documentation to demonstrate that any changes made to the components had no negative effect on emissions. A change from leaded to lead free solder would have a significant change to the architecture of the electronics and would trigger the full complement of transparency testing which can include re-certification of the engine overall in some markets. These emission certification test cells are in extremely high demand due to the length of the testing required. Validation testing for lead-free solder for current production engines means that these facilities may not be available for new product development which offer improvements such as increased fuel efficiency among other aspects.

16.3. Critical review

16.3.1. 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

[64] This has been found to occur when testing substitute engine bearings

[6565] eCFR :: 40 CFR Part 1068 -- General Compliance Provisions for Highway, Stationary, and Nonroad Programs

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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds. None of these entries are, however, relevant for the use of lead in the scope of exemption III-44 (cf. section 4.2 on page 51 for details).

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

16.3.2. Scope clarification

Types of equipment that require the exemption

(EUROMOT 2023a) provided an indicative list of examples of NRMM, adding that some are clearly not in scope of RoHS (cf. section 16.1.3 on page 289). In the consultants' view, a more relevant and comprehensive list of applications is needed to better understand the applications' requirements. *When asked, (EUROMOT 2024a) stated that EUROMOT members produce combustion engines which are used in vast range of different end use applications, so it is not possible to provide an exhaustive list of products, some indicative end uses that require the use of exemption 44 are:*

- *Air compressors,*
- *Liquid and Gas Fluid pumps (including pumps such as irrigation pumps, fire pumps),*
- *Trailer mounted equipment,*
- *Generator sets (GENSETs) including emergency generators, uninterruptable power system (UPS) installations, and Battery Energy Storage System (BESS),*
- *Non-professional non-road mobile machinery (NRMM) applications such as construction, agricultural and forestry equipment such as bulldozers, mobile welders, truck-type loaders, diesel engine powered compressors, hydraulic excavators, mobile welders, fork-lift trucks, cranes, aerial lifts, drilling machines, screeners, conveyors, utility tractors, turf-care equipment, rock crushers, wheel loaders, crawler tractors, crawler loaders, road maintenance equipment*

The consultants inquired whether the 'product category codes' mentioned by the applicants could be shared for a more comprehensive list of applications. *(EUROMOT 2024c) did share the list but explained that it was only used in conjunction with trying to estimate the change in market size since the last renewal application, therefore influencing the amount of lead being placed on the market from this exemption. The most appropriate categories of products were selected as part of this review; however, it can be seen from the associated descriptions that this will not aid in the concise but through explanation of the products within*

the scope of this exemption. The consultants agree and the list is not reproduced in this report.

Reference to the NRMM Emissions Regulation in the exemption wording

The wording requested by (EUROMOT 2023a) omits the reference to Regulation (EU) 2016/1628 (hereafter: the NRMM Emissions Regulation)[66], which is part of the currently valid wording. Assessing EUROMOT's initial application for this exemption conducted by (Gensch et al. 2019), the consultants note that the reasoning for including the reference in the currently valid wording was based on one of the applicants' arguments at the time: All equipment for which the exemption was requested was understood to be in scope of the NRMM Emissions Regulation. At the time, EUROMOT explained that this Regulation has mandatory emission and durability requirements and requires extensive engine testing before equipment is allowed on the market. Therefore, switching to RoHS-compliant components requires long testing and verification periods. In the consultants' view, removing the reference to the Regulation from the wording of exemption III-44 could therefore mean broadening its scope. Whereas the currently valid wording restricts the type of equipment in its scope to those that are also in scope of the NRMM Emissions Regulation, which co-determines their testing and verification procedures, the new requested wording would potentially also include equipment that is outside the scope of the NRMM Emissions Regulation.

When asked for their rationale to omit the reference to the NRMM Emissions Regulation in their requested wording, (EUROMOT 2023b) clarified that the Regulation refers to internal combustion engines for non-road mobile machinery. This category of machinery is already excluded from the scope of the Directive and therefore it is deemed that the direct reference to the Regulation can create misunderstanding in the interpretation of the exemption. The removal of the explicit reference to Regulation 2016/1628 would not change the equipment in scope of exemption 44 but aid in the clarity of understanding of the types of products in scope of the exemption.

(EUROMOT 2024a) reiterated that the change in the wording of exemption 44 would not change the equipment in scope of the exemption but provide clarification to the interpretation of the scope of the exemption. Moreover, due to the criticality of EUROMOT's applications, they are already subjected to the same challenging requirements of durability and reliability and require extensive engine testing before equipment is allowed on the market, as required by the NRMM Regulation.

On request, (EUROMOT 2024b) confirmed that all applications highlighted by EUROMOT members requiring the use of Exemption 44 are, in fact, in scope of both RoHS Directive and the NRMM Regulation, stating that "all of EUROMOT's equipment that contains ECUs is also in scope of the NRMM Regulation 2016/1628".

Despite the definiteness of the last cited statement that all of EUROMOT's equipment that contains ECUs is also in scope of the NRMM Emissions Regulation, the consultants consider removing the reference from the exemption wording carries the risk of broadening

[66] Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC

its scope. Adopting a conservative approach may be preferable, which implies maintaining the current wording of the exemption.

16.3.3. Substitution and elimination of the restricted substance

Engine manufacturers have successfully phased out the use of lead in solders used in sensors and actuators associated with internal combustion engines, and now the only remaining application for leaded solder in the scope of this exemption are ECUs.

The applicants make the following arguments for why a renewal is needed:

- Lead-free solders are available, but additional time is required to qualify those for the use of ECUs in scope of this exemption
- Lead-free ECUs are already available on the market, but as qualification needs to be undertaken for individual applications, and results from one model cannot necessarily be transferred to others, more time is needed to complete the final stages of qualification
- Other bonding methods are available but not suitable, so lead-free solders are thought to be the most viable alternative to leaded solders

The applicants provided information describing the issues of lead-free solders in demanding environments as they occur for engine control units, particularly those mounted on engine blocks. *When asked whether the exemption wording could be adapted to reflect the latter, (EUROMOT 2024c) explained that this would be unsuitable. While the majority of ECUs are mounted on the engine block, some of the multiple ECUs needed in a single system are not mounted on the engine block. At least some of these are mounted in close proximity to the engine, so they are also subjected to the described conditions of high temperature, vibration, and exposure to electromagnetic interference. For example, ECUs can be found in the after-treatment system, where the working temperature and vibration loading (from the engine and operational environment such as an excavator) is high. Moreover, the after-treatment ECU is also used for very harsh operating conditions such as vibration and corrosion.*

In the consultants' view, the line of reasoning is plausible, so restricting the scope of the exemption explicitly to only those ECUs that are mounted on an engine may not be sufficiently broad to cover other ECUs that may be subject to similarly harsh conditions.

The consultants contacted two suppliers of ECUs to inquire for which applications and environmental conditions lead-free ECUs (if any) had been qualified, but no information that would be useful for this review was received.

(EUROMOT 2023a) stated that lead-free ECUs are currently available on the market. *When asked when lead-free ECUs first became available, (EUROMOT 2024a) reiterated that although lead-free ECUs are available, they are not a feasible solution for all applications. Each company needs to undertake their own testing as there is no industry standard test to qualify alternatives, with the testing of each manufacturer specific to the end use their equipment will serve. As such, although EUROMOT companies have been investigating lead-free alternatives, in some instances from prior to 2011 this has only allowed for lead-free solders for some applications to be introduced in new designs from 2017. However, there are still highly complex legacy equipment that still require the lead-ECUs as there is no drop in substitute available.*

When asked why redesign of legacy equipment had not yet been completed although it has been clear since at least 2011 that they would be in scope of RoHS category 11, (EUROMOT 2024a) reiterated that retrofitting of legacy ECM's with lead-free alternatives would require substantial redesign, and further system level testing to ensure continued compliance to exhaust emissions would need to be performed and products needs to be recertified for exhaust emissions and other non-emissions requirements. For this reason, although lead-free ECM are a known technology and can be used in certain applications the challenge is not with testing but rather in the retrofitting of legacy parts.

When asked to confirm whether only legacy parts or also newly designed ECUs contained leaded solder, (EUROMOT 2024b) responded that development of new and updated products have been reducing and removing the use of lead-containing ECUs wherever possible. Lead-containing ECUs are not being developed into wholly new designs, however, the definition of legacy design as it is not underpinned by a formal definition is not consistently or clearly understood as an industry sector. As such making a statement that only legacy devices use ECU's is challenging. For example, there are products which contain some newly designed sub-systems, but also utilising legacy designs of other sub-systems - the determination of if this is a legacy product or not is challenging.

When asked for which reasons legacy ECUs have not been re-designed to be lead-free, while new designs of lead-free ECUs have been on the market from 2017, (EUROMOT 2024b) state that they are not aware of any additional technical challenges in the design of legacy lead-free ECUs. Rather, the challenge relates to the systems level assessment which need to be undertaken to allow their implementation into legacy devices. For new products, these tests are intrinsically built into the initial qualification of the product, whereas for devices which this phase has already passed requires additional time.

(EUROMOT 2024b) further specify the challenges that have been identified in the progressions towards the implementation of lead-free alternatives:

- *A system often relies on multiple ECU's with completely different architectures and communication protocols. Even if a lead-free alternative is implemented for one of the ECU's this might create communication issues with the rest of the system. Due to the complexity of the system only a few components can be designed out or fundamentally changed at a given time which significantly delay the implementation of changes.*
- *As EUROMOT manufacturers have a large number of products, more than 50 products within a single company with several different models for each product type. Each product needs not only the redesign of the ECU module but also the correlated sensors and wiring harnesses. Moreover, this requires re-calibration and certification which is a time demanding task. Due to the extensive requirements in terms of testing and system qualification, this is a demanding time effort as only few designs can be implemented and tested for qualification at the same time. The complex and highly specific nature of the testing rigs is such that only a limited number of tests can be completed in parallel. Additionally, to correctly simulate operating conditions, long testing times are required for the qualification of those parts. Due to the long operating lives of the equipment the time required for validation can be several years to correctly evaluate safety and reliability during the lifetime of the product. Moreover, priority is given for the development and qualification of new lead-free designs*

(EUROMOT 2024a) further describe that EUROMOT manufacturers' applications share a consistent share of their supply chain with the automotive industry. Although automotive applications are not in scope of RoHS while EUROMOT applications are, automotive application are leading the market trend in the manufacturers. Therefore, in many cases the parts supplied are shared by the two industries, where Exemption 8(a) of the End of Life Vehicle Directive 2000/53/EC (ELV) mirrors the scope of exemption 44 in RoHS and therefore still permits parts with lead. A possible divergence between the scope of the exemption in the two Directives might result in EUROMOT members not being able to rely on their supplier chain.

The consultants note that exemption 8(a) of the ELV Directive covers "Vehicles type approved before 1 January 2016 and spare parts for these vehicles". During the last review of exemption 8(a) by (Zangl et al. 2010), the stakeholders had stated that it takes about five to seven years to undergo a type approval for the whole car fleet of a vehicle manufacturer. When interpreting the upper limit of this timeline strictly, the consultants assume that vehicles in scope of the ELV Directive should no longer rely on this exemption since 1 January 2023. However, first, the timeline was an approximation ('about five to seven years'), and secondly, the applications making use of exemption III-44 is different from applications (vehicles) in scope of the ELV Directive.

EUROMOT stated in their renewal request document that one challenge is that tin-lead ball grid array (BGA) microchips are usually older designs often without lead-free equivalents and so new circuit designs are needed to accommodate alternative types of BGAs. When asked to specify whether BGAs were the only component that hindered the transition to fully lead-free ECUs, (EUROMOT 2024c) confirmed that at present, only BGA microprocessors rely on exemption 44. An ECU incorporates a substantial BGA microprocessor. In cases where the ECU utilizes a lead-free BGA microprocessor, it has been determined that there is no direct pin-to-pin upgrade version available that is also lead-free. If a transition to a lead-free BGA is attempted, it will necessitate modifications to the BGA microprocessor's dimensions and potentially affect certain interface definitions. Consequently, this will entail more extensive changes to the overall printed circuit board (PCB) design due to the limited space on the ECU PCB, which is already populated with electronic components. Even minor adjustments might necessitate a complete redesign to maintain the original form factor, re-validation of electromagnetic compatibility / interference compliance and vibration resistance, as well as verification of essential functions.

When asked whether exemption 15 of Annex III would cover the BGAs in scope of EUROMOT's exemption request, (EUROMOT 2024d) stated that the scope of exemption 15 and 44 is different and there are instances where BGA's under exemption 44 would not be covered by exemption 15. It is also worthwhile noting that exemption 44 has a much more bound scope and is focused on the system application of the component and therefore has greater relevance to only EUROMOT applications. It is also worthwhile considering that that exemption 15 of Annex III has currently not been recommended for renewal. Due to the timeframe that exemption 15 would allow and the criticality of the application a transition to the use exemption 15 would not be feasible for ECU applications. The consultants note that indeed exemption 15 has not been recommended for a renewal after its most recent review conducted by (Deubzer et al. 2022). In the light of the applicants' above statement it should, however, be considered to exclude the scope of exemption 44 from the scope of exemption III-15.

The applicants were asked whether a more specific wording of the exemption would cover applications in scope of their renewal request, in case it was found that a renewal of the

exemption was justified: “Lead in BGAs used in engine control units of combustion engines installed in equipment used at fixed positions while in operation, which is designed for professionals, but also used by non-professional users”. However, *(EUROMOT 2024d) stated to disagree with the change in wording as the solder material used on the BGA is dictating the material used on the remaining components on the same board. The soldering process consists of the soldering paste being spread across the board according to a specific geometry designed priorly. This stage is developed simultaneously for the entirety of the components placed on the board that are therefore reflowed at the same temperature. For this reason, the limiting component of the board will dictate the characteristics of the entire board including temperature of reflow and consequently material used for the soldering process. In ECUs, as it has been stated in the exemption renewal submission the limiting component is the BGA, which requires lead solder, which will limit the rest of the board to the same solder material due to compatibility. Although EUROMOT members are not an electronic component manufacturer they are aware that different solder materials on the same board have been attempted. However, due to the different specific temperatures of reflow of the solder materials, specifically that lead-free solder requires higher temperature, this resulted in damage of the BGA connections. Therefore, it is recommended that the original wording is maintained, with particular consideration to the already narrow scope of the exemption and the fact that only legacy applications are still reliant on this exemption.* The consultants agree with the explanation provided by the applicants in principle.

Overall, from the information that was provided, the consultants derive that scientifically and technically, substitution or elimination of lead in solder in ECUs is practicable, but the reliability of the lead-free solutions has to be ensured via a redesign/new design of the ECUs to accommodate the specific properties of lead-free solders.

Lead-free ECUs have been available on the market, and new designs do not necessarily require lead in solder. Rather, it appears that some older designs of ECUs have not been redesigned or replaced by new models for new models of engines to work with lead-free components, as they rely on older designs of e.g. BGA microchips. The consultants assume that this might be a problem of model policy and cost rather than technical feasibility.

16.3.4. Environmental, health, safety, and socioeconomic impacts

The potential impacts described by EUROMOT remain vague overall. The consultants find it plausible that some equipment may no longer be available on the EU market in case the exemption renewal was not granted. However, given that progress has been made using lead-free ECUs and that the phase-out of lead-containing ECUs is foreseen to be complete until January 2027, it appears reasonable to assume that only a small number of equipment would be affected, thereby limiting the scope of potential negative impacts.

16.3.5. Summary and conclusions

EUROMOT request the renewal of exemption III-44 with the wording “*Lead in solder of engine control units of combustion engines, installed in equipment used at fixed positions while in operation which is designed for professionals, but also used by non-professional users”* for equipment of category 11 until January 2027.

Since the original exemption request, leaded solders have been phased out from sensors and actuators. For engine control units, EUROMOT claim to be in the final stages of qualifying lead-free solders. They also acknowledge that lead-free ECUs are already available in the market but have not yet been qualified for all applications due to the required individual testing to ensure reliability. Accordingly, EUROMOT applied for a renewal of this exemption with an adjusted wording that reflects that sensors and actuators no longer require the exemption to complete the qualification.

In the consultants' view, it is plausible that ECUs are subject to particularly harsh environmental conditions because they are mounted on and in the vicinity of engine blocks. EUROMOT point out that retrofitting of legacy ECUs with lead-free alternatives would require considerable redesign and testing efforts. The only remaining components that necessitate the leaded solder are certain microchip ball grid array (BGA) packages.

The consultants conclude from these statements that substitution of lead is scientifically and technically practicable but require the redesign/new design and subsequent testing and qualification of the lead-free ECUs to ensure their reliability.

Exemption 8(a) under the ELV Directive covers the same applications for vehicles in its scope. The exemption covers vehicles type approved before 1 January 2016. During the last review of that exemption, a full 'renewal' of an OEM's vehicle fleet was approximated to take five to seven years, meaning vehicles may not rely on this exemption any longer beyond January 2023. However, this timeline may not be directly transferable to the equipment in scope of this exemption request. The consultants consider it plausible that the completion of the phasing out of lead-containing ECUs for equipment in scope of exemption III-44 may take some more time.

The exemption wording requested by the applicants omits a reference to Regulation (EU) 2016/1628 (NRMM Emissions Regulation), arguing that it would remove ambiguity in the wording while not changing the scope in practice. However, in the consultants' opinion, this change in the wording carries the risk of broadening the scope of the exemption and therefore consider it preferable to maintain the currently valid.

16.4. Recommendation

The consultants recommend renewing the exemption until 21 January 2027, as this will give the industry sufficient time to complete remaining redesign, testing and qualification tasks for lead-free parts to ensure their reliability. Thus, the reliability of lead-free substitutes for this specific application is not yet ensured. The consultants consider that a further renewal after this date will not be justifiable, and the exemption can expire thereafter.

If the COM decides to follow this approach, the below wording is recommended for the renewal of exemption III-44:

No.	Exemption	Scope and dates of applicability
III-44	Lead in solder of engine control units of combustion engines within the scope of Regulation (EU) 2016/1628 of	Applies to category 11. Expires on 21 January 2027.

	the European Parliament and of the Council ([67]), installed in equipment used at fixed positions while in operation, which is designed for professionals, but also used by non-professional users.	

Applicants' feedback on recommendations

(EUROMOT 2024e) stated to have no further comments on the recommendation.

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[67] Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53).

EUROMOT (2024b): Answers to questionnaire 3 sent by Maitheya Riva, RINA, to Christian Clemm via e-mail. RoHS Pack 27. EUROMOT (RoHS 29).

EUROMOT (2024c): Answers to questionnaire 4 sent by Maitheya Riva, RINA, to Christian Clemm via e-mail. RoHS Pack 27. EUROMOT (RoHS 29).

EUROMOT (2024d): Answers to questionnaire 5 sent by Maitheya Riva, RINA, to Christian Clemm via e-mail. RoHS Pack 27. EUROMOT (RoHS 29).

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17. Requested new Exemption 2022-1 of Annex III: optical calomel components

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

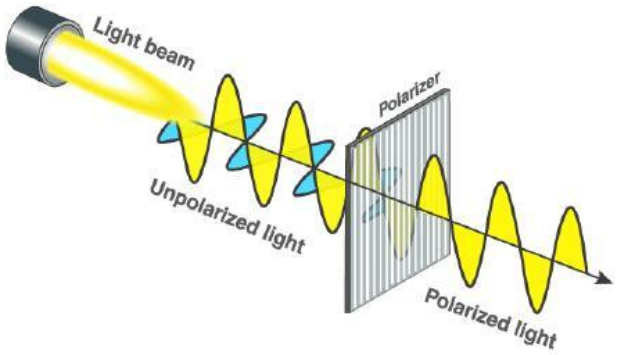
Acronyms

AO	Acousto-optic
AOD	Acousto-optic deflector
AOM	Acousto-optic modulator
AOTF	Acousto-optic tuneable filters
BBT	BBT Materials Processing
Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
CAGR	Cumulative average growth rate
COM	European Commission
EEE	Electrical and electronic equipment
IMCIs	Industrial monitoring and control instruments
LWIR	Long wavelength infrared
MWIR	Medium wavelength infrared
NDF	Neutral density filter
QKD	Quantum key distributor
QRNG	Quantum random number generator
RoHS 1	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	Directive 2011/65/EU, current RoHS Directive, RoHS 2
SWIR	Short wavelength infrared

TIR	Thermal infrared

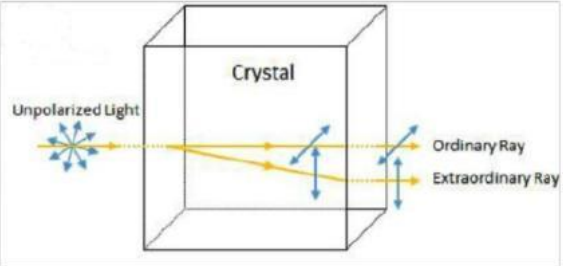
Definitions

Damage threshold	Highest quantity of laser radiation incident upon the optical component for which the extrapolated probability of damage is zero. Source: ISO 21254
Elastic wave propagation	Transmission of mechanical disturbances, or waves (sound), through a material that returns to its original shape after the disturbance passes. These waves are characterised by the propagation of stress and strain within the material. (BBT 2023b)
Extinction ratio	In context of polarisation optics in simplified terms indicates how effectively the part of an electromagnetic radiation in a specific direction can be blocked. A higher extinction ratio indicates a more effective polariser. (BBT 2023b)



Source: https://byjus.com/physics/polarization-of-light/ in (BBT 2023b)

Figure of merit	A critical parameter for acousto-optic components to assess their performance and suitability for various applications. In the context of this exemption request, the figure of merit is the diffraction efficiency, i.e. how effectively the acousto-optic device scatters or modulates the incident light. It is often expressed as the ratio of the optical power in the diffracted or modulated beam to the incident optical power. A higher diffraction efficiency indicates a more efficient acousto-optic device. (BBT 2023b)
Index of refraction	Change in the speed of light when entering a material compared to the speed of light in a vacuum, also “optical density”. In anisotropic crystals, birefringence will occur because light of different polarizations has varying refractive indices (ordinary (o) and extraordinary (e) within the crystal and causes the light rays to behave differently as they pass through the material. n0 expresses the index of refraction of an ordinary beam while ne indicates the refraction of an extraordinary beam. (BBT 2023b)



Source: https://www.chegg.com/homework-help/questions-and-answers/part-2-mineralogy-crystal-unpolarized-light-1--ordinaryray-extraordinary-ray-figure-2-lig-q53324072, referenced in (BBT 2023b)

Mercury-free	Not containing mercury in the applications covered by the scope of the exemption to be reviewed.
Neutral density filter	Filter used at the output of the laser to achieve the desired power level needed to observe quantum effects. (BBT 2023c)
Optical resistance	In the context of this exemption request, the resistance and stability of optical parameters under the influence of energy emitted from high-power lasers. This parameter is not exactly defined but is closest in meaning to laser load resistance. (BBT 2023b)
Transmissivity	Measure of how much of incident light passes through a material, typically expressed as a percentage. It quantifies the ability of a material to transmit light without absorbing or scattering it. Transmissivity takes into account all the light that is both transmitted and refracted, and it can be affected by factors such as the material's thickness and the angle of incidence. (BBT 2023b)
Transparency	Qualitative term describing how well a material allows light to pass through it and how easily objects can be seen through the material. Transparent materials are those that allow light to pass through with minimal absorption or scattering, and they typically have high transmissivity. Transparency is often used to describe materials that are clear, like glass or certain plastics, and they allow for good visibility through them. Transparency depends on the wavelength of light. Materials are transparent only in a limited range of wavelengths of light, which is one of the fundamental optical properties of a given material. (BBT 2023b)
Infrared spectrum	Electromagnetic waves in the range of around 0.7 µm to 30 µm (for details see Table 17-1: Wording and scope of the requested exemption Table 17-1 on page 317).

17.1. Background and technical information

On 19 January 2022, (BBT 2022) requested the new exemption displayed in Table 17-1 for EEE of category (cat.) 9 industrial monitoring and control instruments (IMCIs), and for cat. 11.

Table 17-1: Wording and scope of the requested exemption

No.	Requested Exemption	Requested scope and dates of applicability
Annex III	*Optical components made of mercurous chloride monocrystal (calomel)*	*Applies to categories 9 industrial monitoring and control instruments and to category 11* *Expires on* - *21 July[68] [date of official publication + 7 years] for category 9 industrial monitoring and control instruments* - *21 July 2027 (= 2022 + 5 years) for category 11*

17.1.1. History of the exemption

The exemption is requested as a new exemption and therefore has never been reviewed before.

17.1.2. Summary of the requested exemption

"Products made of mercurous chloride monocrystals (solid state, stable crystal) represents a unique, synthetically prepared optical components with extraordinary properties, especially in the infra-red part of the electromagnetic spectrum. Nowadays, there are no other materials that can offer such a strong birefringence (Δ_n = 0.6) and simultaneously broadband transparency reaching from visible (0.38 µm) up to mid-thermal IR region (17 µm).

These extraordinary properties will find application mainly in ground sector applications such as polarization optics and, spectroscopy, acousto-optics, microscopy, etc., as well as in the space environment sector, too. Calomel is only crystal transparent in MWIR and birefringent too, what makes him a great candidate for a polarization optics with many technical advantages over the wire-grid systems used today. Even if the optical products made of mercurous chloride monocrystals are not directly electronic devices, many of the final calomel based components are used as a subcomponent for the electronic devices. Calomel windows, prisms, cubes, plates and other forms of products are usually mounted into the protective housing for its particular use and then distributed to the final customers

[68] Even though the exemption was submitted on 19 January 2022, the expiry data was assimilated to the expiry of most other exemptions on Annex III.

reaching from private companies and corporates, up to technology institutes, universities and scientific centres producing or using corresponding electronic devices.

Even though calomel is mercurous based compound, handling represents no health risk[69] *since the mercury molecules are firmly bonded in the crystal lattice. The material is insoluble in water and no harmful substances can be absorbed through the skin or mucous membranes."* (BBT 2022)

17.1.3. Technical description of the exemption and use of the restricted substance

According to (BBT 2022), in addition to chlorine, mercury (Hg) is one of two essential atoms forming the Hg_2Cl_2 molecule (mercurous chloride) monocrystal. The crystal lattice, formed by the long linear chains of the Cl-Hg-Hg-Cl molecules, is responsible for unique physical properties. This crystalline form of the mercurous chloride is a synthetically prepared monocrystal. The calomel (solid form) based optical components are used in polarization optics, acousto-optical components and general optical components like prisms, windows, cubes and other standard optics used in laser and photonics industry. All electrical or electronic devices equipped with calomel are used by professionals in research and development photonics institutes, universities and private companies dealing mainly with the infrared part of the electromagnetic spectrum, worldwide.

The calomel (solid form) based optical components are used in ***polarization optics****,* ***acousto-optical components*** *and* ***general optical components*** *like prisms, windows, cubes and other standard optics used* ***in laser and photonics industry****.*

All electrical or electronic devices equipped with calomel are used by professionals in research and development photonics institutes, universities and private companies dealing mainly with the infrared part of the electromagnetic spectrum, worldwide.

Polarisation Optics

(BBT 2022) claim that calomel IR polarisation components are unique devices showing an exceptionally high extinction ratio (ER)[70] *in comparison with the market competitors targeting the MWIR/LWIR*[71] *spectral band.* Table *17-2* below illustrates a subdivision of the infrared spectrum.

[69] Inter-Academic committee ČSAV. *Symposium on mercury (I) halides*. I. Liblice: Institute of Solid State Physics ČSAV, Praha, 1976; source as *referenced by BBT 2022.*

[70] C.f. section "Definitions" on page 21

[71] SWIR/MWIR/LWIR/TIR stands for specific wavelength ranges; Short Wavelength Infrared (SWIR), Medium Wavelength Infrared (MWIR), Long Wavelength Infrared (LWIR) and Thermal Infrared (TIR)

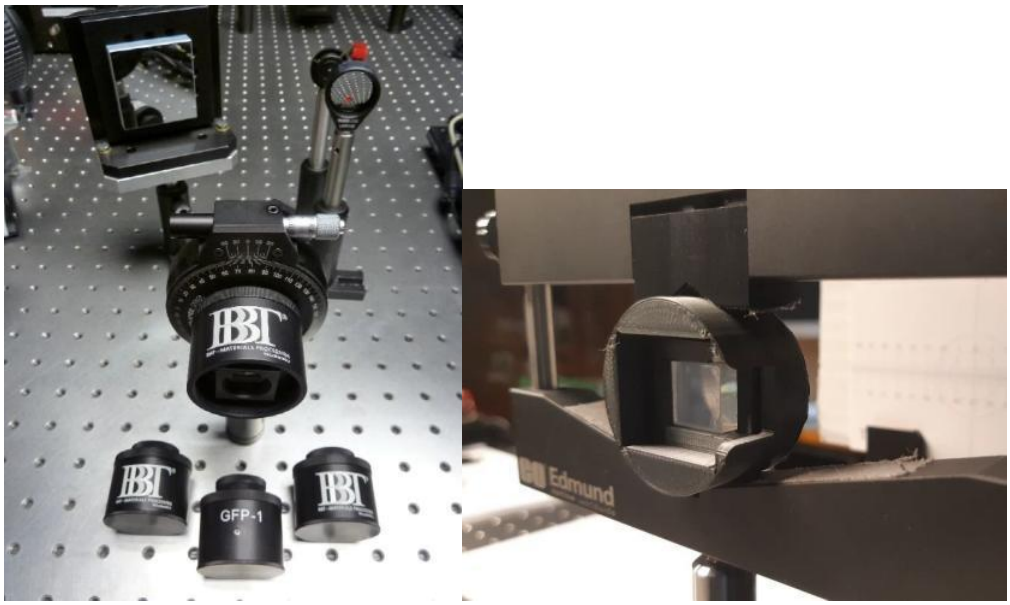
Table 17-2: Spectral ranges of the IR spectrum

IR spectrum	Spectral range	
Near IR spectrum (NIRS)	0.78 µm to 3 µm	Thermal infrared (TIR)
Medium wavelength IR spectrum (MIRS)	3 µm to 8 µm	
Long wavelength IR spectrum (LIRS)	8 µm to 15 µm	
Far infrared	15 µm to 1,000 µm	

Sources: Zeiss (https://www.zeiss.de/spectroscopy/loesungen-und-anwendungen/measuring-principle/nahinfrarot-spektroskopie.html#die-wissenschaft) et al., in (Deubzer et al. 2021); Land/AMETAK (https://www.ametek-land.com/pressreleases/blog/2021/june/thermalinfraredrangeblog)

The below figure shows examples of optical polarisers.

Figure 17-1: Calomel based optical polarisers mounted in protective housings

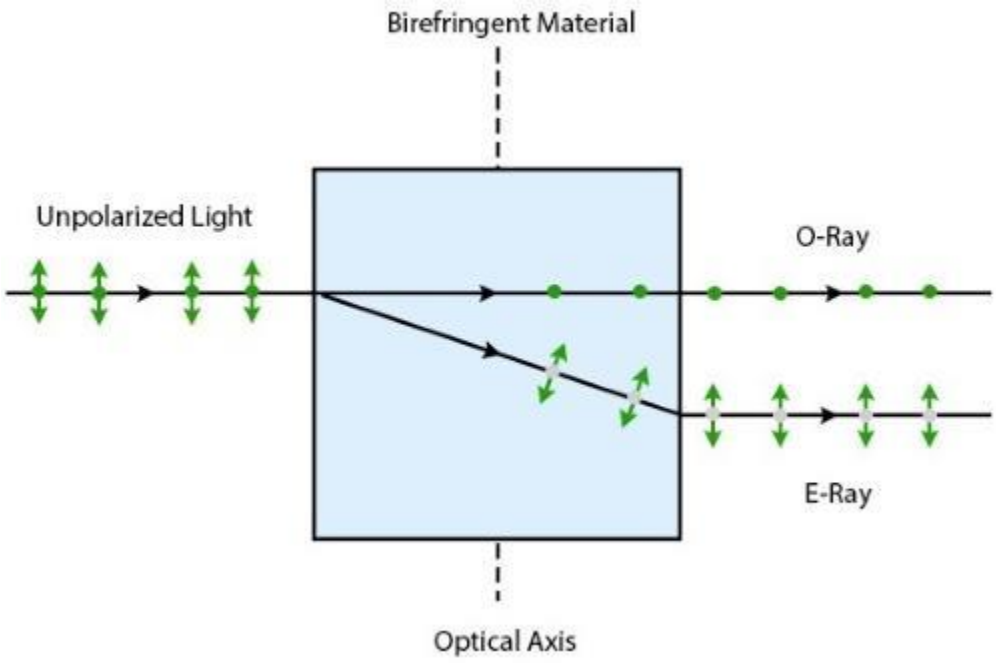


Source: (BBT 2022)

The current optical market of MWIR/LWIR polarizers is covered only by wire-grid or holographic types of polarizers. These types provide only low, or limited ER values and damage threshold which limit the final application performance of the products. The combination of calomel's two unique material properties: a high value of birefringence (n_o=1.973, n_e=2,656 @ 589 nm) and a wide transparency range makes it a great candidate for infrared polarizers.

(BBT 2023a) explain „birefringence: In an optically anisotropic medium (in this case, a crystal), the speed of light depends on the direction of propagation and polarisation. As a result, the incoming unpolarized light beam splits into two polarised beams (ordinary (O-ray) and extraordinary (E-ray) whose polarizations are perpendicular to each other. These beams propagate through the crystal at different speeds and as a result propagate in different directions. This phenomenon is called birefringence. Figure *17-2* illustrates the situation.

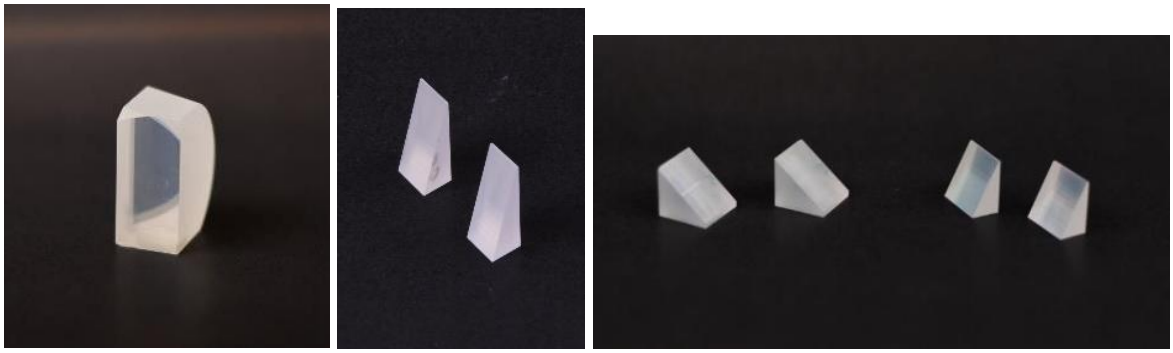
Figure 17-2: Birefringence



Source: Go Photonics, https://www.gophotonics.com/community/what-is-birefringence, referenced by (BBT 2023c)

*In terms of material, (BBT 2022) distinguish two main types of optical polarizers: **polymer film polarizers or grid polarizers**, and **crystal (prism) polarizers**.*

Figure 17-3: Different types of polarization prisms made from mercurous chloride crystalline material



Source: (BBT 2022)

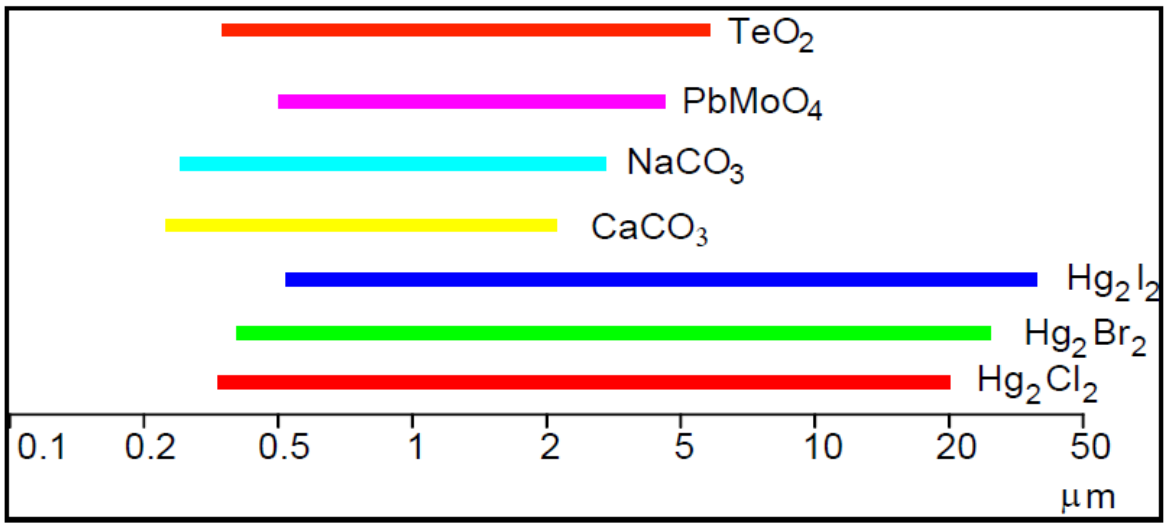
The film/grid polarizers are the order of magnitude cheaper (especially applies to film polarizers) compared to crystal polarizers but film/grid polarizers exhibit lower extinction ratios (ER, 10^2 -10^3) and due to the higher absorption (50-90 %) in the IR spectrum, they are not good for high power laser applications.

The crystal polarizers (calomel based prism) exhibit high ER (up to 10^4 – 10^5), transparency (95-98%) and high optical resistance. (BBT 2022)

A typical and traditional representative material of crystal polarizers is a Calcite. Calcite ($CaCO_3$) is a naturally occurring birefringent crystal with excellent polarization properties including very high extinction ratio and transmission efficiency. Unfortunately, Calcite material exhibits only limited transmission performance in a wavelength bands from 320 nm

to 2.300 nm. Figure 17-4 proves that mercury halides (including calomel) cover much wider a spectral region than other optical materials. (BBT 2022)

Figure 17-4: Comparison of optical transmission spectra of calomel vs. other materials with logarithmic scale



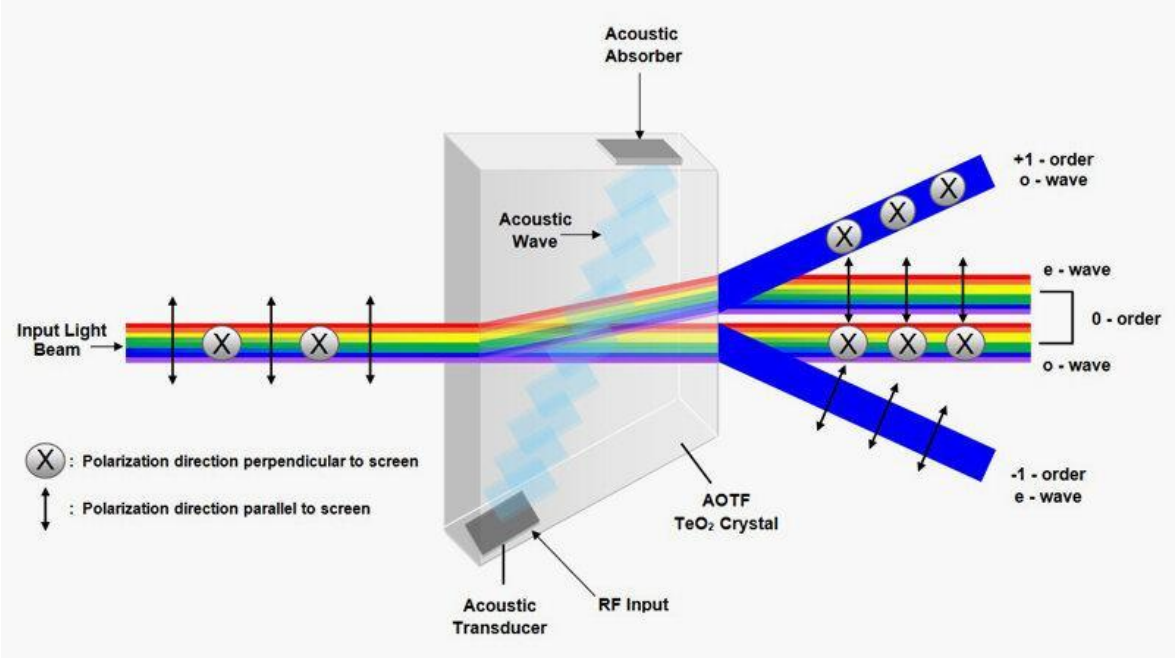
Source: (BBT 2022)

Acousto optical filters

According to (BBT 2022), calomel is suitable for the construction of acousto-optical (AO) devices such as AO tuneable filters (AOTFs), AO deflectors (AODs), and modulators (AOMs). (BBT 2023b) define these as three different types of acousto-optic devices that use acoustic waves to control and modify the passage of light through optical materials.

(BBT 2023b) describe AOTFs as optical devices that can selectively transmit - or block - certain wavelengths of light based on specific acoustic wave frequencies that propagate through an optical material, e.g. calomel. Figure 17-5 illustrates their components and functionality.

Figure 17-5: Schematic description of AOTF functionality



Source: Brimrose, https://www.brimrose.com/fiber-coupled-ao, source as referenced by (BBT 2023c)

According to (BBT 2023b), AOTFs cause diffraction of incident light whereby the angle of diffraction is directly related to the wavelength being filtered. AOTFs are often used in spectroscopy and spectral analysis to quickly change the sensing wavelength.

*AODs uses the same physical principle as AOTFs but are used for **light beam direction control** and fast scanning in a variety of applications, including sound-guided lasers, laser scanning systems, laser-based printing, and laser material processing. (BBT 2023b)*

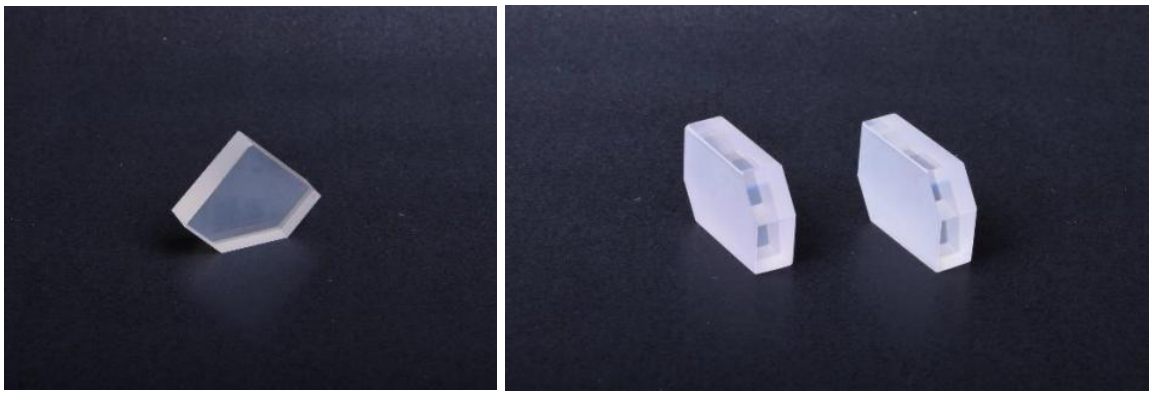
*AOMs are used to modulate the intensity or phase of a laser beam by varying the intensity of the acoustic wave. Its purpose is **to modulate light.** In other words**,** by controlling the intensity of the acoustic wave, the intensity or phase of the diffracted light can be controlled. This is particularly useful in laser communication, optical signal processing and generally wherever amplitude modulation or phase shift is needed. (BBT 2022)*

(BBT 2023b) put forward that calomel's figure of merit is comparable with tellurium dioxide (TeO_2) and more than one order better than lead molybdenate $PbMoO_4$. Moreover, the transparency of calomel (0.38 to 17 µm) enables the use of AO units in a broad spectral range (compared with TeO_2 which is limited only up to 5 µm) covering an additional part of the thermal IR region where no other materials can be applied. No other tuneable acousto-optical filter for the TIR region is currently available on the market which demonstrates the significant market advantage for this material. (BBT 2022)

Other optical elements

Optical elements as filters, beam-splitters, prisms, and windows offer a variety of non-polarizing optical elements for operating light sources from the SWIR to TIR spectral regions. (BBT 2022)

Figure 17-6: Custom made calomel optical components

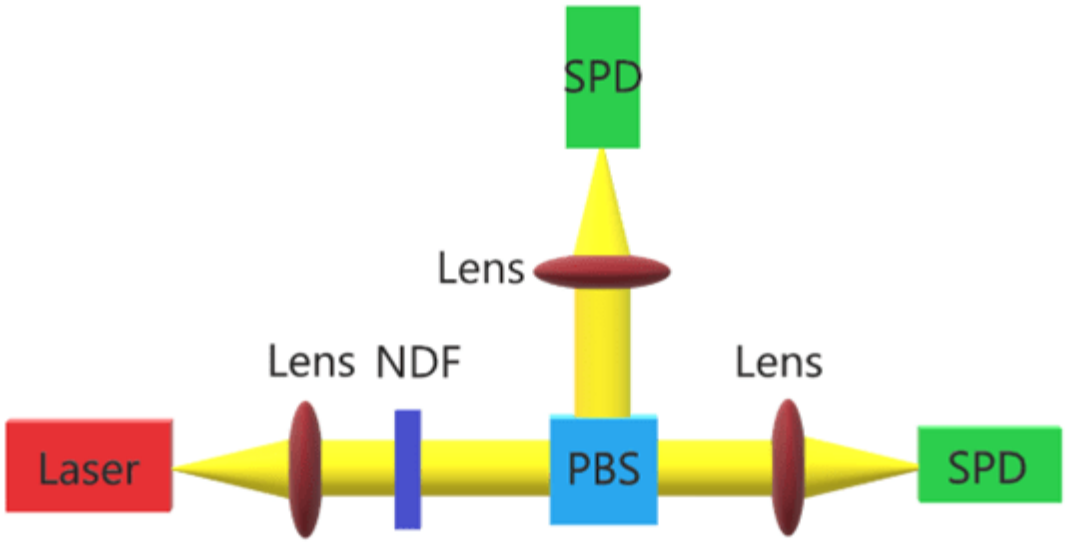


Source: (BBT 2022)

Custom made optical components may be supplied in different shapes, angles and configurations, and may be used for a wide range of applications, such as OPD (optical path difference), spectroscopy or sample substrates. It may be also used in IR optical systems, where other IR transparent materials are struggling with low damage threshold or transparency. (BBT 2022)

In the last year and a half since their application, (BBT 2023a) started developments of, among others, quantum mechanical devices like quantum random number generators (QRNGs) which use calomel optical elements. QRNGs work on a completely different principle, the principle of quantum mechanics. Briefly and simplified it starts with a source that generates single photons (Laser in the picture below). The single photon is sent to a beam splitter (PBS), made of calomel, as well as the polarizing optics used, which can let it pass through or reflect it, each with a 50 % chance. Before the photon hits the beam splitter, it exists in two possible states at once (= Quantum Superposition). After the beam splitter, the photon goes through a device that measures its polarization state (SPD). The result of the polarization measurement is used to create a random '0' or '1' bit. Several additional steps may be performed afterwards to ensure that the numbers generated are truly random and secure.

Figure 17-7: Quantum Random Number Generator



Source: (BBT 2022)

PBS Polarising beam splitter

SPD Single photon detector

NDF Neutral density filter

(BBT 2023a) believe that the three technologies "polarisation optics", "acousto-optics" and "optical elements" are general enough to cover all the systems considered so far.

17.1.4. Amount(s) of restricted substance(s) used under the exemption

(BBT 2022) indicate the mercury content in the calomel compound to be 85 % (given by the standard atomic weight). The mass content depends on the size of the optical components produced, usually between 5-30 g, giving 4.25-25.5 g of mercury.

Considering the size of the optical market dealing with the infra-red polarization optics, (BBT 2022) expect annual production of around 100 pieces of polarization components with a growth rate around 10 % per year plus eventually another 50-100 pieces for custom designed products. (BBT 2022) are specifically engaged in the production of small optical pieces (approximately 0.5 – 4 cm^3 with a weight about 5 - 20 g per one piece), which means that the final output doesn't go beyond 3.5 kg per year.

17.2. Justification of the requested exemption

17.2.1. Substitution and Elimination of the restricted substance

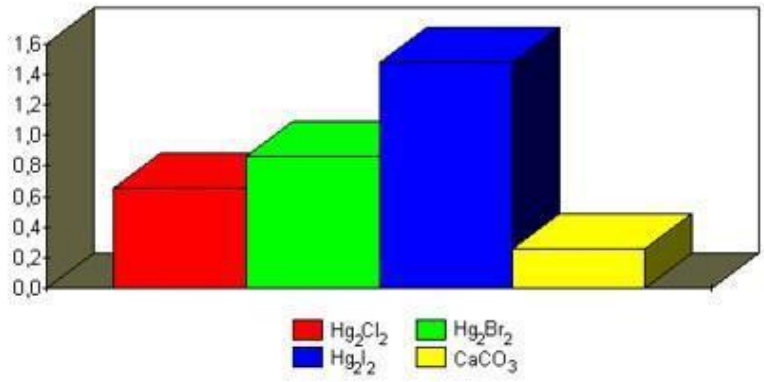
(BBT 2022) highlight the extraordinary characteristics of calomel:

- Broadband spectral range from the visible spectrum to TIR (0.38 µm to 17 µm).

- High value of birefringence (for example four times higher than Calcite, which is nowadays commonly used because of the lack of materials as good as calomel).
- Very high indices of refraction (n_o = 1.973, n_e = 2.656).
- Extremely low velocity of elastic wave propagation (347 m/s).
- Extremely high values for acousto-optical figures of merit.

In the second half of the last century, (BBT 2022) began a research trying to find some optically proper replacement for the commonly used calcite ($CaCO_3$) crystal in optics. Calcite exhibits birefringence almost as good as calomel, but its transparency, damage threshold and other parameters essential for optical and photonic use are insufficient. discovered the crystalline form of mercurous halides and its astonishing optical properties, some of them enormously outnumbering those of calcite or other known materials with birefringence values almost as good as calomel. Next to the broad spectral range of calomel (c.f. Figure 17-4 on page 321), (BBT 2022) illustrate its high birefringence compared to calcite in Figure 17-8.

Figure 17-8: Birefringence values for mercurous halides and calcite



Source: (BBT 2022)

There is no other optical material combining such optical properties as mercurous chloride. (BBT 2022) therefore consider looking for substitutes as ineffective.

17.2.2. Environmental, health, safety and socioeconomic impacts

(BBT 2022) point out that calomel monocrystal is a highly durable and stable compound, with almost endless lifetime cycle. When handling properly, there is zero risk of material decomposition and/or degradation. Naturally occurring crystals of calomel are present in nature for thousands of years without any change. The only possible way of the product degradation is a mechanical damage by user, or accidental deposition to ultraviolet or X-ray radiation. Their products are designed to be used by photonics specialist or industry engineers for simple application, however, when use is no more possible because of the above mentioned cases, calomel parts should be dismantled and sent for proper treatment back to the manufacturer. Other parts of electronic devices (that are using calomel) should be recycled accordingly.

As to socioeconomic impacts that might arise if the exemption is not granted, (BBT 2022) are afraid that progress of scientific research would be reduced in some sectors due to

absence of suitable materials for IR polarization, acousto-optics, laser and/or microscopy devices which would affect exploration.

17.2.3. Roadmap towards substitution or elimination of the restricted substance

The applicant does not present a roadmap to substitute or eliminate the use of mercury in applications in the scope of the requested exemption.

17.3. Critical review

17.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Annex XVII of the REACH Regulation contains several entries restricting the use of mercury and of mercury compounds. Entry 18 restricts[72] placing on the market, or use, as substances or in mixtures mercury compounds where the substance are intended for certain uses, e.g. in treatment of industrial sewage or for the impregnation of heavy-duty industrial textiles and yarn.

Mercury in the applications in scope of the requested exemption is not used for any of the above applications, and the restrictions are therefore not applicable.

Entry 18a[73] restricts the use of mercury:

- *in fever thermometers;*
- *in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers);*
- *in a number of specified measuring devices intended for industrial and professional uses, in particular barometers, hygrometers, manometers, sphygmomanometers[74],*

[72] ECHA, https://echa.europa.eu/documents/10162/5a7222b0-9d3a-4a90-9e55-258149e92b1a

[73] ECHA, https://echa.europa.eu/documents/10162/dbcaaec7-bd5b-4a7d-b164-23fa97950a86

[74] Device used to measure blood pressure.

strain gauges to be used with plethysmographs[75], tensiometers, thermometers and other non-electrical thermometric applications, mercury pycnometers and mercury metering devices for determination of the softening point.

To the consultants' best knowledge, the applications in scope of the requested exemption do not include the use of mercury in any of the above products/articles so that the above restrictions do not apply.

Entry 62 lists several phenylmercury compounds[76], which are, however, not related either the use of mercury in the applications in the scope of the requested exemption.

No other relevant entries in regard to the use of mercury could be identified in Annex XIV and Annex XVII. Based on the current status of these Annexes, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

17.3.2. Compliance with the Mercury Regulation

Mercury is also restricted in certain applications through the Mercury Regulation 2017/852 implementing the international Minamata Convention on Mercury of 2013. The Mercury Regulation refers to the RoHS Directive in Article 8(1) on *"New mercury-added products and new manufacturing processes"* and stipulates that *"Economic operators shall not manufacture or place on the market mercury-added products that were not being manufactured prior to 1 January 2018 ('new mercury-added products') unless authorised to do so by means of a decision taken pursuant to paragraph 6 of this Article or allowed to do so under Directive 2011/65/EU of the European Parliament and of the Council"*.

If the COM grants the requested exemption the use of mercury would be allowed under Directive 2011/65/EU so that the above restriction would not be applicable. The coherence with the Mercury Regulation should therefore be established if the exemption is granted.

17.3.3. Timing of the exemption request

(BBT 2023a) launched their first standardised calomel products (Glan Foucault and Wollaston polarizers) in 2019, with some tailor-made products having been delivered even earlier. This situation raises the question why the applicant requests the exemption now, several years after mercury-containing optical elements had begun to be placed on the market. No exemption of RoHS Annexes III or IV have covered the use of mercury in optical components.

(BBT 2023a) explain that those components were mainly used for research and development (R&D), and for scientific activities, not for commercial purposes. However, over time, the company transformed from a research institute to an SME and therefore focused on commercialisation. At that time, the company realised that RoHS is necessary to facilitate its penetration of the world market (not only the EEA market, but also the Asian

[75] Device for measuring changes in volume within an organ.

[76] ECHA, https://echa.europa.eu/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

and American markets were being considered). (BBT 2023a) claim that this exemption will significantly increase their competitiveness in the market. The parameters of this optical material significantly exceed those of the components used so far.

The applicant refers to Art. 2(4)(j) which excludes from the scope of RoHS *equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis*. Assuming that Art. 2(4)(j) is applicable, the applicant's explanation is plausible that entering other markets in the European Economic Area (EEA) brings the applicant's calomel products into the scope of the RoHS Directive, which explains why the applicant had not requested the exemption prior to 2019 already.

17.3.4. BBT as only applicant and producer

BBT are the only applicant requesting this exemption. They were therefore requested to explain why no other producers or stakeholders request or at least support the exemption request. (BBT 2023b) claim that they (BBT) are the ***only manufacturer and supplier of calomel single crystals and calomel-based optical components in the world****.*

An investigation on the internet showed that two companies[77] offer devices with calomel components of the sort described by the applicant, which seems to contradict the applicants' above statement.

Upon request, (BBT 2023c) state that BBT produce the calomel devices for Knight Optical, a producer and distributor of scientific optical components. (BBT 2023c) further explain that the French Fastlite Group owns approximately one third of BBT due to a capital investment in BBT around 2010, due to the outstanding acousto-optic parameters of the calomel cuts. Thus, it is still the case that BBT is the only manufacturer of the elements mentioned.

This situation explains why no other producers of calomel optics applied for this exemption or supported the applicant's exemption request. Still, BBT's exemption request has not been supported by producers of EEE who want to use the applicant's calomel optical components in their EEE.

(BBT 2024a) explain this situation pointing out that their various technologies are in different stages of development. Users/producers have expressed their interest. However, they have identified the lack of legislative approval such as RoHS as a problematic point. For the development of an FTIR spectrometer in collaboration with the Italian company NIREOS (nireos.com), it was considered necessary to have a RoHS exemption before launching a commercial campaign and obtaining a sufficient competitive advantage.

17.3.5. Scope clarification

(BBT 2022) request the new exemption for cat. 9 IMCI, and for cat. 11. To ensure a correct scope of the exemption, the categorisation of BBT's equipment was discussed with the

[77] C. f. Fastlite, https://fastlite.com/categorie/mid-ir-lwir-optics/, and Knight Optical, www.knightoptical.com

applicant. It was clarified with BBT which of their products are actually used as components for other EEE, and which ones are EEE for themselves that are used by end users. For their products, (BBT 2024a) could not think of any cat. 11 EEE which would either be an EEE for itself or be used as a component in cat. 11 EEE, and they agreed that the exemption is not required for this category.

(BBT 2023b) specify their products as follows:

- Polarizers and prisms for polarizing optics are usually sold as components that must then be integrated into the EEE. A manufacturer will build e.g. a polarising IR camera.
- FT spectrometers and interferometers are end products.
- AO components can be used both as end products namely for research and development purposes, and as components of other EEE.
- In QRNG or QKD (Quantum key distribution), the calomel-based components, specifically the beam splitter and a type of polarizer, are used as components while the devices themselves are the end product.

(BBT 2023c) were asked to fill out the below table to clarify which categories of EEE may be of relevance besides cat. 9 IMCI.

		Calomel EEE[78]	Calomel components		Calomel EEE and components
Calomel technology	Component or EEE	EEE category other than cat. 9 IMCI	EEE in which component is used if different from EEE of cat. 9 IMCI	Cat. of EEE in which component is used if different from cat. 9	Product example for calomel EEE, or EEE which contain calomel components
Acousto-optical (AO) components & devices	AO tuneable filters (TF)	-	-	-	Hyperspectral camera
	AOTF	3	AOTF	-	Optical spectral analyser (OSA)
	AO modulators (M)	-		-	A confocal microscope
	AOM	-		-	Laboratory & lasers
	AOM	3	AOM	-	Optical communication lasers
	AOD	3	AOD	-	Laser printer, Laser scanner, Laser material processing
Polarisation optics & device	Polarisers	-	-	-	IR Camera
	Polarisers	-	-	-	Astronomical telescope
	Polarisers	-	QKD	3	QKD
	Depolarizers	-	-	-	Microscope, Spectrometer
	Beam Splitter	-	-	-	Microscope, Spectrometer,
	Beam Splitter	-	QRNG	3	QRNG
	Savart plate	-	-	-	IR camera, ultra-high sensitive detectors
	Wave plate	-	-	-	Laboratory optical setup
	Specific cut	-	-	-	Hyperspectral FT interferometer
	Specific cuts[79]	-	-	?	?*

Table 17-3: Classification and categorisation of calomel element uses

Source: (BBT 2023c)

According to (BBT 2024a), Savart plates are usually manufactured in either calcite or quartz from two equal thickness plates of birefringent material cemented together, each with their optic axes at 45° to the surface normal and rotated through 90°with respect to each other. Light entering the first plate is split into its two constituent polarization states, the ordinary and extra-ordinary polarized rays. The ordinary ray propagates undisturbed, but the extra-ordinary ray is displaced parallel to one edge. On entering the second crystal, the ordinary ray in the first crystal becomes the extra-ordinary ray in the second crystal and is displaced in a direction perpendicular to the first beam displacement. Each polarization component effectively passes through its own shearing interferometer and produces a set of straight line fringes. Savart plates made of calomel can measure 4 times weaker polarized signals than calcite ones and in addition it works in IR region where calcite does not work anymore.

In most cases where the calomel optical elements are used as components, the applicant refrained from categorising the EEE in which they are used. The product examples in the table show that most of these EEEs could be cat. 9 IMCI, or possibly cat. 8 medical devices. According to the above table, cat. 3 is of relevance for the calomel elements as well.

(BBT 2024a) agree that the scope of the exemption should only include categories 3, 8 and 9 IMCI whereas cat. 11 is not applicable.

17.3.6. Substitution and elimination of the restricted substance

The applicant highlights the unique individual properties and their combination in calomel optics which differentiate it from other materials that could potentially be used as well:

- Broadband spectral range from the visible spectrum to TIR (0.38 µm to 17 µm).
- High value of birefringence (for example four times higher than Calcite, which is nowadays commonly used because of the lack of materials as good as calomel.
- Exceptionally high extinction ratio in the MWIR/LWIR spectral band
- High transparency (95-98 %) and high optical resistance
- Very high indices of refraction (n_o = 1.973, n_e = 2.656).
- Extremely low velocity of elastic wave propagation (347 m/s).
- Extremely high values for acousto-optical figures of merit.

BBT substantiate this claim with examples, e.g. with calcite exhibiting birefringence almost as good as calomel, but inferior transparency, damage threshold, etc.. For acousto-optic applications, the figure of merit of TeO_2 is comparable to calomel but is limited in its application by its narrower spectral range so that only calomel-based tuneable acousto-optical filters are currently available for the TIR region.

It is, however, questionable whether and how far these properties and/or the combinations thereof are required in all uses. Figure 17-4 on page 321 shows that mercury-free polarizers operate in the wavelength spectrum up to around 5 µm, like the above-mentioned TeO2 (BBT 2022) state that calomel's figure of merit is comparable with TeO2 in acousto-optic applications, and possibly also in other uses where the extended spectral range of calomel is not relevant.

(BBT 2023a) agree that in theoretical terms it could be possible, but the advantage of calomel is not only that it covers a wavelength > 5 µm but that it covers a wavelength > 5 µm plus(!) the visible (VIS) and short-wave infrared (SWIR) spectrum (cf. Figure 17-4 on page 321). E.g., each molecule has specific vibrational bands that are characteristic of its structure and chemical bonds, across the entire VIS (visible) and TIR (thermal infrared) bands.

(BBT 2024b) explain vibrational bands as the effect when a molecule absorbs IR radiation which it causes chemical bonds in the molecule to vibrate (resonates) it leads to absorption bands that are specific for the molecule and can be used for its detection. According to (BBT 2023a), usingthe example of an AOTF (acousto-optic tuneable filter), this device makes possible the electrical tuning of specific wavelengths. Should the device be placed on a satellite for the purpose of remote sensing of the earth, the greatest added value is the

ability to compare over as many wavelengths as possible. The proposed limitation would restrict the use to almost 30 %. In addition, we would have to place additional equipment there for other wavelengths, which inevitably increases the weight and power consumption, both of which are undesirable. Similar examples may be found for spectrometers.

Space applications are excluded from the scope of the RoHS Directive. The applicant was therefore requested to substantiate the demand for the broad spectral range of calomel optics with example EEE that are in the scope of the RoHS Directive.

(BBT 2023c) explain that such remote sensing imaging devices can be applied on platforms for terrestrial applications like drones, automobiles, or also handheld applications e.g. in the case of civil security, power engineering or the civil engineering industry. For further advantages of EEE using calomel, (BBT 2024a) exemplarily point out the case of a hyperspectral infrared camera with calomel polarization optics which can not only operate in the thermal infrared region like other conventional cameras, but additionally is capable of applying a polarization effect in this spectral region and exhibits an unprecedentedly higher degree of polarization than other systems. The user can benefit not only from conventional non-polarized infrared data, and in addition has information about the polarization of the detected signal, which significantly increases the information value of the acquired data. Specific advantage could be seen by availability of a detection of absorption lines from VIS up to LWIR.

As an example for the specific differences which the calomel optics can make, (BBT 2024a) state that the four times higher degree of polarization [efficiency] of calomel compared to calcite polarizers generates signals or images that are four times more contrasting. In practice, this means that weakly polarized signals that are not detected by calcite polarizers can still be detected. In addition, calcite is transparent only in a very limited spectral region of 0.3 - 2.3 µm. Additionally and of relevance for polarization and acousto-optical uses, calomel, unlike calcite and other mercury-free materials, has an unrivalled resistance to high power lasers. (BBT 2024a) thus deem the role of calomel to be unique and without substitution.

The consultants understand that the broad spectral area which calomel optical elements can cover increases the operational range of EEE in which these elements are used.

The applicant was also asked whether there are any products that did not exist prior to the introduction of calomel optical elements, i.e. that these products cannot be built without the calomel optical elements.

(BBT 2024a) name compact Fourier transform infrared spectrometers and high-efficiency polarization optics for thermal infrared polarizers such as Glan-Foucault, Glan-Taylor, Wollaston, Glan-Thompson polarizers, half- and quarter-wave plates, Savart plates, etc.

The above products are, however, products that can be produced from other birefringent materials like magnesium fluoride, quartz, rutile, and yttrium orthovanadate.[80] The applicant's statement as to the products that cannot be manufactured without calomel optical elements thus only refers to the performance of these products. The existence of the

[80] See for example Thorlabs, https://www.thorlabs.com/navigation.cfm?guide_id=2458

mentioned types of products (Glan-Foucault, Wollaston polarisers etc.) per se does not depend on the availability of calomel optical elements.

The birefringent materials identified on the internet - magnesium fluoride, quartz, rutile, and yttrium orthovanadate – were not mentioned in BBT's exemption request. The applicant was therefore requested to explain the performance of these materials compared to calomel. (BBT 2024b) submitted the below tables.

Table 17-4: Parameters of acousto-optic materials

Crystal	Transmission [nm]	Refractive indices, n_e, n_o [-]	Density, [g/cm^3]	Acousto-optic figure of merit, M2 [10^{-15}s^3/kg]	Damage threshold [J/cm^2]
Hg_2Cl_2 (Mercury(I) chloride, calomel)	400-17000	n_o = 1,898 n_e = 2,445 @ 10000 nm	7,19	640	5x10^7 @ 1064 nm
SiO_2 (Quartz)	180-2300	n_o = 1,450 n_e =1,460 @ 2000 nm	2,203	2,4	20 @ 1064 nm
TeO_2 (Tellurium dioxide, Paratellurite)	350-5000	n_o = 2,02 n_e =1,94 @ 2000 nm	5,99	793	n/a
$PbMoO_4$ (Lead molybdate)	420-5500	n = 2,2679 @ 2000 nm	6,86	20,969	0,00491 @ 532 nm
KRS-5 (Thallium bromoiodide TlBr-TlI)	530-50000	n_o = 2,23 n_e =2,21 @ 2000 nm	7,56	1200	50 W/cm^2
$LiNbO_3$	420-5200	n_o = 2,204 n_e =2,282 @ 2000 nm	4,3	11,62	0,48 @ 800 nm

Source: (BBT 2024b)

(BBT 2024b) explain that the materials with the highest values of acousto-optic figure of merit are Hg_2Cl_2, TeO_2 and KRS-5. KRS-5 is transparent for an even broader wavelength spectrum than Hg_2Cl_2 but has a tendency to cold-flow so that the shape of these optics may change over time, and it is a toxic material. Lead molybdate actually exhibits the highest acousto-optic figure of merit but cannot be used as a substitute for calomel due to its lead content.

Table *17-4* and the applicants' explanations show that calomel is not the only material exhibiting good acousto-optic properties.

Table 17-5: Parameters of birefringent crystals

Crystal	Transmis-sion[nm]	refractive indices, n_e, n_o [-]	birefringence $\Delta n = n_e - n_o$	extinction ratio, ER [-]	Damage threshold [W/cm²]
Hg_2Cl_2 (Mercury(I) chloride, calomel)	400-17000	n_o = 1,898 n_e = 2,445 @ 10000 nm	+ 0,547	1:15000 for 3000-5000 nm 1:25000 - 1:100000 for 7000-15000 nm	>5x10⁷ @ 1064 nm*
$CaCO_3$ (Calcite)	300-2300	n_o = 1,658 n_e =1,486 @ 2000 nm	-0,172	1:20000 for 300-2300 nm	20 @ 1064 nm
YVO_4 (Yttrium orthovanadate)	488 - 3400	n_o = 1,964 n_e = 2,155 @ 2000 nm	+0,191	1:100000 for 900-400 nm	10 @ 1064 nm
α-BBO (Alpha-barium borate)	190-3500	n_o = 1,808 n_e = 1,586 @ 2000 nm	-0,222	1:100000 for 190-3500 nm	10 @ 1064 nm
MgF_2 (Magnesium fluoride)	200-6000	n_o = 1,330 n_e =1,347 @ 2000 nm	+0,017	1:10000 for 200-6000 nm	10 @ 1064 nm
TiO_2 (Titanium dioxide, rutil)	500-4500	n_o = 2,45 n_e =2,53 @ 2000 nm	+0,08	1:100000 for 2200-4000 nm	0,34 @ 800 nm
CaF_2 (Calcium fluoride)	180-8000	n_o = 1,42 n_e =1,39 @ 2000 nm	-0,03	1:150 for 3 µm 1:300 for 8 µm	2 @ 2050 nm
ZnSe (Zinc selenide)	600-22000	n_o = 2,58 n_e =2,65 @ 2000 nm	+0,07	1:150 for 3 µm 1:300 for 10 µm	200 @ 2940 nm

Source: (BBT 2024b)

(BBT 2024b) explain that calomel exhibits the highest birefringence, the widest range of spectral transmittance, high damage threshold and extinction ratio. The positive value of the birefringence is convenient when investigating ordinary beams which are less sensitive to material inhomogeneities. Another advantage of calomel is it´s high resistance to damage. When using a laser, calomel did not show any damage under the given conditions.

The table shows that calomel exceeds the performance of the other materials in the parameters listed. The extinction ratios are, however, not comparable since they are related to specific wavelength spectra.

Overall, calomel shows better performances in many of the parameters than other birefringent and acousto-optic materials even though mercury-free alternatives outperform calomel in some individual properties. A specific quality of calomel is the combination of these good performance parameters which other materials cannot offer. It is, however, to be noted that mercury-free birefringent and acousto-optic materials are available.

Since, in the absence of the requested exemption, calomel so far could not be applied in EEE that falls into the scope of the RoHS Directive due to the missing exemption, these mercury-free materials were the only birefringent and acousto-optic materials which the market could offer. Recommending the exemption to be granted can therefore be justified

with Art. 5(1)(a) for those cases where the performance of mercury-free materials is not sufficient so that the specific properties and combination thereof which calomel can offer are actually required. In this field, substitution and elimination of mercury is scientifically and technically still impracticable. The wording and scope of the respective potential exemption must safeguard this condition.

17.3.7. Wording of the exemption

The consultants proposed a wording based on the applicant's proposal and additionally 12 specific performance parameters to describe the conditions where the performance of mercury-free materials is not sufficient so that the use of calomel can be justified.

(BBT 2024c) stated that some of these parameters are interdependent and suggested the below ones that are independent from each other:

> Optical components made of mercurous chloride monocrystal (calomel) where at least one of the below conditions applies:
>
> a) The **wavelengths to be detected**, tuned, manipulated or used otherwise include the spectrum 3 - 17 µm
> b) **Value of birefringence** of more than +0,50
> c) **Indices of refraction** of no > 1,89 and ne > 2,44 at λ = 10,6 µm, and no > 2,11 and ne > 3,18 at λ = 0,38 µm
> d) **Extinction ratio** of more than 1 : 20 000 in the infrared wavelength spectrum between 3 - 17 µm.
> e) **Velocity of elastic wave propagation** less than 400 m/s
> f) Value for **acousto-optical figure of merit** of M2 = 640 x 10-15 s^3/kg at λ = 632.8 nm or higher
> g) **Damage threshold** more than 5 x 10^5 W/cm^2 at λ = 1 064 nm
> h) **Transmissivity** of more than 60 % in the spectral range of 0,38 µm to 17 µm

This wording was discussed with (BBT 2024d, 2024e) via questionnaires and in a web conference to clarify last wording details until (BBT 2024e) agreed to the below wording:

Table 17-6: Wording of the exemption elaborated with the applicant

No.	Exemption
III-X	*Mercury in optical materials made of mercurous chloride monocrystal (calomel) for use in applications requiring a polarising material or in acousto-optic applications, if at least one of the below properties is required:* *a) A crystal material is required for the specific application, and its transmission must include at least one wavelength in the spectrum from more than 8 µm up to 17 µm.* *b) Indices of refraction of n_o > 1,89 and n_e > 2,44 at 10,6 µm wavelength, and n_o > 2,11 and n_e > 3,18 at 0,38 µm wavelength, as well as a birefringence of more than +0,5 at any part of the wavelength spectrum from 0,38 µm to 17 µm.* *c) Extinction ratio of more than 1:20 000 in the infrared wavelength spectrum between 3 µm and 17 µm.*

	d) Velocity of elastic wave propagation of less than 400 m/s *e) Value for acousto-optical figure of merit M2 = 640 x 10^{-15} s^3/kg at 632,8 nm wavelength* *f) Damage threshold of more than 5 x 10^5 W/cm^2 at 1.064 nm*

The number of sub-clauses was reduced by merging the sub-clauses addressing the birefringence (sub-clause b)) and refraction (sub-clause c)) of the first proposal, and the transmissivity clause was skipped since this property does not sufficiently differentiate calomel from mercury-free alternatives.

The formulation of sub-clause a) takes account of the fact that calomel on the one hand offers a broad transmission for wavelengths between 0.38 µm and 17 µm which, however, is outperformed by the transmission range of zinc selenide (ZnSe) and KRS-5 on the upper end of the wavelength spectrum. On the other hand, calcium fluoride (CaF_2) has a transmission up to 8 µm and should thus demarcate the field where mercury-free alternatives are available for the wavelength spectrum of 8 µm and less. To exclude the use of calomel from this field, the lower wavelength limit for the use of calomel was set at 8 µm. Still, however, the wavelength spectrum of calomel in the range of more than 8 µm up to 17 µm overlaps with the transmission ranges of ZnSe and KRS-5 which both also cover the spectral range from 8 µm to17 µm. This would allow the use of calomel for wavelengths of 8 µm and more for which mercury-free alternatives are available. The wording therefore needed to be refined to exclude these potential abuses of calomel.

ZnSe has a broad transmission range but low birefringence and thus low polarisation efficiency, and it is not an acousto-optic material. Adding the condition that calomel can only be used “in applications requiring a polarising material or in acousto-optic applications” excludes the use of calomel in cases where only the transmission spectrum above 8 µm is required, for which ZnSe can be applied.

KRS-5 is not a crystal material. Introducing the additional condition into sub-clause a) in Table 17-6 that the specific application of the optical material requires the use of a crystal material excludes the use of calomel where the non-crystal mercury-free KRS-5 would be sufficient. The consultants noted that KRS-5 is toxic due to its content of thallium and that its use may therefore be of limited benefit compared to calomel. There is, however, no information available as to whether the use of KRS-5 instead of calomel is likely to outweigh the total negative environmental, health and consumer safety impacts, and as a matter of fact the use of KRS-5 as acousto-optic material is not legally restricted. Further on, in principle, other non-crystal materials may be made available on the market in the coming years that can be used as RoHS-compliant substitutes.

If a crystal polarizing or acousto-optic material is required, the formulation of sub-clause a) in Table 17-6 allows the use of calomel for wavelengths of 8 µm and less, as long as wavelengths of more than 8 µm and up to 17 µm are part of the required transmission spectrum. This avoids the case that a specific EEE conceived to operate at less than 8 µm and up to 17 µm must contain two different birefringent or acousto-optical materials:

- One material for the spectrum from 3 µm to 8 µm (mercury-free);
- A second material for the wavelengths of more than 8 µm up to 17 µm (calomel).

Since calomel can cover the entire spectrum from 3 µm to 17 µm, it can still be used in cases like the above one whereas the formulation of the sub-clause a) excludes its use if the specific application does not require the spectrum above 8 µm.

The other sub-clauses in the consultants understanding are also designed in a way that they facilitate the use of calomel where its specific properties are required and exclude its use where mercury-free alternatives provide sufficient performance.

The applicant was asked whether the exemption could be further restricted by requiring at least two of the exemption sub-clauses to be applicable instead of only one without excluding calomel from applications where its properties are required.

(BBT 2024d) stated that they would rather avoid meeting two sub-clauses. At the moment, we cannot think of any application where the physical parameters are not met, but it is more up to the end users.

The consultants think that, taking account of the fact that calomel is introduced into new market segments, it is acceptable to maintain the currently agreed wording. The applicant should, however, collect the necessary information to enable an informed decision on the further restriction of the exemption in case its renewal is requested later.

17.3.8. Environmental, health, safety and socio-economic impacts

The applicant describes in section 17.2.2 on page 325 environmental, health and safety impacts as well as socioeconomic impacts if the exemption is not granted. *(BBT 2024b) point out that KRS-5 as a material competing with calomel in its transmission and acousto-optic figure of merit, contains thallium that is very toxic by ingestion with cumulative effects, harmful in contact with skin, toxic to aquatic organisms, and may cause long term adverse effects in the aquatic environment. In calomel, the mercury is bound by a strong covalent bond, which means it can not be released from the molecule easily.*

(BBT 2023c) describe the largest terrestrial markets for remote sensing as an example of markets to which they would not have access if the exemption is not granted. The commercial figures describe the total market.

- *IR Cameras - Size USD 8.55 Billion (2022) and "cumulative average growth rate" (CAGR) of 7 % (2022 - 2023)*
  Possible ground applications for "calomel case" in: energy, civil engineering and in the automotive industry
- *Acousto-optics - size USD 469 million (2022), CAGR (2022-2023) 6.3 %*
  Possible ground applications for "calomel case" in: medical, communications, measurement and detection
- *Spectrometry - size USD 111 billion (2021), CAGR 6.2 % (2022-2031)*
  Applications: testing and scanning of drugs, raw materials detection
- *Lasers - size 1.7 billion (2022), CAGR 4.5 % (2023-2030)*
  Applications: communication, processing, measurement and detection.

If the exemption is not granted, the applicant sees disadvantages for research and development in the European Economic Area. The consultants cannot exclude thatthe potential related to the superior performance of calomel optical elements would actually not be accessible in this case so that such disadvantages may arise.

17.3.9. Summary and 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.

(BBT 2022) request an exemption for the use of calomel in optical elements. The available information suggests that BBT are the only producer of this material. BBT and their customers have been using calomel in applications outside the scope of the RoHS Directive in the past years and now see market potential for this material within the scope for which the exemption is required.

The applicant could not present substantial efforts to substitute or eliminate the use of mercury which is, however, reasonable in the consultants' understanding in the light of the up to now out-of-scope use of calomel.

Technically, calomel exhibits advantageous properties that are in few cases outperformed in individual parameters by mercury-free alternatives. Overall, and in particular in its combination of these properties, calomel is a material that enables higher performances in EEE of categories 3, 8 and 9 IMCI.

The consultants therefore conclude from the accessible information that calomel optical elements provide specific individual properties and combinations thereof which mercury-free alternatives cannot provide. Where these properties are required, **substitution and elimination of mercury in calomel are scientifically and technically not yet practicable**, and the use of mercury in the applications at hand does not weaken the environmental and health protection afforded by the REACH Regulation. The exemption can therefore be recommended to be granted in line with Art. 5(1)(a).

Mercury-free alternatives have been used in the past in the type of applications where calomel can be used as well, and these mercury-free materials should be continued to be used where their performance is sufficient. The consultants elaborated with the applicant a wording that restricts the use of calomel to applications where its specific properties are actually required (cf. section 17.3.7 on page 336) in EEE of categories 3, 8 and 9 IMCI.

17.4. Recommendation

The consultants recommend granting the exemption for use in categories 3, 8 and 9 IMCI. Calomel enables higher performances of acousto-optic devices and devices that apply polarising materials, for which substitution or elimination of mercury in calomel, or of calomel itself, is scientifically and technically not yet practicable.

To avoid the use of calomel where the performance of mercury-free materials is sufficient, the consultants propose the below wording.

No.	Exemption	Scope and dates of applicability
III-X	Mercury in optical materials made of mercurous chloride monocrystal (calomel) for use in applications requiring a polarizing material or in acousto-optic applications, if at least one of the below properties is required: a) A crystal material is required for the specific application, and its transmission must include[81] at least one wavelength in the spectrum from more than 8 µm up to 17 µm. b) Indices of refraction of n_o > 1,89 and n_e > 2,44 at 10,6 µm wavelength, and n_o > 2,11 and n_e > 3,18 at 0,38 µm wavelength, as well as a birefringence of more than +0,5 at any part of the wavelength spectrum from 0,38 µm to 17 µm. c) Extinction ratio of more than 1:20 000 in the infrared wavelength spectrum between 3 µm and 17 µm. d) Velocity of elastic wave propagation of less than 400 m/s e) Value for acousto-optical figure of merit M2 = 640 x 10^{-15} s^3/kg at 632,8 nm wavelength f) Damage threshold of more than 5 x 10^5 W/cm^2 at 1.064 nm	Applies to categories 3, 8 and 9 industrial monitoring and control instruments. Expires on (date of official publication + 5 years) for cat. 3, 8 and 9 industrial monitoring and control instruments.

Since mercury-free alternatives are not foreseeable to become available within the next five years, it is recommended to grant the exemption for the maximum validity period of five years.

BBT are expected to collect information for a potential future renewal request as to whether the exemption scope could be further narrowed by requiring two of the above sub-clauses to be applicable as a pre-condition for the use of calomel. Further on, the applicant should have undertaken efforts to substitute or eliminate the use of mercury and present a roadmap for further such activities in a future renewal request, and stakeholders are invited to contribute information concerning potential substitutes and alternative technologies to avoid the use of mercury in future stakeholder consultations.

Applicants' feedback on the recommendation

(BBT 2024e) agree to the above recommendation.

17.5. References

BBT (2022): RoHS Annex V Request for a new exemption for mercury in optical calomel components. RoHS Pack 27. BBT – Materials Processing (RoHS 29).

[81] This implies that calomel can be used for wavelenghts of 8 µm and less if at least one wavelenght in the spectrum of more than 8 µm up to 17 µm is required as well for the foreseen function/use of the EEE in which the calomel element is used.

BBT (2023a): Answers to questionnaire 1 (clarification questionnaire) sent via e-mail by Ondrej Ballada, BBT, to Dr. Otmar Deubzer. RoHS Pack 27. BBT – Materials Processing (RoHS 29). Retrieved from https://rohs.biois.eu/Ex-III-2022-1_NEW_BBT_Questionnaire-1_Clarification_.pdf.

BBT (2023b): Answers to questionnaire 2 sent via e-mail by Ondrej Ballada, BBT, to Dr. Otmar Deubzer. RoHS Pack 27. BBT – Materials Processing (RoHS 29).

BBT (2023c): Answers to questionnaire 3 sent via e-mail by Ondrej Ballada, BBT, to Dr. Otmar Deubzer. RoHS Pack 27. BBT – Materials Processing (RoHS 29).

BBT (2024a): Answers to questionnaire 4 sent via e-mail by Ondrej Ballada, BBT, to Dr. Otmar Deubzer. RoHS Pack 27. BBT – Materials Processing (RoHS 29).

BBT (2024b): Answers to questionnaire 5 sent via e-mail by Ondrej Ballada, BBT, to Dr. Otmar Deubzer. RoHS Pack 27. BBT – Materials Processing (RoHS 29).

BBT (2024c): Answers to questionnaire 6 sent via e-mail by Ondrej Ballada, BBT, to Dr. Otmar Deubzer. RoHS Pack 27. BBT – Materials Processing (RoHS 29).

BBT (2024d): Answers to questionnaire 7 sent via e-mail by Ondrej Ballada, BBT, to Dr. Otmar Deubzer. RoHS Pack 27. BBT – Materials Processing (RoHS 29).

BBT (2024e): Answers to questionnaire 8 sent via e-mail by Ondrej Ballada, BBT, to Dr. Otmar Deubzer. RoHS Pack 27. BBT – Materials Processing (RoHS 29).

Deubzer et al. (2021): 11th adaptation to scientific and technical progress of exemptions 2(c)(i), 3 and 5(b) of Annex II to Directive 2000/53/EC (ELV). Final report. In cooperation with Dr. Deubzer, Otmar, Fraunhofer IZM und UNITAR, UNITAR Christian Clemm und BioIS Shailendra Mugdal. Retrieved from https://data.europa.eu/doi/10.2779/373311

18. Exemption 1(a) of Annex IV: Pb and Cd in ion selective electrodes

The below Table 18-1 shows the wording, scope and expiry dates of the exemption.

Table 18-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
IV-1(a)	Lead and cadmium in ion selective electrodes including glass of pH electrodes	Applies to categories 8 and 9 and expires on - 21 July 2021 for category 8 other than in-vitro diagnostic medical devices (IVD) and for category 9 other than industrial monitoring and control instruments (IMCI); - 21 July 2023 for category 8 in vitro diagnostic medical devices; - 21 July 2024 for category 9 industrial monitoring and control instruments.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

BGS	Blood gas system
Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instruments
IVD	In-vitro diagnostic medical devices
POC	point of care
RoHS 1	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 Directive 2011/65/EU, current RoHS Directive

18.1. Background and technical information

On 19 January 2022, (COCIR 2022) requested the renewal of the exemption as displayed Table 18-2 for EEE of category (cat.) 8 in-vitro diagnostic medical devices.

Table 18-2: Wording and scope of the requested exemption

No.	Requested Exemption	Requested scope and dates of applicability
IV-1(a)	*Lead and cadmium in thick film pastes in ion selective electrodes used for blood gas systems.*	*Applies to category 8 in-vitro diagnostic medical devices and expires on 31 August 2026*

No contributions to the stakeholder consultation were made.

18.1.1. History of the exemption

Exemption 1(a) of Annex IV was not part of RoHS Directive 2002/95/EC (2003) (RoHS 1). It was first evaluated by (Goodman 2006) and subsequently listed on Annex IV of RoHS Directive 2011/65/EU (2011) (RoHS 2) when this was officially published in 2011.

Exemption 1(a) was first reviewed by (Deubzer et al. 2022). At the time, JBCE requested a renewal of the exemption for the use of lead in glass electrodes of three specific geometric forms (types) in EEE of cat. 9 monitoring and control instruments including industrial monitoring and control instruments (IMCI). (Deubzer et al. 2022) concluded that lead-free glass electrodes could not yet substitute leaded glass electrodes in all applications. This was based mainly on performance differences between lead-containing electrodes and their lead-free alternatives with respect to repeatability of measurements, tap water response time, and the ability to measure extreme ends of the pH spectrum. At the time, no application was received for a renewal of the exemption for cadmium. However, after the submission of the draft report, the consultants received information that cadmium was in fact contained in some ion selective electrodes that detect cadmium ions. Further, no application was received to renew the exemption for cat. 8 in vitro diagnostic medical devices at that time.

(Deubzer et al. 2022) recommended two exemption wording options, option A and option B. Option B takes into account that the renewal request was submitted by JBCE around three years earlier than the minimum 18 months prior to exemption expiry so that the evaluation of the exemption with relevance to cat. 9 IMCI also took place several years prior to the exemption expiry date. Therefore, in option B, the exemption for cadmium was recommended to be renewed for a limited period of time so that stakeholders not aware of the early review of this exemption had time to transition or apply for renewal. Both wording options are reproduced below, with option A displayed in Table 18-3 and option B in Table 18-4.

Although the applicants at the time had requested a renewal for the maximum validity period, i.e. 7 years, the consultants recommended a shorter period, as JBCE could not produce unambiguous evidence that the reliability of available lead-free alternatives was in fact not ensured. (Deubzer et al. 2022) stated that a renewal of the exemption for a time

frame below the maximum validity period would be sufficient to allow JBCE and other stakeholders to comprehensively test available lead-free electrodes against leaded electrodes and gather information on applications where repeatability, tap water response time and extreme ends of the pH spectrum are of relevance.

Table 18-3: Wording option A recommended by (Deubzer et al. 2022)

	Exemption	Scope and dates of applicability
1(a)	*Lead and cadmium in ion selective electrodes including glass of pH electrodes*	*Expires on 21 July 2023 for cat. 8 in vitro diagnostic medical devices*
1(a)(I)	*Lead in the stem glass of pH glass electrodes and ion selective electrodes equipped with a pH glass electrode with complex shape as following:* *- Micro type pH glass electrode* *Composite electrode that has a spherical or tube-shaped pH responsive glass membrane with a diameter of 4.0 mm or less and a reference electrode with a liquid junction at a position vertically within 6.5 mm from the tip;* *- Flat type pH glass electrode* *pH glass electrode with a flat pH response membrane at the tip of a glass tube with a diameter of 6.0 mm or more;* *- Needle type pH glass electrode* *Composite electrode that has a conical pH response membrane with a tip angle of 40 ° or less and with a diameter of 10 mm or more."*	*Expires on 21 July 2025 for cat. 9 monitoring and control instruments including industrial monitoring and control instruments.*

Source: (Deubzer et al. 2022)

Table 18-4: Wording option B recommended by (Deubzer et al. 2022)

	Exemption	Scope and dates of applicability
1(a)	*Lead and cadmium in ion selective electrodes including glass of pH electrodes*	*Expires on 21 July 2023 for cat. 8 in vitro diagnostic medical devices*
1(a)(I)	*Cadmium in ion selective electrodes including glass of pH electrodes*	*Expires on 21 July 2024 for cat. 9 industrial monitoring and control instruments*
1(a)(II)	*Lead in the stem glass of pH glass electrodes and ion selective electrodes equipped with a pH glass electrode with complex shape as following:* *- Micro type pH glass electrode* *Composite electrode that has a spherical or tube-shaped pH responsive glass membrane with a diameter of 4.0 mm or less and a reference electrode with a liquid junction at a position vertically within 6.5 mm from the tip;* *- Flat type pH glass electrode* *pH glass electrode with a flat pH response membrane at the tip of a glass tube with a diameter of 6.0 mm or more;* *- Needle type pH glass electrode* *Composite electrode that has a conical pH response membrane with a tip angle of 40 ° or less and with a diameter of 10 mm or more."*	*Expires on 21 July 2025 for cat. 9 monitoring and control instruments including industrial monitoring and control instruments.*

Source: (Deubzer et al. 2022)

At the time of the current evaluation of exemption IV-1(a), the COM have not yet officially published their decision as to the adoption of the above recommendation. The COM wish the consultants to assess in this current review round whether there are any substantial reasons in line with Art. 5(1)(a) against the adoption of the above recommendation for EEE of categories 8, 9 and 11.

18.1.2. Focus of the review of this renewal request

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status January 2024). (COCIR 2022) therefore applied for the renewal of the current exemption 1(a) for cat. 8 IVD since it was earmarked for expiry on 21 July 2023 for this subcategory of cat. 8 EEE. The exemption thus became due for review even though the recommendation for the renewal of exemption 1(a) of (Deubzer et al. 2022) included cat. 9 IMCI.

In the light of this situation, the COM tasked the consultants to assess in their review of the exemption renewal request at hand whether and how far the recommendation of (Deubzer

et al. 2022) can be adopted to cat. 8 IVD in line with Art. 5(1)(a). A re-evaluation of the previous review by (Deubzer et al. 2022) is not intended. The consultants will rely on the critical review conducted by (Deubzer et al. 2022) and on the resulting conclusions and recommendation unless the renewal request or stakeholder contributions give reasons to reassess the state of science and technology.

18.1.3. Summary of the requested exemption

"Blood gas analysis systems use ion selective electrodes in their sensors, to detect blood gases such as pO_2 and pCO_2 and biomarkers in patients blood. Blood gas systems are used to accurately diagnose various conditions such as asthma, chronic obstructive pulmonary disease (COPD), kidney failure, uncontrolled diabetes and severe infections, as well as treat patients in respiratory and/or metabolic distress.

Lead and cadmium are constituents of thick film screen printable paste used in the sensors. These constituents are used to promote reaction bonding and for ensuring strong adhesion of the paste base metal (typically gold or palladium) to the ceramic substrate material on firing. A planar sensor array can contain up to 10 sensors, with performance integral to the reliability, sensitivity and quick response time of the system. With the sensors themselves reliant on the integrity of the connections formed by the thick film paste. For good connections to be made the paste is required to have a precise viscosity to allow for the printing of fine features and low resistivity (≤ 4.5mΩ @ 10µm) which is determined by the percent solids, the ability to form a dense film with minimal defects and good adhesion to the substrate.

Testing is still ongoing for alternative RoHS compliant thick film pastes, with a focus on alternatives developed by the same manufacturer to minimise the changes to the technical characteristics of the paste, and thus reduce the timeframes for qualification. Alternative technologies which avoid the use of thick film pastes are possible but would require additional time to qualify alternatives due to more major product design and production process changes. In addition to these changes, the many decades of experience and reliability data gathered while using thick film pastes would also have to be overcome, resulting in considerably longer timeframes for qualification." (COCIR 2022)

18.1.4. Technical description of the exemption and use of the restricted substance

Types of EEE for which the exemption renewal request is relevant

According to (COCIR 2022), the scope of this exemption is sensors for blood analysis systems, using ion selective electrodes for the detection of blood gases such as pO_2 and pCO_2 and biomarkers. These point of care blood gas systems are categorized as in-vitro diagnostic medical devices within RoHS Annex I EEE category 8.

(COCIR 2022) describe that lead and cadmium are constituents of thick film screen printable paste (also referred to as 'ink'), used in the fabrication of planar sensors used in

point of care blood gas systems. The lead and cadmium within the paste is cited[82] as promoting reaction bonding and ensuring strong adhesion of the paste base metal (typically gold or palladium) to the ceramic sensor substrate material on firing.

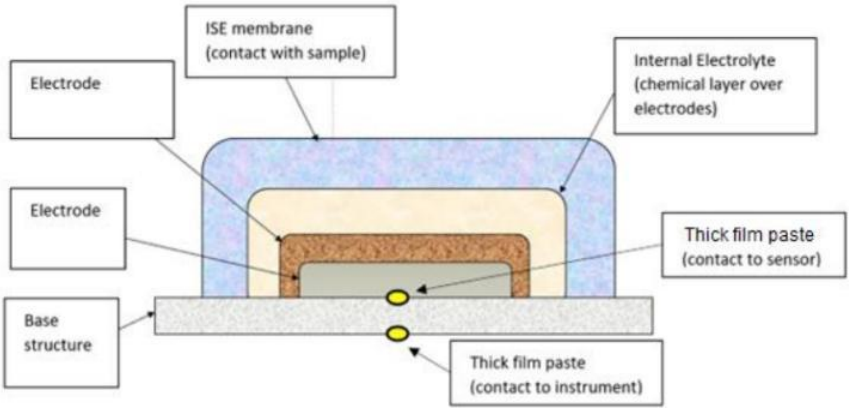
Material and/or component in which lead and cadmium are used

(COCIR 2022) describe that lead and cadmium are used as constituents of thick film screen printable pastes, also known as inks. 'Thick film' technology, uses conductive, resistive and insulating pastes containing glass frit (a glass powder which acts as a filler which is typically used for producing the thick film pastes, (COCIR 2023), deposited in patterns defined by screen printing and fused at high temperature onto a ceramic substrate. Compared with solder pastes, the particle sizes are much smaller, and the suspensions therefore more stable. The printable paste is designed to give an appropriate viscosity for the screen-printing process.

The paste is applied (screen printed) onto a substrate in the fabrication of potentiometric and amperometric planar ion selective sensors. Potentiometric sensors measure the potential difference between two electrodes under the conditions of no current flow. The measured potential is then used to determine the analytical quantity of interest based on the Nernst equation. Amperometric sensors measure the current response to detect the concentration of an analyte at a fixed potential. The applied potential drives the electron transfer reaction of the analytes, and the measured current indicates the analyte concentration.

According to (COCIR 2022), the pastes are used for providing the electrical contact within the sensors, and between the sensors and the blood gas system. They are critical for the reliable transduction of the measured sensor response into an electrical signal that is further converted by the blood gas system and associated algorithms into analysis results. A technical illustration was provided by (COCIR 2023), reproduced in Figure 18-1.

Figure 18-1: Technical illustration of the thick film paste as part of the sensor



Source: (COCIR 2023)

The sensors are assembled into linear arrays which are incorporated into replaceable measurement cartridges used in point of care blood gas systems.

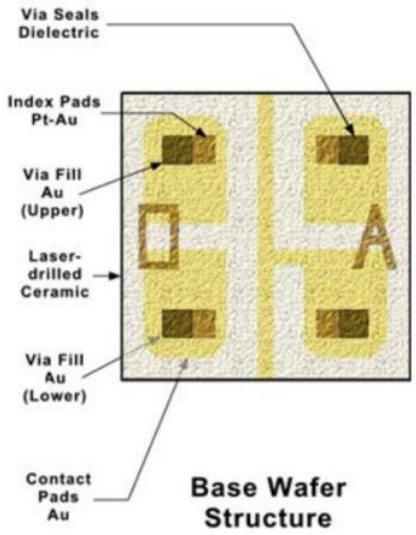
[82] Rapson, W.S. The bonding of gold and gold alloys to non-metallic materials. Gold Bull 12, 108–114 (1979). https://doi.org/10.1007/BF03215110

Figure 18-2: Exemplary image of replaceable blood gas system cartridge

Source: (COCIR 2022)

(COCIR 2022) describe that the method for measuring a sample involves flow of the aqueous fluid or patient blood sample (analyte) over the planar sensor and a standard reference electrode, the sensor and reference form an electrochemical cell. The resulting electrical signal from the electrochemical cell is converted by the system into a meaningful reading of the analyte. An example of the usage of the paste is shown in Figure 18-3. The pastes are used on the contact pads as well as the 'Via Fills' that connect the planar sensors to make electrical contact with the blood gas system.

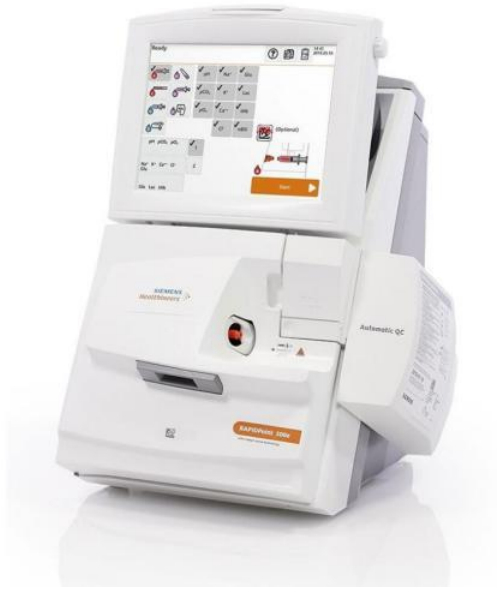
Figure 18-3: Exemplary schematic showing the printing layers wherein the paste is used on the substrate layer



Source: (COCIR 2022)

The sensors are arranged in a linear array of up to 10 different sensors in some blood gas systems, with each sensor designed to detect different analytes. These sensors form a critical part of blood gas systems. The blood gas system measures pH, pCO_2, pO_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, total haemoglobin, haemoglobin fractions, neonatal bilirubin, and several calculated parameters. A typical example of such a product is shown in Figure 18-4.

Figure 18-4: Exemplary image showing a blood gas system



Blood gas systems are known to help in accurate diagnosis of various conditions such as asthma, chronic obstructive pulmonary disease (COPD), kidney failure, uncontrolled diabetes and severe infections, as well as treat patients in respiratory and/or metabolic distress. Further details of their application can be found in this referenced document Clinical Utility of Blood Gas[83]. The use of such devices has increased considerably in the recent past and they have become an integral part of intensive care units (ICUs) and emergency medical services.

(COCIR 2022) claim that blood gas systems have been essential in supporting COVID-19 response efforts, where blood gas systems play a critical role in managing infected patients and monitoring their respiratory distress. Arterial blood gas testing is also performed when patients require critical pulmonary assessment, managing sepsis and kidney function evaluation. These tests provide the clinician with a health assessment of the patient and help direct treatment options.

Arterial blood gas testing is not a routine blood test. The tests are performed on patients who are critically ill in the intensive care units, operating rooms and emergency rooms. In these locations, time is critical for the clinician to provide the best treatment based upon these tests. Analysis results are available in approximately 60 seconds. Faster diagnosis helps prescribe accurate therapy at an early stage of disorder, which helps avoid complications. The performance of the sensors is integral to the reliability, sensitivity and response time of the system, the sensors themselves are reliant on the integrity of the connections formed by the thick film paste. A significant advantage of this type of sensing technology is that only a small sample of blood is required (typically 100µL), this is advantageous especially when assessing infants or patients from whom obtaining a larger sample due to their condition would be difficult.

Characteristics of lead and cadmium for which they are required

[83] Siemens: Clinical Utility of Blood Gas. bg_clinical_utility_poster_fnl4-00278011_1800000000278011.pdf (scrvt.com)

According to (COCIR 2022), in order to be able to manufacture the sensors, the paste has to be suitable for application by screen printing. Screen printing is attributed to be a reproducible and efficient method for large scale production of planar sensors[84].

The key attribute of the paste to ensure printability is the viscosity, this is required to be in the range 190 - 350 Kcps [kilo centipoise]*. This not only determines the flow of the paste but also the ability to print features to the required resolution (typically >75 µm lines and spaces), which is critical to minimising the size of the sensors.*

The paste must also provide consistent physical and chemical properties after firing (the process of heating the paste to temperatures of >800ºC, often multiple times to facilitate bonding to the substrate).The key attribute required from the paste after firing is resistivity, this is required to be ≤ 4.5mΩ @ 10 µm fired film thickness, which is determined by the percent solids, the ability to form a dense film with minimal defects (pin holes) and good adhesion to the substrate. Defects or pin holes in the fired paste act as air gaps increasing the overall resistivity. These attributes also ensure the integrity and reliability of the connections made by the paste.

The lead and cadmium within the paste is cited[82] as promoting reaction bonding and ensuring strong adhesion of the paste base metal (typically gold or palladium) to the ceramic sensor substrate material on firing.

(COCIR 2022) highlight that manufacturers have built up many decades of experience, with some utilising the principles of this technology for over 45 years and as such have refined both the hardware and software of the system to maximise the analytical capability.

18.1.5. Amount(s) of restricted substance(s) used under the exemption

(COCIR 2022) indicate the cadmium content in the thick film paste to be up to a maximum of 1.5 % by weight and lead compounds (frits) up to a maximum of 3.5 %. Through application for which the exemption is requested, an estimated 82 g of cadmium and 191 g of lead are placed on the EU market annually. These numbers are based on calculations including confidential market information.

18.2. Justification of the requested exemption

18.2.1. Substitution and elimination of the restricted substance

Replacement thick film pastes (substitution)

(COCIR 2022) state that lead and cadmium have been used in thick film pastes for many decades and have known to have been used successfully for the manufacturing of sensors for blood gas systems for the past 20+ years, citing William Rapson (1979)[82]. However, they also highlight that several manufacturers of thick film paste exist, including Du Pont[85],

[84] Tymecki L, Glab S, Koncki R. Miniaturized, Planar Ion-selective Electrodes Fabricated by Means of Thick-film Technology. Sensors (Basel). 2006 Apr 7;6(4):390–6. PMCID: PMC3872359.

[85] https://www.dupont.com/mobility-materials/thick-film-materials.html

Koartan[86], Ferro[87], and Heraeus[88], all of which have been developing lead- and cadmium-free alternatives, the exact formulation of each paste however is proprietary to the paste manufacturer.

According to (COCIR 2022), there are a number of variables inherent to each of the thick film pastes based on the following, which influence the technical characteristics:

- *The constituents themselves, including rheology modifiers;*
- *The ratios of constituents;*
- *The constituent particle size and shape etc.*

(COCIR 2022) explain that these variables impact the firing temperature, viscosity, shear rate and printability of the paste, including the ability to print and resolve sufficiently fine features. They also impact the performance of the paste after it has been fired to form a conductor, in terms of resistivity, bond strength, and reliability. Consequently, to optimise the chances of success in transitioning to a new paste for a particular application, it is prudent for manufacturers to minimise the number of variables by first testing alternatives with the same paste manufacturer. This helps to minimise these differences, but also utilises the close technical relationship which usually is already in place to minimise the qualification timeframes.

(COCIR 2022) describe that one thick film paste manufacturer launched a lead- and cadmium-free paste in late 2018[89] which was intended to be the replacement for pastes containing lead and cadmium. As well as changing the constituent formulation, changes have also been made to the particle size and shape of the constituents, with the intent of improving performance. (COCIR 2022) describe that initial trials of this particular paste, by a manufacturer of blood gas systems and the sensors therein, were started in early 2019, with a batch of 6 wafers manufactured. Of this batch, 2 wafers failed due to print voids and the production associate which produced the samples noted it was difficult to work with. The sensors are required to pass a 100% conductivity test, which only 66% of the samples passed, compared to the typical passing rate of the current paste >95%. As such, the investigations into this potential alternative were halted to try to investigate a more promising alternative.

A second alternative paste was investigated which printed well and showed no continuity issues. However, the sample was only able to achieve an average use life of 21 days, with some samples failing at as early as 12 days, rather than the warranty use life of 30 days which is currently offered for one system. (COCIR 2022) explain that the signal produced by the sensor (recovery) was also identified as being different to that of the current paste. Testing showed that the potential alternative had a mean recovery less than that of the current paste of 37 mg/dL, which was confirmed when a second lot was tested. This difference in sensor signal was investigated by repeating the fabrication and creating a

[86] https://koartan.com/thick-film-pastes/conductor-pastes/gold-pastes

[87] https://www.ferro.com/

[88] https://www.heraeus.com/en/group/home/home.html

[89] https://www.heraeus.com/en/het/company_het/press_and_news_het/2018_het/09_imaps.html

second batch (lot 2) of the sensors, and installing the sensors in other cartridges but keeping the same reagents as the first test; all of which showed the same difference in sensor results.

(COCIR 2022) provide more testing details for all of the above in a confidential submission that cannot be reproduced in this report.

(COCIR 2022) conclude that given all of these issues and with the advent of the COVID pandemic, which impacted resource availability (due to a combination of a 31% rise in product demand and lockdown restrictions between 2019 and 2021), trials at this stage were halted until late 2021. However, trials are still on-going for the currently selected alternative with feasibility, conductivity testing completed and use life testing for 5 out of 13 of the analyte sensors, across multiple models of blood gas systems. However, additional time is still required to undertake all of the required testing.

Potential Alternative Technologies (elimination)

(COCIR 2022) state that there are no currently qualified alternatives that provide a technical solution. They claim that it has been established[90] that thick films based on nano-scaled powders offer better sensing properties than thin films deposited through methods such as sputtering, chemical vapor deposition, or laser ablating. As detecting analyte to very small quantities is one of the defining technical characteristics of blood gas systems these technologies are unsuitable for this application.

According to (COCIR 2022), photolithography is used on silicone wafers in the integrated circuits industry. However, such technology requires extremely clean operating conditions which are not currently in place. Although there have been some academic papers exploring photolithography and its use on ceramics, the work has been limited thus far and has not demonstrated this technology is suitable for the ceramic wafers used in blood gas systems.

(COCIR 2022) further explain that microprinting and inkjet printing was deemed as an unsuitable alternative methodology as the resulting process was thought to be too inconsistent. The inconsistency arises from the head space within the print heads, which would cause different pressures to be applied to the print as the volumes of ink in the print head changes. It is conceivable that the optimisation of such parameters to overcome this, and other design characteristics such as the redesign of the printer head, may be possible given sufficient time. However, more crucially the areas of the printed ink are quite large, with the smallest droplets deposited by this method being about 100 µm across[90] which is not suitable for sensors in blood gas systems.

According to (COCIR 2022), these are the main manufacturers of blood gas systems:

- *Radiometer: https://www.radiometer.co.uk/*
- *Siemens: https://www.siemens-healthineers.com/blood-gas/blood-gas-systems*
- *Nova: https://www.novabiomedical.com/*
- *Medica: https://www.medicacorp.com/products/blood-gas-analyzers/*

[90] Tomchenko, Alexey. (2006). Printed Chemical Sensors: from Screen-Printing to Microprinting. In book: as "Thick-Film Semiconductor Chemical Sensors" in Encyclopedia of Sensors (pp.279-290).

- *Synergy Medical Systems: http://www.synergymedsys.com/Blood-Gas-Analyser.html*
- *Eshweiler: https://www.eschweiler-kiel.de/en/eschweiler-automatic-analysing-systems/*
- *Sensa Core: https://www.sensacore.com/product/blood-gas-analyzer-abgem*
- *Roche: https://diagnostics.roche.com/global/en/products/product-category/blood-gas.html*

(COCIR 2022) state that of these, it is known that some manufacturers do not use planar sensors, instead they are likely to use macro sensors. However, even if manufacturers relying upon planar sensors were to switch technology to macro sensors, the development cycle of a new gas system is typically ten years so a suitable time period to allow for this development to occur would need to be permitted.

Reliability of possible substitutes

(COCIR 2022) point out that both manufacturability and finished product performance need to be established in assessing the suitability of alternatives. According to (COCIR 2022), in the first instance, the following properties determine the manufacturability or suitability for screen printing and achieving the desired pattern resolution, adding that the precise values can impact the printing mesh required, the print speed and achievable thickness and resolution:

- *Viscosity: 190 - 350 Kcps %*
- *Solids: 84.5 – 88 ±2%*

The following are sought after the firing step(s) has been completed, firing is typically at a peak of between 850 and 950ºC, the precise firing cycle, overall duration and dwell time at peak temperature will need to be assessed for alternative pastes under consideration:

- *Resistivity: ≤ 4.5 mΩ @ 10 µm fired film thickness*

These features impact the performance and reliability of the sensors themselves which in turn impacts the performance and reliability of the blood gas system.

(COCIR 2022) further explain that in some blood gas systems, the sensors are arranged in a linear array of up to 10 different sensors each for detecting different analytes, it has been shown that changes made to one sensor in these arrays can impact the performance of other sensors, so changes to the paste used in the construction of each sensor need to be assessed sequentially rather than making changes to all of the sensors.

It is known that a manufacturer will carry out 100 % electrical conductivity testing on sensors, scrapping any non-conforming product. Sample performance testing of sensors (between 0.27 and 1.7 % of sensors), to verify performance in measuring analytes is also carried out, all sample sensors are scrapped after testing. The slope of the signal produced by the sensor over time when exposed to a known analyte and any drift of this signal are the key parameters assessed to ensure suitable performance is achieved from each batch.

18.2.2. Environmental, health, safety, and socioeconomic impacts

(COCIR 2022) only stated that without this exemption, certain blood gas systems would not be able to be sold in the EU. (COCIR 2024a) added that without this exemption, using alternatives to blood gas systems could lead to delays in patient results and treatment.

18.2.3. Roadmap towards substitution or elimination of the restricted substance

Actions taken to develop further possible alternatives

(COCIR 2022) explain that a newly developed RoHS and REACH compliant paste, from a known paste manufacturer is being evaluated. Initial trials of a RoHS compliant paste, by a manufacturer of blood gas system and the sensors therein, were started in 2019. However with the advent of the COVID pandemic, which impacted resource availability (due to a combination of a 31% rise in product demand between 2019 and 2021 and lockdown restrictions), trials were halted until late 2021.

(COCIR 2022) highlight a number of factors that can influence the quality of the final product when undertaking changes to thick film processing, including:

- *Screen type, mesh size, filament diameter, frame size, wet print thickness.*
- *Requirement for an emulsion layer to ensure that the stencil can seal onto the substrate whilst holding the mesh filaments clear of the substrate at the edge of the stencil apertures. This ensures that pastes can flow underneath the wires to the edge of the apertures therefore producing clean print edges.*
- *Tension of screen and squeegee design and pressure, all of which influence the ability to deposit the correct amount of paste on the surface of the substrate.*
- *Screen-substrate gap needs to be tailored to ensure smudging doesn't occur when it is too small, but also not too large to allow distortion of the print.*

(COCIR 2022) explain that after printing, the substrates must be fired, according to the thermal profile specified by the paste manufacturer and assembled into its final form. Due to the critical nature of the end product, such factors needed to be considered and trialled during the manufacturing feasibility testing. Currently there are 13 affected sensors, on multiple model types, which require testing. Testing has been completed for 5 out of 13 of the analyte sensors. The remaining testing is on-going.

Other alternative paste manufacturers are also being considered alongside the primary alternative paste of interest, however for the reasons discussed earlier this is less likely to yield the required results.

Necessary stages and timeframe for establishing possible substitutes

According to (COCIR 2022), the steps for a change from an existing paste to a newly developed RoHS compliant paste involves the following steps. In total the whole process requires an additional 4 1/2 years to complete. This timeframe allows for the assessment of up to two potential replacement pastes from two different paste manufacturers. Each of the steps noted below have to be performed sequentially and following strict internal change control procedures.

Table 18-5: Timeframe for the assessment of two potential replacement pastes

Step	Description	Detail	Est. duration
1	Feasibility (completed for 5 out of 13 sensors)	Determining the equivalency of the paste in terms of manufacturability, to include thick film printing and subsequent process steps, conductivity, and performance testing for up to 13 different sensors.	18 months remaining
2	Use - Life Testing (completed for 5 out of 13 sensors)	Manufacture of lots and testing of sensors against a known control sensor. Measurement of spiked blood samples with different levels of analyte for a period of up to 30 days depending on the system. This test needs to be undertaken on multiple lots of sensors, inks, and systems. Testing timeframes are limited by capacity and test cycles.	14 months remaining
3	Shelf-life testing	Storage of the sensors and then conductivity and performance testing repeated to verify there has been no degradation in function.	8 months
4	Verification	Repeat of conductivity and performance testing for up to 13 different sensors to verify there has been no degradation in function.	8 months
5	Implementation	Transfer of the new paste from R&D into mainstream manufacturing.	6 months

Source: (COCIR 2022)

18.3. Critical review

18.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several restrictions of cadmium and its compounds are listed on Annex XVII (cf. section 4.1 on page 48). None of those, however, is applicable to the use of cadmium and cadmium compounds in the scope of exemption IV-1(a).

Further on, uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds. None of those entries are, however, relevant for the use of lead in the scope of exemption IV-1(a) (cf. section 4.2 on page 51 for details).

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

18.3.2. Adoption of the recommendation from the previous evaluation report

Exemption IV-1(a) was reviewed by (Deubzer et al. 2022) who recommended a renewal, proposing two wording options to the European Commission (COM): Wording option A and wording option B, reproduced in section 18.1.1 “History of the exemption” in Table 18-3 and in Table 18-4, respectively.

During the review of the current exemption renewal request, the applicants were informed that if this review shows that the applicants’ arguments justify the renewal of the exemption, the consultants would recommend the wordings, scopes and expiry dates given in Table 18-6 (reflecting option A) and Table 18-7 (reflecting option B), adapted from the recommendations by (Deubzer et al. 2022).

Table 18-6: Renewal of exemption 1(a) reflecting wording option A, adapted from (Deubzer et al. 2022).

No.	Exemption	Scope and dates of applicability
IV-1(a)	Lead and cadmium in ion selective electrodes including glass of pH electrodes.	Expires on 21 July 2023
IV-1(a)(I)	Lead in the stem glass of pH glass electrodes and ion selective electrodes equipped with a pH glass electrode with complex shape as following: - Micro type pH glass electrode Composite electrode that has a spherical or tube-shaped pH responsive glass membrane with a diameter of 4.0 mm or less and a reference electrode with a liquid junction at a position vertically within 6.5 mm from the tip; - Flat type pH glass electrode pH glass electrode with a flat pH response membrane at the tip of a glass tube with a diameter of 6.0 mm or more; - Needle type pH glass electrode	Applies to cat. 8 in vitro diagnostic medical devices starting 22 July 2023 and cat. 9 monitoring and control instruments including industrial monitoring and control instruments. Expires on - 21 July [2023 **+ X***] for cat. 8 in vitro diagnostic medical devices - 21 July 2025 for cat. 9 monitoring and control instruments including

	Composite electrode that has a conical pH response membrane with a tip angle of 40° or less and with a diameter of 10 mm or more.”	industrial monitoring and control instruments

*X can be a maximum of 7 years

Table 18-7: Renewal of exemption 1(a) reflecting wording option B, adapted from (Deubzer et al. 2022)

No.	Exemption	Scope and dates of applicability
IV-1(a)	Lead and cadmium in ion selective electrodes including glass of pH electrodes.	Expires on 21 July 2023
IV-1(a)(I)	Cadmium in ion selective electrodes including glass of pH electrodes.	Applies to cat. 8 in vitro diagnostic medical devices starting 22 July 2023 and cat. 9 monitoring and control instruments including industrial monitoring and control instruments. Expires on - 21 July [2023 **+ X***] for cat. 8 in vitro diagnostic medical devices - 21 July 2024 for cat. 9 industrial monitoring and control instruments
IV-1(a)(II)	Lead in the stem glass of pH glass electrodes and ion selective electrodes equipped with a pH glass electrode with complex shape as following: - Micro type pH glass electrode Composite electrode that has a spherical or tube-shaped pH responsive glass membrane with a diameter of 4.0 mm or less and a reference electrode with a liquid junction at a position vertically within 6.5 mm from the tip; - Flat type pH glass electrode pH glass electrode with a flat pH response membrane at the tip of a glass tube with a diameter of 6.0 mm or more; - Needle type pH glass electrode Composite electrode that has a conical pH response membrane with a tip angle of 40 ° or less and with a diameter of 10 mm or more.”	Applies to cat. 8 in vitro diagnostic medical devices starting 22 July 2023 and cat. 9 monitoring and control instruments including industrial monitoring and control instruments. Expires on - 21 July [2023 **+ X***] for cat. 8 in vitro diagnostic medical devices - 21 July 2025 for cat. 9 monitoring and control instruments including industrial monitoring and control instruments.

*X can be a maximum of 7 years

When requested to comment on and explain any obstacles to the adoption of the above proposal for the requested exemption for category 8 in vitro diagnostic medical devices,

(COCIR 2023) responded that the proposal would not cover all of the uses highlighted in their exemption renewal request and therefore they could not agree its adoption.

Regarding their use of cadmium, *(COCIR 2023) stated that from Table* 18-7 *(option B), exemption IV-1(a)-(I) would be suitable for the use of cadmium if X equated 7 years.* The consultants note that exemption IV-1(a)(I) was recommended by (Deubzer et al. 2022) to provide a transition period for manufacturers of cadmium-containing electrodes to transition to cadmium-free alternatives in the absence of applications for a renewal of exemption IV-1(a) for cadmium. At the time, the applicants had only requested the renewal of exemption IV-1(a) for lead, but not for cadmium, in equipment in scope of RoHS Annex I cat. 9 IMCI.

Regarding the use of lead, (COCIR 2023) state that the recommended exemption 1(a)-(II) only permits the use of lead in stem glass of specific geometry types, which are not applicable to blood gas systems. The consultants agree that the thick film paste and its use in planar sensors in sensors in blood gas systems (BGS) for which the renewal of this exemption is requested would not be covered by the recommendations made by (Deubzer et al. 2022).

In this review of exemption IV-1(a), the consultants therefore focus on establishing whether substitution and elimination of lead and cadmium are scientifically and technically practicable in the applications and equipment in scope of COCIR's renewal request.

18.3.3. Substitution and elimination of the restricted substances

Substitution

When asked to clarify the functions of lead and cadmium in the thick film paste, (COCIR 2023) responded that both substances contribute to the required viscosity and resistivity by lowering the melting temperature of the glass frit. With lower viscosity during the firing step, the ink readily moves to the interface between the inks and the substrate. The lower viscosity also helps the ink migrate into substrate pores to fill them. This forms a strong mechanical bond between the metallic inks and the substrate.

When asked to clarify the typical composition of thick film paste in scope of this exemption renewal request, (COCIR 2024a) provided the information reproduced in Table *18-8*, showing the constituents of thick film paste that remain after firing.

Table 18-8: Constituents of thick film paste after firing

Constituent	*% weight*	*Function*
Gold	*Up to 90*	*Provides electrical chemical connectivity for the microsensor*
Cadmium	*Up to 1.5*	*Aid in the avoidance of defects and pin holes*
Lead compounds (frits)	*Up to 3.5*	*Aid in the avoidance of defects and pin holes*

Source: (COCIR 2024a)

When asked whether both lead and cadmium were required to achieve the desired attributes of the pastes, (COCIR 2024a) declared that pastes with either only lead or only cadmium had not been tested, as efforts have been focused on fully RoHS compliant solutions only. This approach appears sensible to the consultants.

When asked about the composition of pastes that have been tested to achieve RoHS-compliance, (COCIR 2024a) stated that they are predominantly gold-based inks to ensure the electrochemical transduction bonding properties, however, the complete composition of the alternative ink is proprietary information (trade secret). COCIR did state, however, that one supplier had specified that their RoHS-compliant gold ink, which is currently under evaluation, uses a formulation that contains doped borosilicates along with the gold to promote the adhesion, with the dopant being an oxide material. These new substances promote adhesion based on a mixed bond mechanism, specifically, both a mechanical and chemical bond.

In the renewal request, the applicants described testing two RoHS-compliant pastes, which resulted in defects, while currently testing is ongoing with a third variant with promising results. When asked why testing had only been done on so few RoHS-compliant variants despite the fact that RoHS-compliant pastes have been described in patents[91], literature[92], and press releases[93] over several decades, *(COCIR 2024a) stated that in order to maximise the likelihood of success of identifying an alternative, and within the shortest time possible, manufacturers tend to try to minimise any changes to the design, as any variation of the established system designs can have significant impact to sensor performance. To minimise the impact of function and manufacturing process, vendors whose products have been previously established at the time of design were prioritised for testing. Another factor is that new suppliers need to be audited and qualified, which is typically done before cost- and time-consuming testing commences, to ensure a supplier is willing to meet all requirements.*

When asked whether the testing of RoHS-compliant pastes had been conducted in correspondence with their respective suppliers to maximize the chances for ideal outcomes, *(COCIR 2024a) confirmed that supplier recommended parameters, such as the temperatures used for curing/drying, have been utilised in the manufacturing processes trailed. They reiterate that this resulted in printability issues with a high rate of print voids which resulted in an approximate 30% failure rate for continuity testing.*

The applicants' line of arguments that the substitution of lead requires more time for development and testing appears plausible to the consultants overall. While the consultants understand the chosen approach is reasonable from the manufacturers' perspective, some uncertainty remains regarding the comprehensiveness of the extent of the testing that has been conducted.

[91] E.g. this patent for a lead-free thick film paste composition from 1993 https://patents.google.com/patent/EP0711255B1/en

[92] E.g. Mussler, B., Schwanke, D. (2009). Validation of alternative RoHS compliant au pastes for the DuPont LTCC 951 system. Journal of Microelectronics and Electronic Packaging 6(1). DOI:10.4071/1551-4897-6.1.20

[93] E.g. EPP Europe. (2004). Lead-free paste for ceramic modules. https://epp-europe-news.com/technology/applications/lead-free-paste-for-ceramic-modules/

Elimination

(COCIR 2022) discuss the following alternative technologies in the context of elimination: Thin films, photolithography, microprinting, and macro sensors, each of which are discussed below.

Thin film technology

(COCIR 2022) stated that stated that thin film technology is unsuitable as detecting analyte to very small quantities is one of the defining technical characteristics of blood gas systems. When asked to explain the technical reasons for this, (COCIR 2024a) stated that detecting specific molecules in complex environments like blood remains challenging, citing two scientific publications[94 & 95], adding that the sensor's sensitivity needs refinement to handle the intricate mix of substances present in real-world samples. This is important as the scalability of the processes is not always ensured from proposing theoretical results, but rather needs to be tested to ensure that the necessary precision and reliability required by the process is ensured. Further, COCIR stated that it is worthwhile noting that the general trend which we are aware of are either for systems which rely upon thick film pastes to move to lead and cadmium free alternatives only, rather than there being a new technology which would replace the need for such paste.

When asked to provide more detail explaining why thin film technology is not suitable for the detection of analytes in small quantities, (COCIR 2024a) explained that thin films are essentially ultra-thin layers with a large surface area compared to their volume. This makes them ideal for micro and nanoscale sensor development. (COCIR 2024b) added that when selecting at the design stage the most suitable manufacturing process, considerations is given to many aspects, including the application requirements, functionality, and mechanical constraints. While thin film technology offers unique advantages, such as enabling miniaturization, thick film is better suited for planar sensors. The fundamental challenge in using thin films is the 1 nm to 1 µm order of magnitude, whereas the range of thickness of planar sensors used for this application are in the tens to hundreds of µm thickness range. The long-term reliability of devices using thin-film technology would also need to be tested, as exposure to blood repeatedly over the course of a month poses a harsh environment. These technical challenges would need to be fully explored and resolved to be able to implement thin film technology in devices of this type, will require significant evaluation, development and validation activities followed by regulatory approvals. To the best of our knowledge no device manufacturer is exploring thin film technology as a potential alternative due to the level of development needed, rather efforts are focused on lead and cadmium free thick film pastes.

(COCIR 2024a) further added that the general trend which they are aware of is either for systems which rely upon thick film pastes to move to lead and cadmium free alternatives only, rather than there being a new technology which would replace the need for such paste.

In the consultants' view, the argument that an alternative technology that is a potential candidate to eliminate the use of restricted substances is not explored due to the level of development needed is generally not acceptable per se in the context of this review.

[94] Schmaljohann, Frank & Hagedorn, Daniel & Löffler, Frank. (2021). Challenges of sensor development based on thin film technology. 10.1016/b978-0-444-63237-1.00003-6

[95] Tvarozek et. al (1998). Thin films in biosensors. https://doi.org/10.1016/S0042-207X(98)00050-5

However, it is understandable that the manufacturers prefer to maintain their existing technology and aim to achieve full RoHS-compliance by developing thick film pastes free of restricted substance, especially considering that the applicants seem to be close to achieving this goal, given that the renewal is only requested until August 2026.

Photolithography

(COCIR 2022) stated that photolithography has not been demonstrated for ceramic wafers. The limitations of photolithography include micro size variance and the need for absolutely flat substrates/surfaces and the need for a cleanroom environment (free from air particulates or chemical containments) for manufacturing. This makes photolithography not viable as an alternative manufacturing process, as cleanroom environments are not in place. When asked about "thick-film semiconductor chemical sensors" as discussed in Tomchenko (2006) [90] as potential alternative to thick film technology based sensors, (COCIR 2024a) stated that although offering immense value for detecting various chemicals, these face limitations that make them unsuitable for most biosensing applications due to following reasons:

- *Biocompatibility concerns: The materials used in thick-film semiconductor chemical sensors, such as metal oxides or polymers, may not be compatible with biological environments. They can potentially denature proteins or generate side products (sensor interferants) or interact with biomolecules in undesired ways, affecting the sensor's performance.*
- *Stability and regeneration challenges: Semiconductor chemical sensors can be susceptible to changes in temperature, humidity, and other environmental factors. Additionally, regeneration of the sensing surface after exposure to biological samples can be difficult, making them less reusable and potentially affecting their longer-term performance. On the other hand, screen printed thick film biological sensor, despite harsh biological environments, are able to maintain their stability and accuracy, and perform reliably for up to a month with repeated use.*

The consultants understand that photolithography may not be immediately applicable to ceramic wafers, as the technology requires extremely flat surfaces for which, typically, semiconductor materials such as silicon dioxide are processed using a number of chemical and mechanical processes. The consultants could not identify demonstrated applicability of semiconductor chemical sensors to biological samples in a limited screening of scientific literature.

Macro sensors

(COCIR 2022) stated that it is known that among the main manufacturers of blood gas systems, some do not use planar sensors, but instead they likely use macro sensors. When asked, (COCIR 2023) confirmed that macro sensors are used to measure the same analytes that are measured by the planar sensors that require the requested exemption. The applicants also confirmed that macro sensors do not require the addition of lead and cadmium to function, unlike micro sensors. When further asked about technical advantages of planar sensors over macro sensors for the application in blood gas systems, (COCIR 2023) explained that a macro sensor in this context is a sensor that is used in large, centralized laboratory systems that need to process a high volume of samples quickly and efficiently. Individual macro sensors that use ion-selective sensor technology can be independently replaced. Ion-selective sensor technology is used for detection of analytes such as sodium, potassium etc. Macro sensors also require regular maintenance by

qualified lab personnel. (COCIR 2024a) further specified that the term 'macro sensors' in this application refers to sensors in non-cartridge-based systems.

In comparison, planar sensors are typically cartridge-based sensor arrays. These analysers use planar sensor-arrays instead of individual macro sensors, which make them maintenance-free and easily replaceable. Cartridge based system are smaller and easier to transport rather than macro-sensor-based systems, making them suitable for both point-of-care and central laboratory settings. While the principle of detection between two systems [macro sensor-based BGS and planar sensor-based BGS, the consultants] *are ion-selective sensor technology principles, the intrinsic design differences do not allow for inter-compatibility of the sensors.*

According to (COCIR 2023) the biggest technical advantage of planar over macro sensors is the ability to integrate sensors and reagents into a single consumable cartridge. This makes it possible to develop smaller footprint cartridge-based detection systems. In addition to the smaller footprint, planar detection systems may also offer lower manufacturing costs and reduced overall cost of system ownership due to reduced maintenance.

When asked whether portability is in fact a requirement for BGS in the context of their use in practice, (COCIR 2024a) confirmed that *they are used in a number applications providing critical point of care. Examples given include neonatal intensive care unit (NICU), emergency rooms (ER), and operating theatres. They add that using alternatives to Blood gas systems could lead to delays in patient results and treatment.*

Other potential alternatives

The consultants inquired about other bonding technologies that could, potentially, be employed to eliminate thick film paste from the planar sensors, such as soldering and ultrasonic bonding. *(COCIR 2024a) stated that the planar sensor array systems leverage screen printing for creating the conductive patterns on ceramic substrates. Alternative methods such as soldering and ultrasonic soldering are unsuitable due to the potential for cavitation issues. This phenomenon, triggered by the acoustic energy from the soldering tools, relies on bubbles in the molten solder breaking apart and violently disrupting oxide layers on both the solder and the metal being joined. While cavitation excels at cleaning certain metals, it falls short when dealing with ceramics and glass. Their inherent oxide composition renders them immune to such forceful disruptions, making them incompatible with cavitation-based soldering techniques.*

Other manufacturers of BGS

When asked to describe and name market-available alternative BGS suitable for point of care (POC) settings that do not rely on planar sensors, and whether these require RoHS-relevant substances to operate, *(COCIR 2024b) stated that it is not possible to provide a list of companies. For the renewal application, the majority of the information has been provided by one main manufacturer. Requested to compare market-available alternatives in POC settings to the BGS in scope of this exemption renewal request (featuring planar sensors), (COCIR 2024b) reiterated on the technical differences and disadvantages of instruments using macro sensors.*

The consultants invited five manufacturers of blood gas systems to comment on whether BGS in their portfolio required RoHS-relevant substances to function and whether they could cover all the same applications (use cases, e.g. laboratory settings, point of care settings) as the applicants' BGS. Some of them engaged in correspondence initially, only

one of them provided the requested information. This supplier of BGS stated that their instruments so use a conductive paste that contains lead in the glass frit.

Requested to comment on a specific example, the Abbott i-STAT 1 analyzer[96], a handheld BGS, and its potential to cover the same applications as BGS in scope of their exemption renewal request, (COCIR 2024b) responded that the Abbott I-STAT system is a handheld single use cartridge-based system and is used in a wide variety of settings including POC. However, the product is single use only. For example, the Abbott I-STAT requires bi-yearly software updates, has non-integrated quality control, and is unable to report certain parameters (e.g., ionized magnesium, CO-oximetry, bilirubin). There are also some instances where the analytical measuring interval is not as expansive as other devices.

According to (COCIR 2024b), another important feature of the cartridge-based devices referenced in the exemption request is the use of a single cartridge to concurrently test multiple analytes including blood gases, electrolytes, metabolites. The same sample is used across the different types of analytes tested, so concurrent results of various analytes in question can be obtained. The iSTAT system has the capability to test a broad range of analytes, however, it requires the use of multiple cartridge types, each of which is a tailored subset menu and does not necessarily consist of the entire menu that some of the other cartridge-based devices for providing concurrent results using a single sample. The throughput also provided by multiuse cartridge-based systems in high turnaround hospital locations such as ERs wherein there are consecutive samples run within very short intervals provides high efficiency and continuity for hospital workflows.

(COCIR 2024b) further outline that there would also be an impact to the provision of healthcare services as this exemption supports devices which are multi-use, with each system supporting many thousands of tests and care provision for patients each year. If only single use devices are permitted, not only would this have significant impact on the amount of waste generated, but also on the ability to undertake the number of tests required to support patient care.

Replacing multiuse cartridge-based system with a handheld POCT blood gas device presents a cost burden to healthcare providers with respect to high volume testing. Refer to the excerpt table below with devices described by this exemption being hybrid analyses and ones such as the Abbott I-STAT a handheld analyser.

(COCIR 2024b) included this excerpt table comparing annual costs for handheld and hybrid POCT systems, which is reproduced in Table 18-9. The consultants note that economic analysis is not part of their mandate, so the information is not taken into account to derive a recommendation.

[96] Website of Abbott on the i-STAT 1: https://www.globalpointofcare.abbott/us/en/product-details/apoc/i-stat-system-us.html (accessed on 13 January 2024)

Table 18-9: Cost comparison for handheld and hybrid point of care systems

TABLE 12.1 Yearly costs for handheld (HH) and hybrid (Hyb) POCT systems for yearly test volumes.

	Costs for one HH analyzer	Cost for four HH analyzers	Costs for one Hyb analyzer	Cost for two Hyb analyzers
Analyzer cost	$8000	$32,000	$19,000	38,000
Cost per test panel	$6.00	$6.00	$2.00	$2.00
500 tests/ year	11,000	35,000	20,000	39,000
1000 tests/year	14,000	38,000	21,000	40,000
2000 tests/year	20,000	44,000	23,000	42,000
5000 tests/year	38,000	62,000	29,000	48,000
10,000 tests/year	68,000	92,000	39,000	58,000
20,000 tests/year	128,000	152,000	59,000	78,000

Source: (COCIR 2024b)

The applicant was also requested to comment on the polyvinyl chloride (PVC)-based cartridge-based sensor systems described in the context of exemption IV-41 / 41a [97]. (COCIR 2024a) stated that exemption IV-41 relates to lead as a thermal stabiliser in PVC, lead in this exemption is used in a thick film paste which doesn't involve PVC. As such although the end applications may seem similar, the technical rationale for the use of lead (and cadmium) is very different.

When asked to describe any technical advantages of, (COCIR 2024b) *replied that the only way to outline technical differences between applications which previously used ex.41 and the ones under this exemption renewal would be to undertake a direct comparison of specific products. The products previously utilizing ex.41 are unknown to the manufacturers involved in this exemption renewal request as they do not use this application. As such it can only be stated that in general most products on the market offer unique technical functionality to differentiate them from other products.*

Exemption IV-41 expired on 31 March 2022, and exemption IV-41a on 31 December 2023. The applicant of the last review of exemption 41 was requested to provide information on whether their cartridge-based sensor systems no longer rely on any RoHS exemptions,

[97] Study by Gensch et al. (2019), available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/RoHS_Pack-14_final_report_amended_20190305.pdf

however, no response was received. Consequently, there is remaining uncertainty as to whether alternative instruments that do not require RoHS-regulated substances are available or not. From the information made available, it is the consultants' opinion that the BGS that use the lead-containing planar sensors in scope of this exemption renewal request can likely be replaced by other technologies, such as those featuring macro sensors in stationary settings and devices like the i-STAT 1 in POC settings. However, the BGS in focus on this review do appear to have some technical advantages over other available technologies, including the capacity to measure a larger number of analytes in parallel, potentially leading to faster results.

18.3.4. Environmental, health, safety, and socioeconomic impacts

The applicants did not provide public information on such impacts, besides stating that using alternative to blood gas systems in scope of their renewal request could lead to delays in patient results and treatment. More detailed information was provided in a confidential submission, which cannot be reproduced here, nor be accounted for to form an opinion regarding the requested renewal of this exemption.

18.3.5. Summary and conclusions

COCIR request the renewal of exemption IV-1(a) with the wording "lead and cadmium in thick film pastes in ion selective electrodes used for blood gas systems" for cat. 8 IVD until August 2026. Following their mandate for this exemption, the consultants assessed whether the result of the previous review of this exemption by (Deubzer et al. 2022) can be adopted for cat. 8 IVD with reference to the application at hand.

The thick film paste used in planar sensors of blood gas systems would not be covered by the exemption wording that was recommended by (Deubzer et al. 2022) after the last review of exemption IV-1(a). The recommended wording, labelled exemption 1(a)(I), would only cover lead in glass electrodes of three specific geometric shapes, as was requested by the applicant at the time. However, the sensor technology in scope of the current exemption renewal request is entirely different. It relies on planar sensors that are manufactured on ceramic substrates in a screen-printing process. Planar sensors are small and are laid out in arrays within cartridges that are swappable in the BGS instruments and that measure a number of analytes in parallel using only a single, relatively small amount of blood sample. The technology employs thick film paste to establish an electrical connection between the sensing elements and the substrate, as well as to instrument analysing the data. Both lead and cadmium are added to the thick film paste to lower its viscosity. Viscosity determines the flow of the paste as well as the ability to print features to the required resolution, which is critical to minimising the size of the sensors.

The applicants' line of arguments for the renewal of the exemption covering their application is that although lead- and cadmium-free thick film pastes have been available, testing has shown that their reliability is not ensured, resulting in defects and reduced lifetime of the sensors. Other variants of Pb- and Cd-free thick film pastes have become available more recently and testing has been described to result in promising results. The applicants

therefore request a renewal not for the maximum validity period but until August 2026 to complete the qualification of the RoHS-compliant paste.

Alternative manufacturing and sensor technologies for BGS that do not require RoHS-relevant substances have been discussed. The applicant provided arguments to demonstrate that the alternative production processes are not suitable to produce the planar sensors in scope of this request. Regarding alternative BGS that do not rely on planar sensors, in the consultants' view, the applicants have not unambiguously demonstrated that the BGS in scope of their renewal request cannot be replaced with lead-free systems. More specifically, during the review process it has not become entirely clear whether the size reduction of instruments enabled by planar sensor-based sensor cartridges is a requirement in practice or whether they can be replaced by larger instruments (e.g., those featuring macro sensors) in laboratory settings and handheld systems in point of care settings. The applicants however have stated that their instruments can measure a higher number of analytes in parallel than some handheld systems, leading to potentially faster results.

Despite this remaining uncertainty, the consultants conclude that the use of lead and cadmium in the sensor technology in scope of this renewal request may not yet be entirely avoidable, as the reliability of substitutes is not ensured. The applicants have requested a renewal of the exemption until August 2026. The consultants consider this timeframe appropriate to conclude testing and qualification of alternatives that do not rely on RoHS-relevant substances until full RoHS compliance is achieved.

The consultants reflected on the possibility that the use of lead in this application may be covered by exemption 7(c)-I [98] of RoHS Annex III, however, came to the conclusion that it would be more appropriate to include both cadmium and lead in the wording of exemption IV-1(a), with a relatively short validity period until August 2026 as requested, to make it clear that both lead and cadmium are no longer needed in this application after that date.

18.4. Recommendation

The consultants recommend renewing the exemption. Substitution or elimination of lead and cadmium are scientifically and technically not yet practicable so that granting the exemption would be in line with the requirements of Art. 5(1)(a).

The consultants conclude the requested validity period until August 2026 seems sufficient to complete the testing of lead-free alternatives. The consultants therefore recommend renewing the exemption as requested with the wording and scope specified in the below table as IV-1(a)(I).

[98] Wording of ex. 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"

No.	Exemption	Scope and dates of applicability
IV-1(a)	Lead and cadmium in ion selective electrodes including glass of pH electrodes.	Expires on 21 July 2023
IV-1(a)(I)	Lead and cadmium in thick film pastes in ion selective electrodes used for blood gas systems.	Applies to category 8 in vitro diagnostic medical devices and expires on - 31 August 2026
IV-1(a)(II)	Lead in the stem glass of pH glass electrodes and ion selective electrodes equipped with a pH glass electrode with complex shape as follows: - Micro type pH glass electrode Composite electrode that has a spherical shape or tube-shaped pH responsive glass membrane with a diameter of 4.0 mm or less and a reference electrode with a liquid junction at a position vertically within 6.5 mm from the tip; - Flat type pH glass electrode pH glass electrode with a flat pH response membrane at the tip of a glass tube with a diameter of 6.0 mm or more; - Needle type pH glass electrode Composite electrode that has a conical pH response membrane with a tip angle of 40º or less and with a diameter of 10 mm or more.	Applies to category 9 including industrial monitoring and control instruments and expires on - 21 July 2025

The consultants reflected on the possibility that the use of lead in this application may be covered by exemption 7(c)-I of RoHS Annex III, however, came to the conclusion that it would be more appropriate to include both cadmium and lead in the wording of exemption IV-1(a), with a relatively short validity period until August 2026 as requested, to make it clear that both lead and cadmium are no longer needed in this application after that date. To prevent overlapping scopes between this new exemption at hand and exemption 7(c)(I), the scope of this exemption should be excluded from the scope of the renewed exemption III-7(c)(I).

The currently valid wording of exemption IV-1(a) was recommended for expiry by (Deubzer et al. 2022) by 21 July 2023. This exemption would in principle cover the applicant's requested exemption, but the recommendation for its expiry in 2023 should be upheld so that it can be superseded by the more specific exemptions IV-1(a)(I) and IV-1(a)(II).

Regarding the wording option B recommended by (Deubzer et al. 2022), which included a transition period for cadmium in ion selective electrodes including glass of pH electrodes to allow suppliers of such electrodes to transition to cadmium-free alternatives or to apply for a renewal, it does not seem to be needed as no such application was received.

Exemption IV-1(a)(II), also recommended by (Deubzer et al. 2022), may be upheld, however, the consultants further recommend that the COM ensures sufficient time between

the official publication of the COM's decision and the expiry date of the exemption to allow for the preparation and timely submission of renewal requests 18 months prior to the expiry of the exemption.

Applicants' feedback on the recommendation

(COCIR 2024c) confirmed to agree with the recommendation.

18.5. References

COCIR (2022): RoHS Annex V Request for renewal of exemption IV-1a. RoHS Pack 27. COCIR (RoHS 29). Retrieved from https://rohs.biois.eu/COCIR-Renewal_Form_1a_IVD_AnnexIV-FINAL.pdf.

COCIR (2023): Answers to questionnaire 1 (clarification questionnaire) sent by Emily Tyrwhitt Jones, RINA, to Christian Clemm via e-mail. RoHS Pack 27. COCIR (RoHS 29). Retrieved from https://rohs.biois.eu/Ex_IV-1a_COCIR_Questionnaire-1_Clarification-AnswersFinal.pdf.

COCIR (2024a): Answers to questionnaire 2 sent by Emily Tyrwhitt Jones, RINA, to Christian Clemm via e-mail. RoHS Pack 27. COCIR (RoHS 29).

COCIR (2024b): Answers to questionnaire 3 sent by Emily Tyrwhitt Jones, RINA, to Christian Clemm via e-mail. RoHS Pack 27. COCIR (RoHS 29).

COCIR (2024c): Comments on recommendation exemption IV-1(b) sent by Emily Tyrwhitt Jones, RINA, to Christian Clemm via e-mail. RoHS Pack 27. COCIR (RoHS 29).

Deubzer et al. (2022): Study to assess requests for renewal of 16 exemptions to Annex IV of Directive 2011/65/EU. 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. Amended Final Report. In cooperation with von Dr. Deubzer, Otmar, Fraunhofer IZM und UNITAR, Saskia Huber, Jana Rückschloss, Fraunhofer IZM, UNITAR Christian Clemm und Bio I. S. Shailendra Mudgal. Hg. v. Publications Office of the European Union. European Commission (RoHS 26, Pack 21). Retrieved from https://op.europa.eu/en/publication-detail/-/publication/f46d5d27-2d8d-11ed-975d-01aa75ed71a1, Last updated 26.02.2024.

Goodman (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report July 2006, amended 19 Sep 2006. ERA Report 2006-0383. In cooperation with von Paul Goodman, ERA Technology Ltd. ERA Technology Ltd. Retrieved from https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf.

19. Exemption 1(b) of Annex IV: Pb in electrochemical oxygen sensors

The below table shows the wording, scope and expiry dates of the exemption.

Table 19-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
IV-1(b)	Lead anodes in electrochemical oxygen sensors.	Applies to categories 8 and 9 and expires on - 21 July 2021 for category 8 other than in-vitro diagnostic medical devices (IVD) and for category 9 other than industrial monitoring and control instruments (IMCI); - 21 July 2023 for category 8 in vitro diagnostic medical devices; - 21 July 2024 for category 9 industrial monitoring and control instruments.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

ATEX	ATmosphère EXplosible (English: explosive atmospheres), referring to the ATEX Directive 2014/34/EU: Equipment and Protective Systems intended for use in potentially Explosive Atmospheres
Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instruments
IVD	In-vitro diagnostic medical devices
MOCON	AMETEK MOCON
NIST	National Institute of Standards and Technology

ppb	Parts per billion
ppm	Parts per million
ppt	Parts per trillion
RoHS 1	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	Directive 2011/65/EU, current RoHS Directive

19.1. Background and technical information

Four stakeholders requested the renewal of exemption IV-1(b) for EEE of RoHS Annex I category 9 industrial monitoring and control instrument (IMCI) as displayed in Table 19-2.

Table 19-2: Wording and scope of the requested renewal of exemption IV-1(b)

Applicants and application date	Requested Exemption	Requested scope and dates of applicability
(Alphasense 2023a), 20 January 2023	*Lead anodes in capillary oxygen sensors*	*Applies to cat. 9 IMCI and expires on* - *21 January 2027 for general applications;* - *21 July 2028 for ATEX rated products.*
(MOCON 2022), 9 December 2022	*Lead anodes in electrochemical Hersch cells for oxygen sensors for measurement of permeation*	*Expires on 21 January 2028 for cat. 9 IMCI.*
(Dräger 2023a), 20 January 2023	*Lead anodes in electrochemical oxygen sensors*	*Applies to cat. 9 IMCI and expires on:* - *31 December 2025 for new instruments that use electrochemical oxygen sensors;* - *21 July 2031 for oxygen sensors that are spare parts for instruments placed on the market before 1 January 2026.*
(Honeywell 2023a), 19 January 2023	*Lead anodes in electrochemical oxygen sensors*	*Expires on 21 July 2031 for cat. 9 IMCI.*

Alphasense's exemption request is stated to be supported by The Council of Gas Detection and Environmental Monitoring (CoGDEM), TROLEX, AFRISO, ANALOX, fatair, GAS DATA, GDS Technologies, GEMLOG controls, GfG, KANE, AMETEK MOCON, QED, Sensotran, and SEWERIN.

(CoGDEM 2023), a Trade Association representing the majority of oxygen sensor manufacturers and gas detector manufacturers, including City Technology, Alphasense, Scientific, Draeger, New Cosmos and Figaro, contributed a statement on the exemption for

leaded oxygen sensors for industrial gas safety. (Trolex 2023), a member of CoGDEM, also contributed a supporting letter.

(COCIR 2023) made a contribution to the stakeholder consultation.

19.1.1. History of the exemption

Exemption 1(b) of Annex IV was not part of RoHS Directive 2002/95/EC (2003) (RoHS 1). It was first evaluated by (Goodman 2006) and subsequently listed on Annex IV of RoHS Directive 2011/65/EU (2011) (RoHS 2) when this was officially published in 2011.

Exemption 1(b) was first reviewed by (Deubzer et al. 2022). At the time, COCIR requested a renewal of the exemption for RoHS Annex I EEE of category (cat.) 8 medical devices other than in-vitro diagnostic medical devices (IVD) and JBCE requested a renewal for cat. 9 monitoring and control instruments including industrial monitoring and control instruments (IMCI). Both applicants requested a renewal without changes to the exemption wording.

(Deubzer et al. 2022) drew conclusions separately for both fields of application:

- In the medical sector (cat. 8), lead-free galvanic oxygen sensors have become viable alternatives to sensors with lead anode and have made progress in penetrating the market of medical devices that use such sensors. As substitution is still an ongoing process, the consultants can follow the applicant's request to renew the exemption until the year 2025 in order to allow the transition to proceed, while no existing, in-use medical equipment need to be retired prematurely due to an abrupt lack of replacement sensors as consumables.
- The use of oxygen sensors in monitoring and control instruments (cat. 9) is a more diverse field with a wider range of requirements compared to medical applications. The two general types of oxygen measurements with monitoring and control instruments are the measurement of dissolved oxygen in liquids and the measurement of oxygen in gases. For dissolved oxygen measurements, lead anodes are still needed to measure concentrations below 30 ppb (parts per billion). For gaseous oxygen measurements, lead anodes are still needed to achieve a response time below 3 seconds.

(Deubzer et al. 2022) recommended to split the exemption to reflect the scientific and technical progress in both separate fields as displayed in Table 19-3.

Table 19-3: Exemption wording and scope recommended by (Deubzer et al. 2022)

	Exemption	Scope and dates of applicability
1(b)	*Lead anodes in electrochemical oxygen sensors.*	*Expires on 21 July 2021 for cat. 8 medical devices others than in-vitro diagnostic medical devices*
1(b)-I	*Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and/or exhaled air for patients and that are consumables in medical devices put on the market before 26 May 2024.*	*Expires on 21 July 2025 for cat. 8 medical devices others than in-vitro diagnostic medical devices*
1(b)-II	*Lead in galvanic oxygen sensors in instruments that are* *(a) designed for the measurement of oxygen in gases with a response time < 3 s (t95) and which are not handheld devices, and* *(b) designed for the measurement of dissolved oxygen in concentrations below 30 ppb.*	*Expires on 21 July 2025 for cat. 9 monitoring and control instruments including industrial monitoring and control instruments.*

Source: (Deubzer et al. 2022)

At the time of the current review of exemption IV-1(b), the COM have not yet officially published their decision as to the adoption of the above recommendation. The COM wish the consultants to assess in this current review round whether there are any substantial reasons in line with Art. 5(1)(a) against the adoption of the above recommendation for EEE of categories 8, 9 and 11.

19.1.2. Focus of the review of this renewal request

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status January 2024). The applicants therefore applied for the renewal of the current exemption 1(b) for cat. 9 IMCI since it was earmarked for expiry on 21 July 2024 for this subcategory of cat. 9 EEE. The exemption thus became due for review even though the recommendation for the renewal of exemption 1(b) of (Deubzer et al. 2022) included cat. 9 IMCI.

In the light of this situation, the COM tasked the consultants to assess in their review of the exemption renewal request at hand whether and how far the recommendation of (Deubzer et al. 2022) can be adopted to cat. 9 IMCI in line with Art. 5(1)(a). A re-evaluation of the previous review by (Deubzer et al. 2022) is not intended. The consultants will rely on the critical review conducted by (Deubzer et al. 2022) and on the resulting conclusions and recommendation unless the renewal request or stakeholder contributions give reasons to reassess the state of science and technology.

19.1.3. Summary of the requested exemption

The exemption request summaries provided by the four applicants are reproduced below.

Alphasense wrote: *"Lead is used as the anode in capillary oxygen sensors which are used to measure oxygen gas in the range of 0-30% in fixed installations, personal monitoring devices and permeation measurements, such that an alarm is triggered if the oxygen levels are above or below a set threshold. Capillary sensors have minimal response to pressure, temperature and humidity, while having a short warm-up time and are self-powered. Other sensors, such as amperometric type sensors can be lead-free but are not able to offer these technical characteristics and are susceptible to high carbon monoxide (CO) and carbon dioxide (CO_2) concentrations and cannot be used in the absence of oxygen. Alphasense and other sensor manufacturers have carried out research into substitute metals and none are drop-in replacements as outlined above. More research is needed develop alternative sensors that offer suitable technical performance, after which the design and validation of analyser instruments including performance certification can be undertaken. Depending on the end use in question the level of redesign and testing will vary, with an estimated timeframe of at least 4 years for general applications and at least another 18-months subsequent to this for ATEX rated products."*

MOCON wrote: *"Lead is used as the anode of a Hersch cell, electrochemical sensor which is used to measure the absolute oxygen permeation in industrial monitoring and control devices. Specifically, Hersch cells are used in the production of pharmaceutical products, medical applications such as wound dressings, assessment of the integrity of food packaging and solar panel lifespan calculations and improvements. Hersch cells can detect oxygen in the range of 200 ppt (parts per trillion) to 70 ppm (parts per million) and is an absolute method of measurement (Coulometric) which removes the need to calibrate the sensor (which would be impossible to undertake at the extremely low levels of detection it undertakes). Alternative lead-free technologies do not offer the same level of detection range as they require calibration and rely on membranes which limit the sensitivity of the sensor. Alternative lead-free anodes are currently being trialled with some anode/ electrolyte combinations showing initial indications that suitable performance may be achievable. Additional testing of critical performance, followed by reliability and productionisation testing needs to be undertaken to determine if a lead-free solution can offer the required technical performance. As such, although an alternative lead-free solution is being actively sought, it is not yet known if any potential alternative is a viable technical solution and additional time is required to determine this."*

Dräger wrote: *"This exemption is necessary to allow the use of electrochemical oxygen sensors to measure oxygen concentration in industrial applications. This primarily includes applications in inerting processes, i.e., when organic vapours or gases occur simultaneously with the oxygen in atmospheres for monitoring the lower explosion limit of industrial processes. Lead-containing organic capsules are intrinsically safe here, as they cannot act as a source of ignition, like potential lead-free sensors with electrodes made of platinum black. The latter generate their working potential via a potentiostat circuit and not via a natural potential gradient between the lead and the gold of the working electrode, as is the case with galvanic oxygen sensors. A shift of the reference potential due to penetrating gases from the sensor environment leads here to a failure of the sensor."*

Honeywell wrote: *"Honeywell is submitting this exemption renewal request for lead in oxygen sensors because the recent Pack 21 review did not consider the types of sensor and end-uses that are described here. Oxygen concentrations in gases can be measured*

using a variety of methods but each has advantages and disadvantages. For some end-uses, such as small portable gas monitors and instruments that can operate in ATEX environments, only instruments with galvanic sensors are suitable and usually only lead anode sensors can be used. One of the advantages of lead anode sensors are that they do not consume electricity so small battery powered portable instruments can be used for whole working shifts. Also, the electrical characteristics of lead anode sensors are different to all other types of oxygen sensors, so alternative types cannot be used as drop-in replacements in existing instrument designs. Research has been carried out with potential substitute anode materials, but all have been found to have disadvantages, the main one being that lead is the only suitable anode metal that does not self-corrode or passivate under any conditions inside the sensor. Research into substitute sensor/instrument options is being carried out by Honeywell, but due to the need for approvals for many of the end-uses, this will take many years to complete."

Summary of the submitted supporting information

The supporting statement submitted by (CoGDEM 2023) highlights the advantages leaded galvanic oxygen sensors have over both alternative anode materials (Zn, Bi, W, etc.) and potentiostatic (3-electrode) sensors: they have significantly lower and very stable zero (baseline) currents, are simple to implement and importantly for the gas safety industry, have decades of field use where they have proven to be reliable and have saved lives; their simpler construction in comparison to potentiostatic sensors has been a main reason for this reliability. Regarding substitution and elimination of lead, CoGDEM state that the market is making progress towards viable lead-free alternatives to lead based oxygen sensors for industrial applications but without further detailed technical analysis it is likely that businesses are going to suffer and market acceptance/usability of detectors is going to be compromised if the exemption is lifted as planned in 2025. A further seven-year exemption is requested to ensure continuing best safe practice in the gas safety industry.

As an active Council of Gas Detection and Environmental Monitoring (COGDEM) member, (Trolex 2023) supports the proposal to extend the permissible use of capillary lead oxygen sensors for the next 4 years or more. Where explosive atmosphere (ATEX) applications are concerned, Trolex would also recommend that a further increase on the extension is considered due to the importance of the proven detection capabilities of capillary lead oxygen sensors, with yet no suitable alternative, and the lengthy time implications on modifying, recertifying and performance testing new equipment.

Summary of contributions to the stakeholder consultation

(COCIR 2023), the European Association of the radiological, radiotherapy and Healthcare IT Industry noted that the proposed wording for 1(b)(I) does not seem to match the findings of the original assessment for category 8. COCIR suggest that the exemption wording is supposed to cover sensors that are used as consumables or sold as consumables for medical devices that are already installed or will be installed before 2024. COCIR note that the recommended exemption wording, however, seems to suggest that it only applies to sensors that were consumables provided with the equipment when it was placed on the market but not to additional spare sensors that will be used as consumables afterwards.

To avoid confusion of wrong interpretations COCIR therefore suggest the following change to the recommended exemption wording:

- *Recommended wording for ex. IV-1(b)(I): Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and/or exhaled air for patients and that are consumables in medical devices put on the market before 26 May 2024.*
- *COCIR's recommended wording: Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and/or exhaled air for patients and that are intended to be used as consumables in medical devices put on the market before 26 May 2024.*

19.1.4. Technical description of the exemption and use of the restricted substance

Types of EEE for which the exemption renewal request is relevant

(Alphasense 2023a) request the renewal for capillary sensors in industrial monitoring and control devices for the electrochemical measurement of oxygen concentrations in which lead metal is used as anode material. The sensors are used within gas detection devices as a consumable part, with devices typically having a lifetime of about 8-10 years, with some devices having a lifetime of decades. The sensors are also used as spare parts for instruments already placed on the market as on average the sensor needs to be replaced every two years. (Alphasense 2023a) indicate the following applications for capillary oxygen sensors:

- *Portable instruments that are either mains or battery powered for monitoring health and safety*
- *Fixed installations for monitoring health and safety*
- *Automotive exhaust monitoring (portable and fixed instruments)*
- *Boiler flue monitoring (portable and fixed instruments)*
- *Biogas monitoring in anaerobic digestion plants (portable and fixed instruments)*
- *Permeation measurements of packaging of food and pharmaceutical packing (fixed instruments)*

(MOCON 2022) request the renewal of this exemption for Hersch oxygen sensors for measurement of permeation in industrial monitoring and control devices used for the absolute oxygen permeation measurement of film, membranes, and packaging. MOCON supply a number of different devices using Hersch cells to undertake permeability testing, with different models offering different technical characteristics, such as package testing under environmental conditions, film testing in standard ranges and conditions, high sensitivity film testing and high throughput film testing, with between 1 to 4 test cartridges containing Hersch cells per device. To the best of our knowledge MOCON is currently the only supplier of lead based Hersch sensors for the global market. Further, (MOCON 2022) note that Hersch cells support a number of industries requiring high-sensitivity oxygen measurement, the following are indicative examples:

- *Manufacture of certain pharmaceutical products which are sensitive to extremely low levels of oxygen*

- *Integrity of food packaging design- for example testing the permeation through packaging barrier material to ensure it is below 0.001 cc/m2 ·day (0.36 ppb v/v) with an upper range of 200 cc/m2 ·day (72 ppm v/v).*
- *Quantifying oxygen breathability for medical wound dressings to help minimise infections*
- *Lifespan of solar panels, which require a high oxygen barrier to ensure component integrity and in order to prolong the lifetime of the panels. Long-lasting Solar Panels are necessary to generate "green" energy; which results in benefits for the environment.*

(Dräger 2023a) request the renewal of this exemption for sensors for measuring oxygen in industrial processes, such as inerting or in helium atmospheres. The concentration of oxygen in air needs to be monitored to ensure that they are no highly flammable or even spontaneously combustible atmosphere conditions. Oxygen concentrations need to be accurately monitored if an atmosphere highly flammable gases or vapors, such as hydrocarbons, alcohols or hydrogen. (Dräger 2024a) specified their sensors are used to monitor contaminated ambient atmospheres in the sense of personal occupational safety or explosion protection in atmospheres with flammable organic vapors. (Dräger 2024a) also state that they have not used lead-containing oxygen sensors in portable gas detectors for decades, indicating they are rather operated in stationary gas measuring transmitters.

Dräger also describe medical applications of their oxygen sensors, but as this exemption request only pertains to industrial monitoring and control instruments of category 9, these descriptions are omitted here.

(Honeywell 2023a) request the renewal of this exemption for oxygen gas concentration analysers in industrial monitoring and control devices. (Honeywell 2023b) added that the use of such devices are in both fixed and mobile applications, and end-uses include:

- *Water treatment works, paper mills, farming*
- *Food packaging*
- *Refining, bio-gas monitoring, boiler flue/emissions analysis*
- *Ships and military applications such as in submarines and for inspection of fuel storage tanks*
- *Semiconductor and photocell manufacture*
- *For working in confined spaces, such as tunnels, sewers, tanks, etc.*
- *Building and construction sites, such as in tunnels and trenches, in mines*
- *Commercial buildings, medical and laboratories, such as boiler rooms, cryogenic zones such as liquid nitrogen storage.*
- *SCUBA diving gas analysis*

Function of the RoHS-regulated substance used

Capillary oxygen sensors

(Alphasense 2023a) describe that capillary sensor are electrochemical sensors with two electrodes; a lead anode and an inert cathode which are immersed in an alkaline electrolyte.

The anode and cathode reactions are:

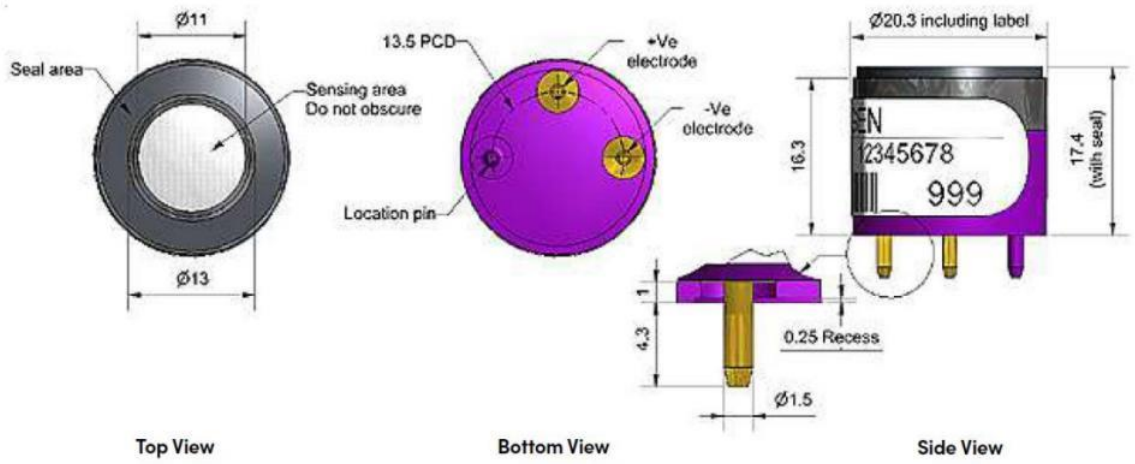
Cathode: $O_2 + H_2O + 4e^- \rightarrow OH^-$

Anode: $2Pb + 4OH^- \rightarrow 2PbO + 2H_2O + 4e^-$

The electrochemical reaction generates an electrical current which flows through the cell which is proportional to the amount of oxygen entering the sensor in accordance with Faraday's Law. The current is measured by a load resistor which is between the cathode and anode which measures the resulting voltage drop.

(Alphasense 2023a) describe that capillary sensors measure oxygen in the range of 0-30% in fixed installations and personal monitoring devices, such that an alarm is triggered if the oxygen levels are above or below a set threshold. (Alphasense 2023a) explain that unlike other sensor designs which use a membrane which the oxygen must permeate through, capillary oxygen barrier uses a small hole (<200 µm in diameter) such that it can be detected by the electrodes. The electrolyte used in capillary sensors is potassium acetate, and lead anode in a wool form. Capillary sensors are also used in permeation measurements operate under the same principle as the capillary sensors described above, with the capillary hole larger in diameter to allow the measurement to levels of oxygen such as 20 ppb. The larger hole size allows for a larger amount of signal to be gathered and therefore a lower level of detection is possible. The only other design difference from the other capillary sensor types is a metal housing to limit oxygen permeation through the housing.

Figure 19-1: Schematic of a capillary sensor



Source: (Alphasense 2023a)

According to (Alphasense 2023a), there are several properties that are important to capillary sensors:

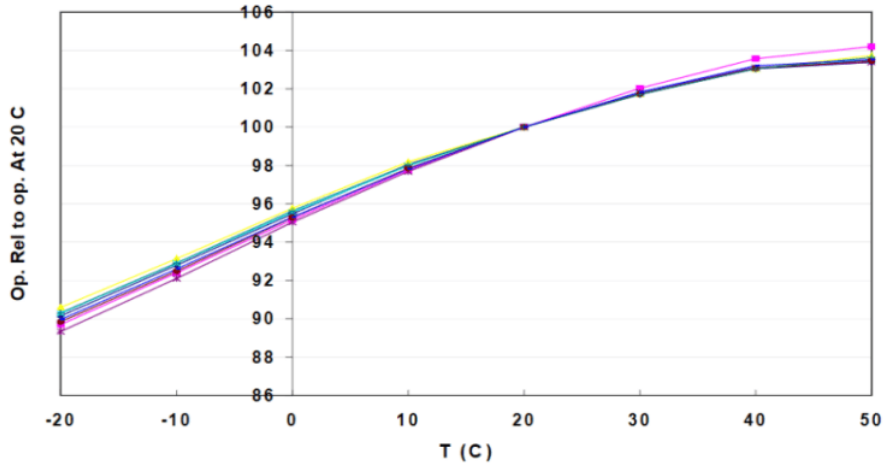
- *Able to measure oxygen within the range of 0-30%*
- *Sensor output of 100µA in ambient conditions which limits the transient sensor response when undergoing pressure changes during which time the sensor cannot be used in. For example, a sensor output of 20 µA would take that much longer to stabilise after pressure disturbances than a 100 µA output.*

- *Operating temperature range of -30 to +50^{o}C*
- *Low output dependence with temperature*
- *Minimal response to pressure changes in the ranges of 80 – 120 kPa*
- *Operable time of over two years before lead fuel is exhausted (for the major sensor types)*
- *A warmup time of <2 mins for portable instruments*
- *High surface area of the electrode to ensure a suitable sensor lifetime*
- *Self-powered systems, without the need for external power sources, allowing detection to be undertaken within seconds and start up times of a few minutes*
- *Mechanical stability of the device such that it can be dropped and still function as intended*
- *Some applications, such as automotive, biogas and boiler flue exhaust monitoring, there are additional requirements for carbon monoxide and carbon dioxide poison resistance*
- *Some applications are limited as to the sensor size the design can accommodate, for example portable devices such as personal monitoring devices would soon become unwieldly if the senor was larger.*
- *Some end uses are also operable within explosive atmospheres so need to be compliant to the requirements of the ATEX Directives*

(Alphasense 2023a) note that for capillary sensors used for oxygen transmission rate through packaging or other barrier layers, for applications such food and pharmaceuticals, it is essential that the sensor is able to measure to very low levels of detection (20 ppb) and able to operate at 0% oxygen concentrations.

On temperature dependence on capillary oxygen sensors, (Alphasense 2023a) provided a figure that is reproduced in Figure 19-2. The data demonstrate that although temperature dependence has some effect on the device, the impact is limited as the rate of the gas diffusion through the capillary is only weakly temperature dependent. This change is due to the change is gas viscosity with temperature. However, the dependence is minimal and the dependence on temperature is highly repeatable. The diagram shows the temperature dependence for capillary oxygen sensors against the output from the sensors as a percentage of the output at 20^{o}C, showing high repeatability between sensors tested. (Alphasense 2023a) emphasize that temperature dependence, including to especially cold temperatures is important as industrial capillary oxygen sensors may be used in portable safety oxygen monitors which operate outdoors or in fixed installations at industrial facilities that may not be heated above the surrounding environments, such as mining operations or oil drilling riggs.

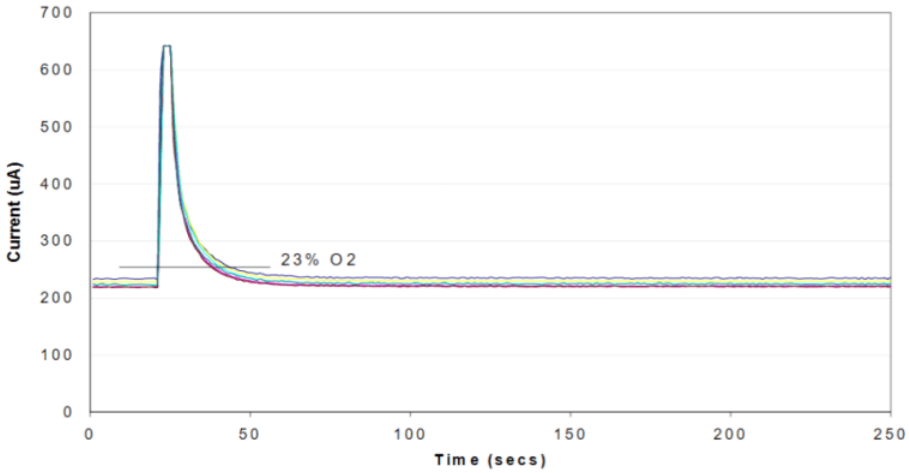
Figure 19-2: Temperature dependence of capillary oxygen sensors



Source: (Alphasense 2023a)

On the pressure dependence of capillary oxygen sensors, (Alphasense 2023a) claim that the amount of oxygen available for the reduction at the cathode depends on the oxygen concentration in the air, and not the oxygen partial pressure. As such the sensor output is nearly independent of ambient pressure. These types of devices are used in applications where the steady state pressure undergoes substantial changes, for example an oxygen monitor in a deep mine shaft taken to the surface. The capillary sensors have a temporary transient pressure response which the oxygen monitors are designed to ignore. On the contrary, designs which rely upon partial pressure by using membranes, have an output which is always proportional to the partial pressure and therefore cannot be used in these applications. Figure 19-3 shows the capillary sensor response when subject to a 10 kPa instantaneous positive pressure step.

Figure 19-3: Capillary sensor pressure response



Source: (Alphasense 2023a)

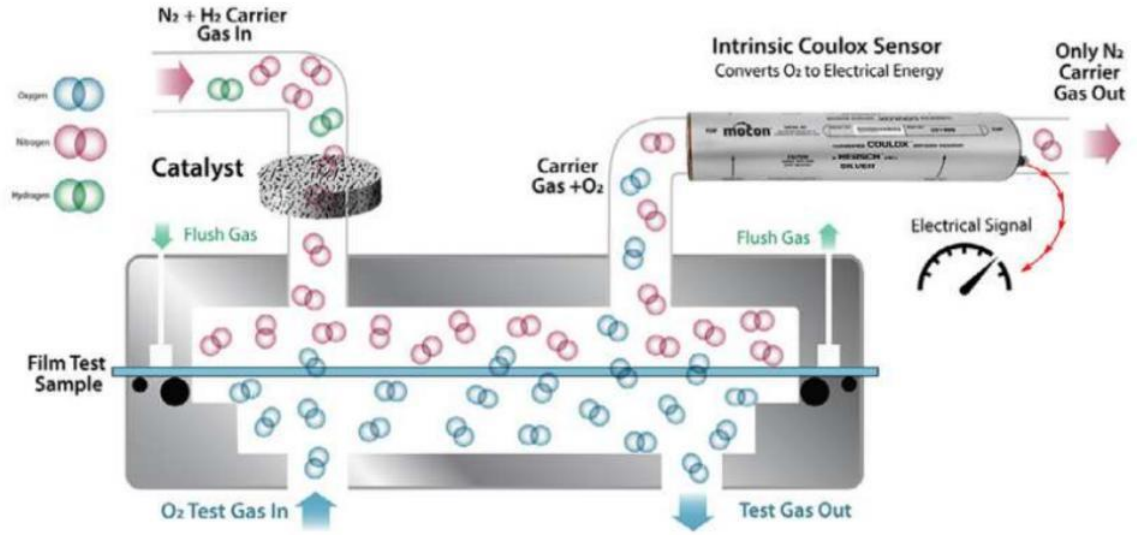
(Honeywell 2023a) also request the renewal of this exemption for capillary cells, but refer to the descriptions provided by Alphasense, reproduced above. (Honeywell 2023a) add that one limitation of capillary sensors is that if the concentration of acidic gases such as SO_2 or CO_2 concentrations in the gases being analysed are high, they can affect the accuracy of measurements (it increases the oxygen signal by about 0.3% per 1% CO_2). CO_2 however

does not pass easily through the diffusion membrane and so membrane cells are much less affected by high CO_2 (or SO_2) concentrations.

Hersch cells

(MOCON 2022) explain that Hersch cells are electrochemical sensors with two electrodes; a lead anode and an inert cathode which are immersed in an alkaline electrolyte. The reactions are the same as described by Alphasense for capillary oxygen sensors. (MOCON 2022) provided a schematic of a test sampling that is reproduced in Figure 19-4.

Figure 19-4: Schematic of test sampling of a Hersch cell



Source: (MOCON 2022)

According to (MOCON 2022), there are several properties that are important in Hersch cells:

- *Must follow Faraday's Law*
- *Oxygen efficiency measurement > 95%*
- *Flat discharge curve (accuracy) to enable the measurement of oxygen concentration below 100 ppm, for example Hersch cells can detect oxygen in the range of 200ppt to 70 ppm*
- *Absolute method of measurement (Coulometric) which removes the need to calibrate the sensor which would be impossible to undertake at the extremely low levels of detection it undertakes.*
- *High Energy Density which results in a sensor with a sensor life of at least a year for this oxygen permeation application at the varying ranges of detection.*
- *Inherent method of maintaining electrolyte health over years allowing an average sensor life of a year for most models, but for some this can be up to 4 years*
- *Temperature independent and able to operate in most sensor designs between 10-40ºC*
- *Sensor response (fast): < 8 minutes to 99 % full reading*
- *Compatible with nitrogen, hydrogen, water vapor*

- *No corrosion of the anode when in contact with the electrolyte or secondary chemical reactions that negatively impact the lead reaction*
- *No chemical effects that cause excessive internal pressurisations of the sensor*
- *Size and format similar to current sensor*
- *Specific to Oxygen: Limited cross sensitivity to ensure that other reactions are not undertaken, and the sensor has high sensitivity*
- *Not affected by moisture, pressure changes or flow dependent.*

(MOCON 2022)highlight that the sensitivity of Hersch cells is critical to the end users it serves as 89% of permeation measurements are made below 70ppm, with 60% of measurements below 2ppm and 10% below 20ppb. Further, coulometric measurement allows for a calibration-free methodology which is critical as there are no calibration standards available at the sensitivity range in which these devices operate. For example, the lowest level of NIST [National Institute of Standards and Technology, the consultants] *calibration gas is 1 Mole% oxygen (10,000 ppm) and the best "Certified" gas is about 10 ppm (± 20%) which is still 10,000 times higher than where the application requires accurate measurements.*

Permeable membrane / partial pressure sensors

(Dräger 2023a) describe permeable membrane oxygen sensors, in which oxygen is measured by small electrochemical sensors that contain lead anodes. These are connected electrically to much larger analyser instruments that calculate and display the oxygen concentration. The sensors are connected to the instrument using electrical cables. The concentration of oxygen in air needs to be monitored to ensure that they are no highly flammable or even spontaneously combustible atmosphere conditions. Oxygen concentrations need to be accurately monitored if an atmosphere highly flammable gases or vapors, such as hydrocarbons, alcohols or hydrogen. Lead (Pb) is used as the anode in the oxygen (O_2) sensor. During the operation of the sensor, oxygen from the gas being analysed permeates through the membrane of the sensor and is electrochemically reduced at the cathode of the sensor. The Pb anode of the sensor is oxidised to PbO / PbO_2. The electrode reactions are the same as described by (Alphasense 2023a) for capillary oxygen sensors. The electrochemical reaction generates an electrical current which flows through the cell (with an additional load resistor) which is proportional to the partial pressure of O_2 in the analysed gas. The voltage across the load resistor is proportional to the current and is measured to calculate the concentration of O_2.

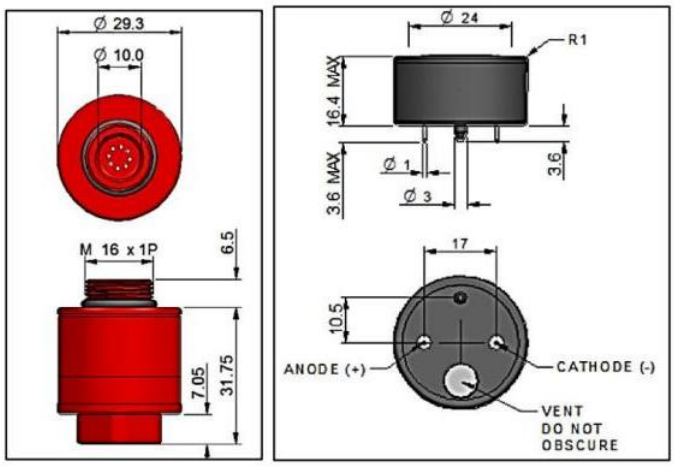
The output current of the electrochemical sensor is therefore dependent on the oxygen concentration in the air that enters the sensor. The rate of access of airoxygen into the sensor is controlled by the design of the sensor, in particular by using diffusion barriers which can be narrow capillaries or a porous layer. The sensor is designed so that the current output is proportional to the oxygen concentration. The diffusion barrier is used to limit the amount of air that passes through the sensor so that only a small amount of oxygen reaches the lead anode so that a proportionally small amount of lead is consumed, ensuring the maximum lifetime of the product. With the increasing conversion of lead to lead oxide, the voltage over the measurement resistor slowly decreases during use. To ensure the correct calculation of the O_2 concentration, the instrument and sensor is calibrated with air every 24 hours.

When the voltage with air drops below 8.9 mV (under normal conditions) the instrument detects that the sensor is consumed and informs the user to replace the sensor with a new one. Under normal conditions the sensor can be used for 1 to 2 years. Ambient temperature also affects the current output of the sensor and so compensation circuits need to be included either within the sensor or in the current measurement instrument. This is straightforward with lead-based sensors, but is also a critical variable with other types of sensor. Accurate O_2-measurement in industrial processes provide explosions by enabling the user to lower the O_2 content of the atmosphere.

One of the main advantages of lead in electrochemical oxygen sensors is that it is not affected by the majority of other gases used in industrial applications, such as inertising. The few exceptions to this are acid gases and CO2 will react with the electrolyte (potassium hydroxide or potassium acetate are usually used) and users are warned that this should be minimised, but combustible gases have only a minimal effect on this type of sensor.

(Honeywell 2023a) also request the renewal of this exemption for membrane diffusion cells / partial pressure oxygen cells, with similar descriptions as above. They provide illustrations from datasheets for several Honeywell lead-anode oxygen sensors, reproduced in Figure 19-5. On the left, they show the AO2 membrane cell, intended for the analysis of vehicle exhausts, and on the right, they show the 7OX membrane cell, a compact type used for analysis of oxygen in the 0 to 25 % range.

Figure 19-5: Examples of Honeywell lead-anode oxygen sensors



(Honeywell 2023a) explain that Sensors are designed for specific oxygen concentration ranges and use outside of these can damage them and severely shorten their lifetime. For example, Honeywell sensors are designed for: 0 to 2ppm, for 0% to 25% and others for 0% to 100%. Further, sensors are designed for specific end-uses such as SCUBA diving and vehicle exhaust analysers. Each design takes into account the environment in which they will be used and the presence of other gases that will be present, CO2, CO, etc in vehicle exhausts and diving gases can contain helium. These analyser instruments are certified by approval bodies for these specific uses. For example, vehicle exhaust gas analysers must be approved by New European Driving Cycle (NEDC) and the Bureau of Automotive Inspection (BAR).

(Honeywell 2023a) list the following examples of locations where oxygen analysers are used, many of which are safety critical applications:

- *Water treatment works*

- *Food packaging*
- *Refining*
- *Bio-gas monitoring*
- *Boiler flue/Emissions analysis*
- *In ships*
- *Military such as in submarines and for inspection of fuel storage tanks*
- *Paper mills*
- *Semiconductor and photocell manufacture*
- *For working in confined spaces, such as tunnels, sewers, tanks, etc.*
- *Building and construction sites, such as in tunnels and trenches*
- *In mines*
- *Commercial buildings, medical and laboratories, such as boiler rooms, cryogenic zones such as liquid nitrogen storage.*
- *Farming*
- *SCUBA diving gas analysis*

(Honeywell 2023a) add that many of the sensor and analysers are designed to be used in industrial areas where potentially explosive gases or liquids may occur such as in fuel tanks, mines, etc., and so only ATEX approved equipment is permitted. The sensors are also used both in fixed positions as well as in some applications as mobile sensors. Sensors that are used for mobile applications need to be very small and lightweight as they are used in small-size lightweight portable oxygen analysers that are worn by users. These analysers alert users if oxygen levels in the air in which they are working drop to unsafe levels.

(Honeywell 2023a) point out that new analyser instruments are sold with oxygen sensors already installed and many designs of instrument also analyse other gases. When the lead-anode in an oxygen sensor is consumed in an analyser instrument, the analyser will no longer function. The sensor therefore needs to be replaced by a new but identical oxygen sensor as a replacement spare part. These replacements will need to be readily available throughout the lifetime of the analysers which can be more than 10 years.

Characteristics and functions of the RoHS-regulated substance

According to (Alphasense 2023a), lead in electrochemical sensors is ideal as it does not self-corrode in the absence of oxygen, so does not produce a current without oxygen present. However, lead reacts rapidly when in contact with oxygen, giving a fast response time to the sensor with devices having a t90 value between 5 and 10 seconds. Capillary lead sensors are able to operate in the absence of oxygen for prolonged periods of time as they do not require reference electrodes. The sensors based on lead do not require power to operate, unlike other sensor types, which allows the sensor as a consumable part to have a relatively long lifetime, typically for 1 to 3 years which is important for sensors which are in hard-to-reach areas where replacement opportunities are limited.

(MOCON 2022) also note that lead does not self-corrode and reacts rapidly. Furthermore, they add that the solubility of lead metal in potassium hydroxide electrolyte is exceptionally low, therefore does not migrate to the sensing electrode, precipitate, or block the sensing electrode sights. This gives the Hersch cell extraordinarily long, stable sensitivity life, in the order of at least a year and up to 4 years for some designs. The lead within the Hersch Cell allows for the "Coulometric" analysis and follows Faraday's Law at ppt levels. This removes the need to calibrate at these extremely low levels, while providing a high degree of sensitivity. Lead anodes in contact with the potassium hydroxide electrolyte do not create any secondary reactions, as such it does not affect the primary reaction which converts the oxygen concentration to a specific current measurement. Gases such as hydrogen are not generated as part of the reaction when using lead, which would otherwise build up pressure and damage the sensor in the bypass state. Energy Density of the lead anode in conjunction with the potassium hydroxide electrolyte are high which gives acceptable sensor life for this oxygen permeation application at the varying ranges of detection.

(Dräger 2023a) highlight that the following characteristics are essential:

- *Fast response. For example, < 15 seconds to respond to a change from air to 100 % oxygen*
- *High sensitivity to small oxygen concentration changes*
- *High accuracy*
- *Long lifetime (at least 1 year, ideally 2 years)*
- *Measure oxygen concentration range of 0 % to 100 %*
- *Must be usable and accurate in the presence of commonly used combustible gases such as hydrogen or organic vapors*
- *Usable at 0 % to 99 % non-condensing humidity*
- *Accuracy should not be affected by typical CO_2 concentrations in inertising atmospheres*

(Honeywell 2023a) list the required characteristics for lead-anode electrochemical oxygen sensors as follows:

- *Capable of continuous analysis of oxygen in the concentration range 0% to 100% oxygen*
- *Lifetime of two years when used for recommended applications*
- *Must not passivate or self-corrode*
- *Capillary sensors are close to linear response for sensor's output signal versus oxygen concentration. Response is S = K loge 1/ (1-C) (S = output signal, C = concentration and K = constant). Partial pressure membrane sensors are inherently linear • Sensor output must be stable throughout its lifetime*
- *A warmup time of <2 mins for portable and fixed instruments*
- *Can operate in the range -20°C to +45°C*

- *Effects of temperature and pressure of lead anode sensors are predictable so that these can be compensated for*
- *Sensor must give a sudden and large drop in output signal when the lead anode has been consumed*
- *The sensor needs to be small, especially for portable air monitoring applications, typically less than 30mm wide and 25mm high. Honeywell's 4-series sensors are typically about 20 mm diameter, 17 mm high and weigh < 16 grams*
- *Power consumption of sensors for use in portable monitoring instruments needs to be sufficiently low (ideally zero) so that the analyser can be powered by small lightweight batteries, ideally rechargeable types, for at least one working shift of 8 – 10 hours.*
- *Effects of other gases on output readings should be as follows: Methane (100%): 0%; Hydrocarbons (100%): 0%; Hydrogen 100%: <-2%; Carbon monoxide 20%: <-0.5%; Carbon dioxide (1%): 0.3%*
- *Mechanical stability of the device such that it can be dropped and still function as intended*

According to (Honeywell 2023a), users will choose an oxygen analyser instrument on the basis of the following characteristics:

- *Accuracy within the range of concentrations required*
- *Resolution by the readout of the instrument*
- *Limited interference with other gases also experienced in the products operating environment. This is mainly affected by the type of sensor chosen*
- *Size and weight. Important for portable analysers*
- *Short warm-up time after being switched off for 24 hours.*
- *Response time is the time taken to give an accurate reading (usually 90 or 95% of the actual concentration). In safety critical applications, this must be short.*
- *Limited drift which is a measure of instrument stability over time. Drift can be caused by changes in the sensor or to the instrument's electronics*
- *Operating time for battery powered instruments (this is maximised as lead sensors do not consume power)*
- *Certification is required for several end-uses including diving, vehicle exhaust emissions analysis and ATEX environments*
- *If used as a personal monitor, it must be small and unobtrusive and not impair the wearer's work function. They are usually worn continuously for the working shift of 8 hours or more so batteries must last much longer than this.*

(Honeywell 2023a) claim that analysers with lead in electrochemical sensors are ideal as the lead metal does not self-corrode in the absence of oxygen, so does not produce a current without oxygen being present. However, lead reacts rapidly when in contact with oxygen, giving a fast response time to the sensor. The sensors based on lead do not require

power to operate, unlike other sensor types. The sensor is a consumable part of the analyser with a relatively long lifetime, typically for 1 to 2 years. This is important for sensors which are in hard-to-reach areas where replacement opportunities are limited.

19.1.5. Amount(s) of restricted substance(s) used under the exemption

(Alphasense 2023a) provide the assumption that 10 g of lead is used per sensor, which deemed as an average amount. Based on estimates from The Council of Gas Detection and Environmental Monitoring (CoGDEM), with some assistance from its members, (Alphasense 2023a) indicate that an estimated 5 tonnes lead is placed on the EU market per annum. This value is calculated for the O2A2 format which consists mostly of sensors sold into the industrial safety and emissions monitoring markets but is not limited to capillary sensors only.

(MOCON 2022) state that 4.075 kg of lead will enter the EU annually, based on confidential information submitted for the review. They add that end-of-life Hersch cell sensors are returned to the original manufacturer in the United States of America for recycling.

(Dräger 2023a) indicate that approximately 8 to 13.5 kg lead enter the EU market annually through their applications. This is based on 9 to 0 grams of lead contained in each sensor cell, with estimated sales in the EU for industrial applications to be about 1,000 to 1,500 sensors per year. They add that Dräger has established a take-back system for used sensors and aims to receive up to 100% back from the market. The sensors are recycled for materials recovery.

(Honeywell 2023a) refer to the same data from CoGDEM as does Alphasense. With regards to end-of-life, they add that customer disposes of used sensors according to local waste requirements and they are not returned to Honeywell.

19.2. Justification of the requested exemption

19.2.1. Substitution and Elimination of the restricted substance

Substitution

According to (Alphasense 2023a), research has been carried out and published with alternative anode metals and with various acid and alkali electrolytes. Metals that have been investigated include antimony, bismuth, copper, tin and its alloys, zinc and aluminium. Citing Cobianu et al. (2021)[99], the applicants explain that the more reactive metals such as tin, zinc and aluminium are unsuitable as they are thermodynamically unstable in suitable electrolytes. Electrolytes such as potassium hydroxide and other alkali solutions, acidic solutions such as phosphoric acid and caesium carbonate solution (mildly alkali) have been investigated.

[99] C. Cobianu, B. Serban, V. Avramescu, B. Hobbs, K. Pratt and M. Willett, "Lead-free galvanic oxygen sensors — A conceptual approach," *CAS 2012 (International Semiconductor Conference)*, Sinaia, Romania, 2012, pp. 161-164, doi: 10.1109/SMICND.2012.6400667.

When a reactive metal anode is combined with an inert cathode, the two different materials generate a galvanic couple which creates a small voltage with the electrode potential of the anode such that they self-corrode, generating a current and generate hydrogen. This generated current between anode and cathode gives a false and incorrect oxygen concentration.

Despite this, limited number of commercial galvanic lead-free oxygen sensors are available, which unlike some other methods is suitable for portable and mobile analysis and measuring instruments. However, their technical performance is different than those covered by this exemption, as outlined in Table 19-4.

Table 19-4: Comparison of lead-containing and lead-free partial pressure galvanic oxygen sensors

Sensor	Current output	Operating temperature	Environmental dependence
Lead containing capillary sensor	100 µA in ambient conditions	- 30° to + 50ºC	Minimal temperature dependence
ITG sensor[100] (using a barrier system)	Not listed	0° to 50ºC	Pressure, temperature, and humidity dependence[101]
Honeywell Envitec[102]	7-13 µA in ambient conditions	0° to 50ºC	Pressure, temperature, and humidity dependence
Figaro[103]	10-15mV	5° to 40ºC	Comparatively more affected by pressure and temperature than a capillary lead oxygen sensor

Source: (Alphasense 2023a)

Further, (Alphasense 2023a) explain that research with less reactive metals such as copper, bismuth and antimony has also been reported, but no commercial products have been developed. The reason why these metals are not used in commercial sensors could be that they can form thin oxide coatings (e.g. during storage before use) which may act as a barrier to further oxidation and so hinder or prevent further electrochemical reaction. Lead may be the optimal anode choice in electrochemical sensors because it does not self-corrode in the absence of oxygen (such as aluminium and zinc) but it responds rapidly when in contact with oxygen, unlike copper, which reacts and then rapidly passivates so stops working.

[100] http://www.it-wismar.de/_documents/specs/I-01_spec.pdf

[101] http://www.it-wismar.de/download.php?id=24

[102] https://sps.honeywell.com/gb/en/products/advanced-sensing-technologies/healthcare-sensing/medical-gas-sensors/ooa-envitec

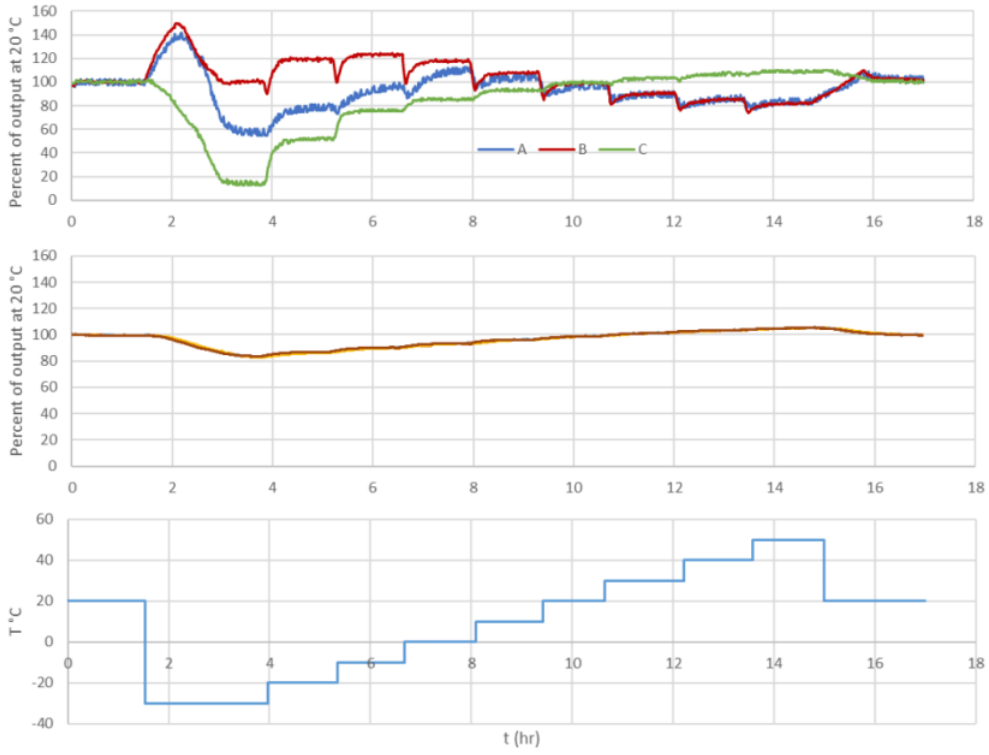
[103] https://www.figarosensor.com/product/docs/ke-lf_product%20information%28fusa%29_rev06.pdf

Nobel metals such as gold and silver do not respond at all as they do not react with oxygen from air.

(Honeywell 2023a) add that the only metals in the periodic table that have standard electrode potentials that are similar to lead are tin and germanium. Germanium is unsuitable as it forms an inert oxide that will passivate the metal (germanium is also very uncommon). Tin has a similar standard electrode potential for divalent ion formation, but the divalent tin ion can be further oxidised to the tetravalent tin ion with a vastly different electrode potential whereas, the divalent lead ion is stable and cannot easily be oxidised. Tin also self-corrodes, generating hydrogen in acid and strongly alkali electrolytes, especially at higher temperatures, so for substitution, the choice of electrolyte is important. Lead however does not self-corrode or passivate at any pH value.

Response of partial pressure galvanic lead-free sensors and lead-containing capillary senors from -30 to +50ºC was tested by Alphasense, the results of which are shown in Figure 19-6, relative to the output at 20ºC. According to (Alphasense 2023a), this shows that despite the thermistor, the output swings widely across the full range compared with lead oxygen. (Alphasense 2024a) add that the results show that lead-based capillary sensors are not overly affected by termpature changes, but lead-free partial pressure sensors are.

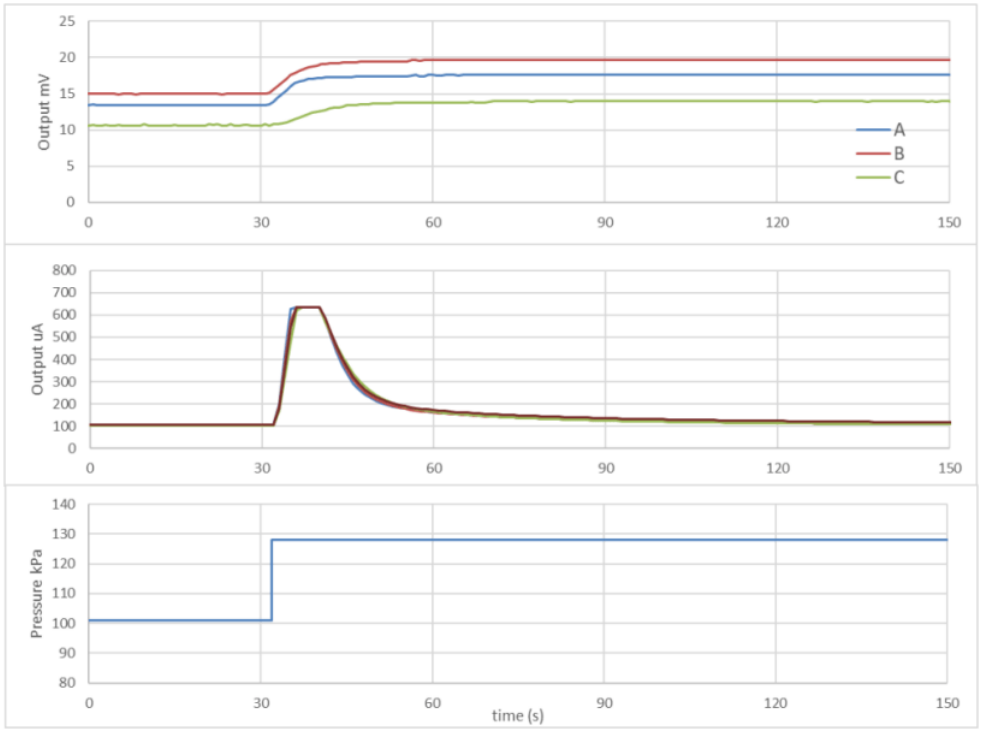
Figure 19-6: Effects of temperature changes on lead-free partial pressure galvanic sensors (top) and leaded capillary sensors (middle) tested from – 30 to +50ºC



Source: (Alphasense 2024a)

The response of partial pressure galvanic lead-free sensors and lead-containing capillary sensors to a pressure step of 25 kPa was also tested by Alphasense, as shown in Figure 19-7*. According to (Alphasense 2024a), the results show that lead-based capillary sensors quickly return to the original output where the lead-free partial pressure sensors do not.*

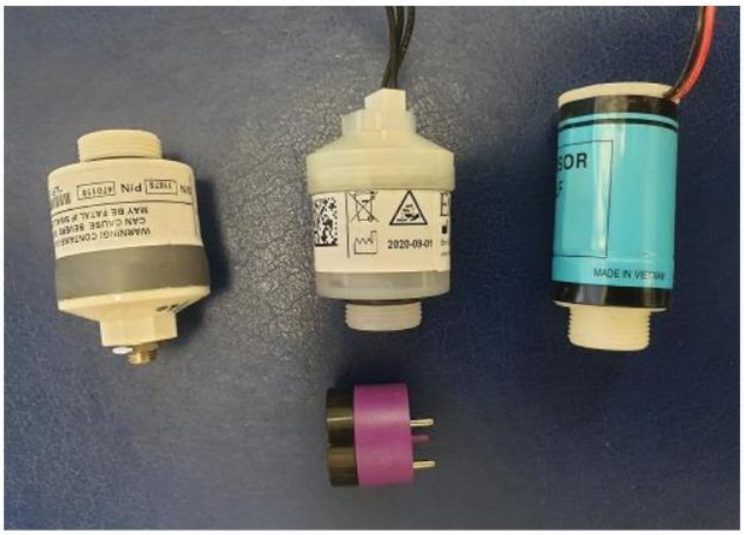
Figure 19-7: Response of partial pressure galvanic lead-free sensors (top) and lead capillary sensors (middle) to a pressure step of 25 kPa at 60s in air



Source: (Alphasense 2024a)

(Alphasense 2023a) claim that there is also a considerable size difference between the Alphasense detector and alternative designs, as show in Figure 19-8. It is estimated that the sensor on the left has around 2.5 x increase in volume.

Figure 19-8: Comparison of an Alphasense O2A2 sensor and galvanic lead-free partial pressure sensors



Source: (Alphasense 2023a)

(Alphasense 2023a) conclude that as can be seen from the technical differences in each sensor, the current lead-free alternative does not offer the necessary technical performance required for the application sensors covered by this application serve and therefore cannot be considered as viable alternatives.

(MOCON 2022) address some of the same points that are addressed by Alphasense, so they are not repeated here.

(Dräger 2023a) added that commercially available oxygen sensors that use tin anodes, as substitute to lead anodes, in a caesium carbonate electrolyte[104] *are being sold in the EU by the company ITG. However, they also state that the applicants of this renewal request have evaluated these sensors for their specific applications and found that they do not meet their specifications when used with existing designs of analysing instruments. (Dräger 2023a) further explain that tests with a type of commercial lead-free electrochemical sensor have been carried out by one manufacturer. Concerning the output signal itself, results indicate that sensors with alternative anode materials should eventually be suitable as a replacement for the lead anode sensors in redesigned instruments. However, test results showed that these sensors have a completely different behaviour in the way that they decrease voltage during operation. The voltage decreases very slowly and does not drop below 8.9 mV even if the anode is complete consumed. In existing designs of oxygen analyser, a consumed sensor with this behaviour would lead to wrong O_2-values with no possibility of detection by the device or the user that the output data was not correct.*

(Honeywell 2023a) also discuss commercialized lead-free galvanic sensors, stating that these products are not drop-in replacements because they are larger size than the smaller lead anode sensors and they also have different characteristics. Differences include:

- *Temperature capability: No lead-free galvanic sensors are recommended for use below 0°C (lead anode sensors are rated down to -20°C). Also, accuracy (static temperature error) of lead-free galvanic sensors at temperatures below 10°C is reported to be only ±10%7 , which is inferior to lead anode sensors.*
- *Pressure and temperature response: The temperature and pressure behaviour of tin anode galvanic sensors is different to that of lead anode sensors, which prevents their use as drop-in replacements.*
- *Electrical behaviour: Testing by a member of COCIR found that the commercial tin anode sensors do not behave electrically in the same way as lead anode sensors, especially when the anode has been consumed as there is no sharp drop in output when the sensor is no longer accurate. Without this sudden change, anode consumption is not detectable by the analyser instrument. This is a severe problem in safety critical oxygen monitors that are used to warn workers of too low oxygen concentrations if they do not provide an immediate alarm.*
- *Response time: For lead-free cells with tin anodes, this varies depending on the type of sensor and ranges from <5 seconds to 1 minute with many types being 25 to 40 seconds8 . Response times for lead anode sensors can be a short as 2 seconds.*
- *Size: Currently there are no lead-free galvanic oxygen sensors that can replace sensors of 20mm diameter and 17mm height. A typical commercial medical lead-free oxygen sensor has dimensions 80 x 48mm7 whereas an industrial lead-free sensor is 31.5mm wide and 40.5mm high (I-01 made by ITG). These are too large for wearable oxygen monitors.*

[104] Material Safety Data Sheet of Lead-free gas sensors of ITG http://www.it-wismar.de/download.php?id=22

- *Approvals: No lead-free galvanic sensors or their analyser instruments are available that are approved for use in automotive emissions monitoring, for diving applications or are ATEX approved. Instruments cannot be used in these applications without having the appropriate certification and approvals.*
- *Low oxygen concentrations: Analysers in the 0 – 2ppm O2 range with lead-free galvanic sensors are not available.*

(Honeywell 2023a) add that their own research has found that all lead-free anode galvanic cell designs have technical issues that prevent them from being drop-in replacements for lead-anode galvanic cells. These issues include (details are given in the request form and are not reproduced here):

- *Honeywell have determined that sensors with tin, antimony, bismuth and copper would all have to be significantly larger than sensors with lead*
- *For alternative anode / cathode combinations, the cell voltage will be different to lead anode sensors and so these sensors cannot easily be used as drop-in replacements.*
- *Trials by Honeywell found that potassium acetate solutions (as electrolyte) that are used in lead anode cells gives inferior performance (such as passivation) as an electrolyte for antimony, bismuth and copper*
- *As far as Honeywell know, all commercial lead-free two-electrode sensors have membrane diffusion barriers, there are no commercial lead-free sensors with capillaries*
- *Honeywell's research with alternative anodes has found that at higher temperatures (above 20°C), self-corrosion becomes an issue so that a current is generated when no oxygen is present. The effect of temperature on output is also different to that of lead anode cells.*
- *Honeywell found that antimony, bismuth and copper will passivate when the sensor is exposed to high concentrations of oxygen.*
- *With zinc anodes, self-corrosion is an issue*

(Honeywell 2023a) conclude that despite these difficulties and limitations, substitution is an option that warrants further research, but significant technical difficulties exist before two-electrode lead-free anode sensors can be developed that are suitable for all end-use applications. In practice, for some end-uses, 3- electrode pump cells can be used, but due to their different characteristics, these cannot be drop-in replacements and are not suitable for many end-uses.

Elimination

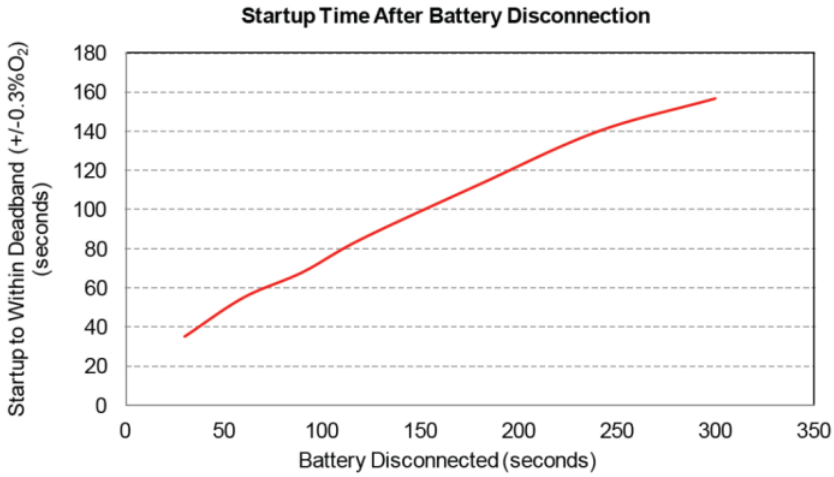
(Alphasense 2023a) confirm that there are other sensor types other than partial pressure galvanic sensors, however these do not offer the same combination of technical characteristics, as discussed below.

Amperometric type sensors (3-electrode electrochemical sensors) measure current as a result of the electrochemical reaction. The sensor operates on an oxygen pump principle where oxygen is consumed at one electrode (the working electrode) and produced at

another (the counter electrode) with a reference electrode. These can be used in a number of different applications to great effect, but have the following disadvantages:

- *Most sensors require power to be applied constantly. If power is lost the internal cavity space will equilibrate with the oxygen content in the air. When power is restored depending on the length of time without power, 15 mins to many hours is required for the output to be stabilised. In comparison, galvanic sensors being self-powered need only have the pins of the device connected to remain operable and so there is no wait when power is restored to display the correct output. Figure 19-9 shows details of one amperometric sensor as an example.*
- *Susceptible to high carbon monoxide (CO) and carbon dioxide (CO_2) concentrations, which is important for automotive, biogas and boiler flue sectors. The recovery time in CO2 conditions were longer when compared with capillary lead oxygen sensors as outlined in Table 19-5 and Table 19-6. In addition to this there was reduced sensitivity of amperometric sensors following exposure to CO above 10,000 ppm which can last several hours. Capillary lead oxygen sensors do not have this susceptibility.*
- *Require a reference electrode to operate to correctly maintain working electrode polarisation and drive the oxygen pump. Due to this, amperometric sensors cannot operate in an absence of oxygen for prolonged periods of time as the reference electrode requires oxygen to work. Galvanic sensors do not require reference electrodes so can operate in the absence of oxygen.*

Figure 19-9: Warm up times of amperometric lead-free oxygen sensor outlining start up time after battery disconnection



Source: (Alphasense 2023a)

Table 19-5: Comparison of lead-free and lead based sensor response when exposed to 8 – 15 % CO_2

		Lead Free Sensor % O2	Lead Based Sensor % O2
	Starting Value	20.94	20.94
Cycle	1	20.28	20.91
	2	20.08	20.90
	3	20.02	20.91
	4	19.99	20.91
	5	19.98	20.90
	6	19.99	20.90
	7	19.97	20.91
	8	19.96	20.90
	9	19.96	20.90
	10	19.94	20.91

Source: (Alphasense 2023a)

Table 19-6: Recovery time of lead-free sensors to a ~20.91 reading for O_2, in comparison lead based sensors always returned to this value within 3 minutes.

Elapsed Time (minutes)	Reading % O2
12	19.94
18	19.82
20	17.71
23	19.48
28	19.29
32	19.96
37	20.39
42	20.57
51	20.71
60	20.78
68	20.82
85	20.87
104	20.91
126	20.94

Source: (Alphasense 2023a)

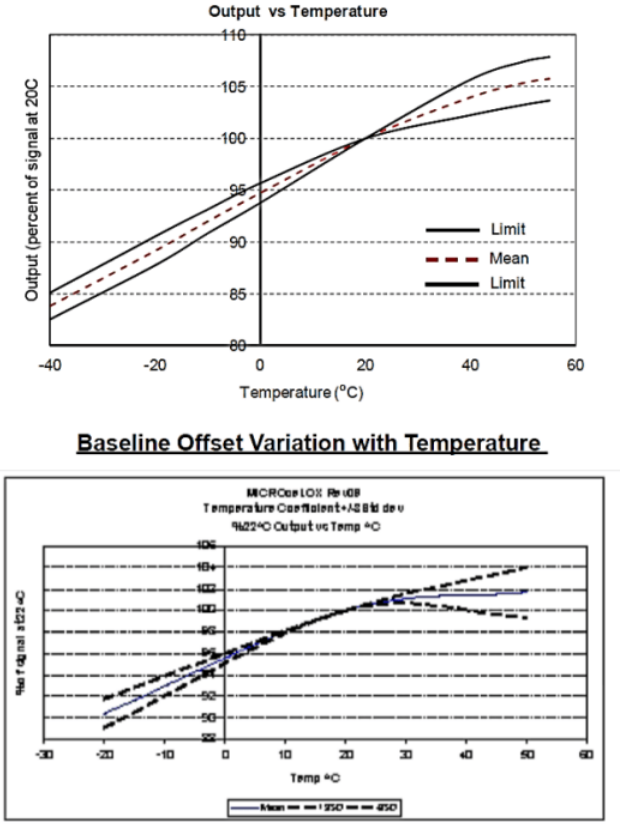
(Honeywell 2023a) describe 3-electrode amperometric type electrochemical cells (pump cells) in a similar manner, providing the following additional information:

- *A disadvantage of this sensor when compared to the lead-anode two electrode sensor is that it requires more complex electronics to control the sensor and measure its output.*
- *Changes in temperature and pressure cause different responses so they cannot be used as a drop-in replacement in applications where accurate sensing of oxygen content is required when these occur. The graphs in Figure 19-10 show that the temperature dependence of electrochemical sensors is not identical to lead-anode capillary and membrane sensors.*
- *Oxygen gas is generated at the counter electrode. This must not reach the sensing electrode as this would give false readings. This is a significant disadvantage in*

ATEX approved analysers as the evolved oxygen gas would usually be vented into the analyser's housing and this could cause a potentially explosive gas mixture when used in ATEX environments. Analyser instrument housings need to be vented to prevent pressure build up from internally vented generated oxygen but venting also allows flammable gases into the inside of the instrument's housing.

- *It can be difficult or impossible to tailor the activity of the sensing electrode to avoid cross sensitivity to contaminant gases that might also be present. This can be achieved with lead anode sensors but with three electrode oxygen pump sensors it is difficult to find an anode material and bias voltage combination that gives sufficient activity for rapid oxygen reduction that does not give unacceptable cross sensitivity.*

Figure 19-10: Dependence of oxygen sensors on temperature – above three-electrode pump-cell electrochemical sensor, below capillary lead anode galvanic sensor



Source: (Honeywell 2023a)

(Alphasense 2023a) explain that partial pressure sensors are a different type of electrochemical sensor (available in lead containing and lead-free containing versions) which but instead uses a membrane, such as Teflon, and inert electrodes in their construction. The membrane is included in the design of the sensor as it increases the life of the sensor. The rate of gas diffusion through the membrane is linearly proportional to the partial pressure of the oxygen on the two sides of the membrane, following Fick's Law. Since oxygen is reduced at the cathode, the partial pressure on the cathodic side of the membrane is virtually zero, giving a driving force which is linearly dependent on oxygen partial pressure, so the rate of gas diffusion (and hence sensor output) is linearly dependent on the oxygen partial pressure.

However, according to (Alphasense 2023a), all of these devices which rely on membranes all have the following characteristics:

- *Any change in atmospheric pressure affects linearly the oxygen partial pressure, so partial pressure sensors are linearly dependent on ambient pressure.*
- *Since the gas must diffuse through a solid polymer membrane, the rate of diffusion is dependent not only on the gas partial pressure but also on the diffusivity of the membrane. The diffusivity of polymer membranes has a high temperature dependence, typically 2 to 3%/K; this is usually corrected by using a thermistor sensor inside the body of the oxygen sensor to compensate for temperature changes. However, during thermal transients the membrane diffusivity and compensating temperature sensor will not be in phase and significant thermal transient errors can result.*
- *Since diffusion through a polymer membrane is slower than through a capillary the response time (as t90) of partial pressure sensors is typically[105] 20 to 40 seconds, in comparison devices using this exemption have a t90 value between 5 and 10 seconds.*

The consultants note that partial pressure sensors / permeable membrane sensors are in scope of the renewal requests submitted by (Dräger 2023a) and (Honeywell 2023a).

There are other types of oxygen sensors based on alternative technologies which are briefly discussed by (Alphasense 2023a):

- *Fluorescence- a fluorescent material is excited by a LED and quenched by oxygen which passes through a permeable layer (membrane). The higher the oxygen content the stronger the quenching and the less fluorescence is detected by the light receiving diode. At high oxygen levels the measurement accuracy decreases due to noise and requires power to operate. See Table 19-7 for a more detailed review of performance characteristics.*
- *Tuneable diode laser absorption spectroscopy sensors (TDLAS)- a laser absorption technique which is based on the reduction of the measured signal intensity of a laser diode. Tuneable diode lasers have a sophisticated sub-micron structure and need for precise temperature control to maintain the selected frequency. Due to its reliance on absorption the technique is limited in terms of sensitivity due to background noise. See Table 19-7 for a more detailed review of performance characteristics.*
- *Zirconia sensors – These are solid state electrochemical sensors based on yttria stabilised zirconia through which oxygen ions can diffuse when operated at high temperature (400-600^{o}C). As such they are used with gases at temperatures between 350-700^{o}C only. Require power to operate and due to interactions with other gases can have poor accuracy*
- *Paramagnetic - able to measure oxygen content between 1-100% due to the paramagnetic behaviour of oxygen. The measurement requires a suspended glass dumbbell which rotates in a magnetic field according to the oxygen concentration of the surrounding gas. As such the equipment is large and susceptible to effects from*

[105] *Alphasense 2023a add that it is recognised that there are some devices on the market with a quicker response time than 20 seconds, as a result of specific design features, however this is not true for all designs and it an important technical offering of Alphasense sensors.*

the installation angle and therefore can only be used in fixed installations. Other magnetic interference, either from other equipment, or paramagnetic gases such as NOx can also affect the results.

Table 19-7: Comparing sensitivity of oxygen sensing devices

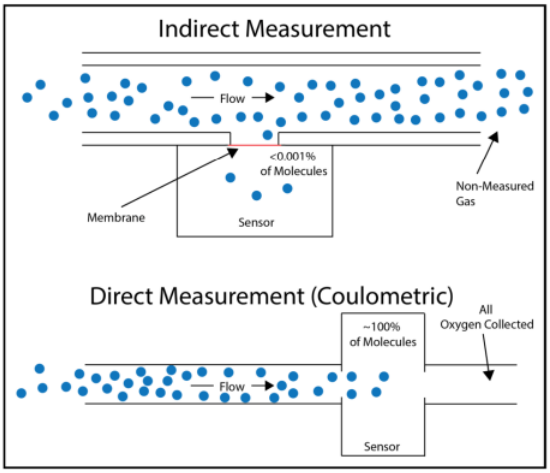
Technology	Sensor type	Operating temperature	Environmental dependence
Lead galvanic capillary sensor	Membrane free so measures 100% of the gas flow	- 30º to + 50ºC	Minimal temperature and pressure dependence
Optical Fluorescence[8]	Only partial flow	-30º to +60ºC	Affected by pressure and temperature
Optical Fluorescence[9]	Only partial flow	0º to +40°C	Affected by pressure
Optical Fluorescence[10]	Only partial flow	0º to +50ºC	Affected by humidity, pressure, and temperature
Tuneable Laser Diodes[11]	Only partial flow	0º to 250ºC (600ºC with additional thermal barrier)	Affected by pressure and temperature

Source: (Alphasense 2023a)

(MOCON 2022) highlight that in contrast to Hersch cells, membranes and capillaries are included in many sensors' designs as they to keep the electrolyte from leaving the sensor and thereby increase the life of the sensor. The principle difference is illustrated in Figure 19-11. As a result, these types of sensors are only measuring a fraction (< 0.001%) of the total oxygen present. Inherently, this means they are far less sensitive to oxygen, and they are not measuring all of the analyte. If a sensor does not collect and measure all the analyte, then it needs to be calibrated because the sensor is only measuring some unknown fraction of the total oxygen. Sensors with membrane or capillaries have to be flow and temperature compensated and are sensitive to pressure transients. These dependencies add to the measurement uncertainty and effect reliability.

(MOCON 2022) detailed why it is highly unlikely that a reference gas to low enough oxygen levels for the calibration of sensors is technically feasible and is why a calibration free method, i.e. Hersch cells, is essential.

Figure 19-11: Comparing direct vs. indirect measurement



Source: (MOCON 2022)

According to (MOCON 2022), the following table aims to provide an analysis of some alternative oxygen sensors currently available on the market, and their sensitivity such that the difference in technical performance is easily identifiable.

Technology	Detection range	Response Time	Carrier Gas Analyzed by Sensor	Sensor calibration required?	Notes
Hersch cell	200ppt to 70ppm	T90 <5 mins	100%	No	Absolute measurement, not affected by flow, temperature, or pressure
Tunable Laser Diodes[2]	Lowest limit 100 ppm	T90 <2 s	Only partial flow	Yes	-
Optical Fluorescence[3]	Lowest limit 100 ppm	T90 < 30s (typical)	Only partial flow	Yes	-
Optical Fluorescence[4]	Lowest limit 0.5 ppm	T90<3sec	Only partial flow	Yes	Affected by pressure

Optical Fluorescence [5]	Lowest limit 50ppm	T90< 2s	Only partial flow	Yes	Affected by humidity, pressure, and temperature
Zirconia[6]	Lowest limit 5000ppm	T90<4s	-	Yes	-
Zirconia[7]	100-1000000 ppm	T90<5s	Only partial flow	Yes	-
Thermal Conductivity Detectors (TCD)[8]	Lowest limit 5000ppm	T90<3s	Only partial flow	Yes	-
Pulsed Discharge Helium Ionization Detector (PDHID)	Due to column analysis the differentiation of oxygen and helium peaks is unable to be established[9] even though helium is normally used as the gas flow in the column				

Source: (MOCON 2022)

(Dräger 2023a) further discuss solid metal oxide semiconductor sensors, mass spectroscopy, optical sensors, and luminescent oxygen sensors, as alternative sensor technologies.

- *Solid metal oxide semiconductor sensors, also known as lambda probes. These are often used in vehicles to measure the differences in oxygen concentrations in supplied air and in exhaust gases by measurement of the current between electrodes. They do not measure the actual oxygen concentration (only a difference) and these usually need to be heated to 300°C and so are unsuitable in medical applications as they pose a safety risk due to the high temperature.*
- *Mass spectrometers can analyse all substances in patients' breath but the response time is too long taking many minutes to obtain a single concentration.*
- *Optical sensors: There are many types of optical oxygen concentration analysis methods, but most are either unsuitable or are designed for analysis of dissolved oxygen only (e.g. in blood). Infrared absorption spectroscopy analysis can be used to analyse many substances in industrial applications, but this technique does not respond to oxygen gas and so is unsuitable. One technique uses substances that change colour when exposed to oxygen and the colour is measured electronically. Response times can be slow and colour measurement is not very accurate and so this method cannot be used for industrial oxygen analysers where fast response times and high accuracy are essential. Another type of optical sensor uses an oxygen permeable polymer containing a luminescent compound. (Dräger 2023a) describe a number of issues that make them less useful. Some are only useful for dissolved oxygen measurements, some have slower response times.*

Besides also discussing the above, (Honeywell 2023a) further discuss the following:

- *Ultrasonic oxygen sensors measure the concentration of oxygen in a gas or liquid by measurement of the speed the ultrasonic sound waves through the gas or liquid. These are suitable when the composition of the gas is known as every substance in*

the gas will affect the speed of sound differently. They are therefore usually unsuitable in industrial environments where the air composition is unpredictable.

- *Tuneable diode laser absorption spectroscopy sensors: These are a type of infrared sensor in which the diode laser produces an infrared light beam that passes through the analysis gas to a photodiode that measures the infrared light received. By tuning the laser to specific wavelengths, they can analyse a variety of gases including oxygen. However, other gases also absorb infrared light at the absorption wavelengths of oxygen gas and so these sensors cannot be used where these gases might occur.*

(Honeywell 2023a) summarize the status of lead-anode and alternative sensor types in a table reproduced below.

Table 19-8: Status of lead-anode and alternative sensor types

Type of sensor	Advantages / Disadvantages
Lead anode galvanic	Fast response, accurate and no power consumption
Tin anode galvanic	Larger sensor size needed, passivation risk and different characteristics to lead-anode sensors
Antimony, bismuth and copper anode galvanic	Anodes passivate and self-corrosion under some conditions
Zinc anode galvanic	Self-corrosion occurs
3-electrode pump-cells	Longer cell lifetime but different control circuit so not a drop-in replacement. Consumes at least 0.5W so not suitable for lightweight small-size personal oxygen monitors. Technical issues prevent use in ATEX applications
Zirconia sensors	Operates only at high temperature
Fluorescent analysers	Interference from many gases that also quench dyes. Suitable only in clean environments. Different characteristics and circuit design to lead anode sensors so not a drop-in replacement
Others	Several other types are used commercially and are suitable for certain specific uses, but not as replacements for lead-anode sensors

Source: (Honeywell 2023a)

(Alphasense 2023a) point out that there are no lead-free drop-in replacements that can be used. Therefore, reliability issues are not relevant for this exemption renewal request. This sentiment is mirrored by the other applicants as well.

19.2.2. Environmental, health, safety and socioeconomic impacts

(Alphasense 2023a) point out that if oxygen sensors were no longer available there could be serious harm to workers which use them both as portable devices and in fixed installations. Oxygen sensors provide key safety functionality to many different industries and without them worker safety it impacted. If these industries choose to operate without

the sensors there is the potential of death from asphyxiation from working in enclose spaces, mines etc. If the industries are unable to operate without the sensors there could be the loss of certain operations within the EU and consequentially the loss of jobs. A quantitative estimate is not able to be provided due to the widespread and dispersive impacts these would have.

(MOCON 2022) point out that there are several users of high-sensitivity Hersch oxygen sensors requiring high sensitivity measurements. Applications affecting human health and the environment include:

- *The pharmaceutical industry uses Hersch cell sensors to ensure certain medications are protected from oxygen. This is required to maintain strength, and therefore public safety. The high instrument sensitivity is required to manufacture some medicines which are extremely sensitive to even trace amounts oxygen.*
- *Freshness and safety in food packaging design, which requires ppt sensitivity, is the largest application of Hersch cell sensor technology. This affects consumer safety and potentially human health.*
- *The solar panel industry relies on ppt oxygen sensors instruments to measure their high oxygen barriers. Oxygen barriers are required to prolong the lifetime of the panels. Long-lasting solar panels are necessary to generate "green" energy, which results in benefits for the environment.*
- *Similarly, the OLED [organic light-emitting diode, the consultants] industry requires oxygen barriers to create OLED screens. Only very sensitive instruments using Hersch cells are capable of measuring at the levels they require.*

(MOCON 2022) further highlight that if this exemption were to expire before an accurate and reliable alternative can be developed and commercialised, there would be a very significant risk to human health due to an ability to manufacture medicines at very low oxygen concentrations and because food safety would be compromised. Some manufacturing may not be possible without Hersch cells. It is not possible to quantify these impacts.

(Dräger 2023a) only consider socio-economic impacts, stating that insufficient monitoring of oxygen in certain industrial applications may cause harmful condition for workers (e.g. hydrogen production plants, hydrogen storage plants) thus this application has a direct influence on occupational safety issues.

(Honeywell 2023a) state that if this exemption is not renewed, EU users of lead anode oxygen sensors will not be able to obtain new instruments. This will negatively affect all of the industries and end-users. Many would be forced to stop operations because not being able to measure oxygen gas concentrations in their work environments would be too dangerous. Some end-users may decide to risk operating without monitoring oxygen concentrations, and this would pose a very severe risk to workers safety, such as when in confined spaces, tunnels, mines, etc. Deaths from asphyxiation are potential outcomes. Some EU manufacturers who produce analysers as well as end users of these analysers may cease to operate in the EU with loss of employment. Honeywell is not able to provide quantitative estimates of these impacts as they are dependent on many other industries.

(Honeywell 2023b) added that if the recommended exemption is not updated to cover lead anodes in electrochemical oxygen sensors for category 9 IMCI, this will lead to significant social, economic and global impacts and the shutdown of manufacturing and processing

sites for energy generation, mining (precious materials), water treatment, petrochemical, chemical, semi-conductor and microchip fabrication.

19.2.3. Roadmap towards substitution or elimination of the restricted substance

Actions that have been taken to develop further possible alternatives

(Alphasense 2023a) reiterate that there are alternative oxygen sensors which do not rely on RoHS restricted substances, however these can only be used in specific uses. For example, lead-free partial pressure galvanic oxygen sensors have pressure and humidity dependence and amperometric type sensors require power, are susceptible to high carbon monoxide (CO) and carbon dioxide (CO_2) concentrations and cannot be used in the absence of oxygen. Alphasense and other sensor manufacturers have carried out research into substitute metals and none are drop-in replacements as outlined above.

(MOCON 2022) explain that the length of a Hersch sensor development is a considerable undertaking due to the technical requirements the sensor has. For example, changing a single component in the cadmium version of the Hersch cell took 3 years to undertake and fully qualify. Testing is underway to identify and qualify an alternative lead-free solution. Testing to determine the corrosion and chemical compatibility has been undertaken, identifying which potential alternatives are worthwhile taking forward for subsequent testing. (MOCON 2022) provided a large table listing unnamed tested anode and electrolyte materials and observations made, which is not reproduced here, as well as more details in a confidential submission that cannot be reproduced here. Out of 32 listed material combinations, 18 are observed to be unsuitable, while the remaining are either potential alternatives for further testing or have a suitable performance for benchmarking. Further tests were carried out and for the most promising combinations, prototype Hersch oxygen sensors were constructed and installed in an AMETEK MOCON OX-TRAN Analysers to test efficiency, response, background and note other reactions. (MOCON 2022) conclude that the results to date show that a number of the potential alternatives do not have the necessary technical characteristics and as such only some combinations will be taken forward for subsequent testing (Table 19-9).

Table 19-9: Prototype Hersch oxygen sensor testing

Anode	Electrolyte	Cathode	Efficiency	Response time	Baseline	Other Reaction
Anode Material 2	Electrolyte Material 3	Cathode Material 1	Started at 70% but reduced rapidly	Acceptable	Acceptable	Possible other reaction
Anode Material 2	Electrolyte Material 1	Cathode Material 1	Not able to be tested*	Acceptable	Too High	Possible other reaction
Anode Material 3	Electrolyte Material 3	Cathode Material 1	Not able to be tested*	Acceptable	Too High	Other reaction occured
Anode Material 3	Electrolyte Material 1	Cathode Material 1	Not able to be tested*	Acceptable	Too High	Other reaction occured
Anode Material 9	Electrolyte Material 1	Cathode Material 1	Shows efficiencies in the 90% or higher	Acceptable	Low background	Acceptable
Anode Material 12	Electrolyte Material 1	Cathode Material 1	85% after 3 days	Needs improvement if taken forward	Testing to be completed	Acceptable
lead	Electrolyte Material 1	Cathode Material 1	>98.75% efficient	Acceptable	Low background	Acceptable
Anode Material 8	Electrolyte Material 1	Cathode Material 1	<5% efficient	Acceptable	Acceptable	Acceptable
Anode Material 9	Electrolyte Material 2	Cathode Material 1	83% efficient	Testing to be completed	Testing to be completed	Acceptable

* Not able to be tested as baseline was too high

Source: (MOCON 2022)

(MOCON 2022) note that in the above table, none of the possible substitutes equals the efficiency of lead. Therefore, there is no certainty that a suitable substitute will be identified, however, this work is continuing with the most promising materials. Subsequent to this, accelerated life testing is planned to be undertaken on the prototype sensors selected to be taken forward, measuring the oxygen transmission rate of the film to ensure there is no drop off in efficiency. Testing for each sensor is a duration of 6 months. Two instruments are available for this testing so only two life tests can occur at one time during a 6-month period. If sensors show suitable characteristics during the accelerated life testing, another key and usually defining characteristic is selectivity testing to ensure that potential alternative sensors do not respond to carrier gases. After this, more testing is planned, including for sensitivity, linearity, backwards compatibility, and manufacturability, reliability, and productionisation.

(Dräger 2023a) claim that research has been carried and published on a wide variety of new lead-free oxygen sensors. Industrial device manufacturers evaluate any commercial products that meet their specifications and appear to be suitable. Paramagnetic sensors are now used in side-stream applications, but cannot be used where rapid and accurate measurements are required such as in industrial applications. New lead-free electrochemical oxygen sensors are being evaluated and tests have shown that these respond very differently and so are not drop-in replacements. As a result, analyser instruments that are used with the sensors will have to be completely redesigned.

(Honeywell 2023a) reiterate that many alternative types of oxygen gas concentration analyser have been developed and each type has specific uses. For most industrial applications, lead anode cells still need to be used as there are no alternatives. For example, of Honeywell's competitors that sell lead-free galvanic sensors, there are none suitable for ATEX, diving gas or vehicle exhaust gas emission applications and most types that are available are lead anode sensors.

Stages necessary for establishment of possible substitutes and timeframes needed

Alphasense

According to (Alphasense 2023a), more research is needed to firstly develop alternative sensors that offer suitable technical performance, after which the design and validation of analyser instruments needs to occur. EU instrument manufacturers are varied, and we are unable to provide details for the full market, however all will need to be certified for their performance and depending on the end use in question the level of redesign and testing will vary. For example, the testing of alternatives have to consider and evaluate the effects of other gases which might occur during the products lifetime, for oxygen sensors up to 60 kinds of interference gases might occur, with different concentration levels depending on the application. The effects of the gases and their relevant concentrations need to be fully verified as they can influence the sensitivity and accuracy of the oxygen concentration measurement. In addition to this many applications require instrumentation be ATEX certified. The following tables provides an estimation on the expected timeframes for the development of an alternative, it is important to note that the following are based on the concept that each test will 'pass' first time. If any further development is required to resolve technical issues the timeframes outlined would be much longer.

Development of lead-free galvanic capillary oxygen sensor

(Alphasense 2023a) state that currently no sensor of this type exists on the market, so it is not certain if a technical alternative is possible. The initial phase of testing will determine if an alternative is viable by testing parameters such as:

- *The development of core chemistry (12-18 months)*
- *Sensor house development, including the tooling required for such sensors (6 months)*
- *Optimisation of the design, including aspects such as the review of differing wetting layers and electrical contacting parts in the sensor (6 months)*
- *Performance and accelerated life testing (12 months)*

Some of this testing can be undertaken in parallel so the overall timeframe is estimated to be around 2 to 2.5 years. Field testing of sensors is critical as it involves testing the performance in variable conditions with regard to temperature and pressure, mechanical shock testing, vibration and drop testing. As well as ensuring the performance in the presence of interfering gases. However, if all of these tests identify a suitable alternative then the timeline outlined in Table 19-10 provides an estimated of how long this would take.

Table 19-10: Development of lead-free galvanic capillary oxygen gas sensor

Development stage	Time required
Sensor manufacture and development	2-2.5 years
Field testing of sensors	12 months
Evaluation by instrument manufactures	6 months +
Performance testing to ISO 50104 and certification	6-12 months
ATEX Approval	18 months - 2 years
Total	4 – 5 years For ATEX rated products: 5.5 - 7 years

Source: (Alphasense 2023a)

According to to *(Alphasense 2023a), performance testing to ISO 50104 and certification mandates 23 tests, including stability testing, environmental testing, performance with other gases, etc.* [for the full list see applicants' exemption request form, the consultants]. *Given the wide range of tests required, the overall time to complete all of the tests will vary with the availability of environmental chambers, gas supply facilities and personnel to undertake the work, and has to be scheduled around other work using the same facilities. As such there is some uncertainty over the timeline estimated.*

Development of lead-free amperometric oxygen sensor

(Alphasense 2023a) highlight that some instrument manufacturers are migrating to amperometric lead-free oxygen sensors already (when the end use application allows for this). Given the technical differences in amperometric sensors as described above for other applications additional time as outlined in Table 19-11 is required. (Alphasense 2023a) note that there may be technical characteristics which will be intrinsically different with this using an amperometric sensor compared to galvanic capillary sensors, which may offer decreased technical performance not acceptable by certain customers.

Table 19-11: Development of lead-free amperometric oxygen gas sensor

Development stage	Time required
Redesign of instruments (in parallel with the below)	12 months
Evaluation by instrument manufactures	6 months +
Redesign of key performance parameters to be undertaken in consultation/testing with end product customers e.g. warm up time	12-24 months
Performance testing to ISO 50104 and certification	6-12 months
ATEX Approval	18 months - 2 years
Total	3 - 4.5 years For ATEX rated products: 4 - 6 years

Source: (Alphasense 2023a)

(Alphasense 2023a) conclude that as the majority of the capillary industrial market is expected to change to amperometric sensors when the technical issues are resolved, they would request the exemption be granted for another 4 years to allow for the necessary testing and development to occur in general applications. For applications which are ATEX rated, they would request that the exemption be granted for another 5.5 years.

MOCON

(MOCON 2022) provided the following table provides an estimation on the expected timeframes for the development of an alternative, it is important to note that the following are based on the concept that each test will 'pass' first time. If any further development is required to resolve technical issues the timeframes outlined would be much longer.

Table 19-12: Qualification requirements and timeframe

Stage	Requirement	Indicative Timeframe
1	Accelerated life testing as outlined above	6-12 months
1	Key parameter testing, such as response time, low level detection, sensitivity to other gases (such as hydrogen, nitrogen, and water vapour), linearity as outlined above and including the build and testing of protypes until the necessary technical performance is achieved.	18-24 months
2	Reliability testing	12-18 months
3	Productionisation	3-6 months
Total		3 ¼ years- 5 years

Source: (MOCON 2022)

(MOCON 2022) note that the above timelines are based on the assumption that suitable technical performance is able to be achieved with one of the currently identified potential

alternatives and further process refinements or alternatives are not required to be undertaken. Until stage 1 and 2 testing is completed it is not known if an alternative is able to provide the necessary technical requirements as much of its viability depends on alternatives intrinsic chemical characteristics. As such there is some uncertainty in the timeline of qualification, with current estimates based on the best information available at the point of writing this request.

Reliability testing will include the following tests to ensure that the sensor is able to operate at the stated technical requirement for its lifetime and no other factors influence its operation:

- *Shock and vibration testing to ensure that the sensor is not affected. Testing for this is estimated to take 2-3 months,*
- *Pressure loading of the sensor. Testing for this is estimated to take 2-3 months,*
- *Impact of exposure to H_2 and N_2 over extended periods of time to ensure that it does not affect the sensitivity of the sensor. The testing for this takes an estimated 3-6 months,*
- *Temperature cycling to replicate shipping and in service use. Testing for this is estimated to take 3-4 months, and*
- *Over-range recovery of the sensor to ensure the sensor is able to operate as effectively in the extreme conditions of the sensor. Testing for this is estimated to take 2-3 months.*

(MOCON 2022) emphasize that, as outlined above, although there are some initial signs that a lead-free alternative might be possible at this time, it cannot be confidently stated that an alternative material exists. It is only towards the end of the above outlined test period that this would be able to be stated.

Honeywell

(Honeywell 2023a) state that For most end-uses, more research is needed to develop alternative sensors that are suitable. It will also be necessary to design suitable analyser instruments for the alternative sensors as these are unlikely to be drop-in replacements as described above. Honeywell is developing alternative sensors and also replacement analyser instruments. For most end-uses, validation testing and approvals are also required before the new instruments can be sold in the EU or globally.

However, depending on the end use application in question it is expected that different levels of redesign work will be required and hence different timeframes will needed. The following timescales refer to instruments that currently use membrane cell sensors. In all cases below, the sensor development phase is uncertain. This would be up to 4 or 5 years if a totally new sensor design is needed, but perhaps only about six months if an existing Honeywell sensor such as a pump cell could be used. The actual timescale will not be known until further development work and testing has been carried out although it is likely that new sensors will be needed for at least some applications.

- *Oxygen gas concentration monitor for safety applications including portable analysers. For portable applications, these must be small and lightweight and need to be accurate and reliable with new batteries or after recharging during at least a working shift. This is an issue with 3-electrode sensors as these have higher power*

consumption than the lead anode sensors. Likely steps and timescales are outlined in Table 19-13.

Table 19-13: Lead-free oxygen sensor development for safety applications

Development stage	Time required
Sensor development	Ca. 6 months
Analyser instrument development	3-4 years
Approvals	1 year
Total	4 to 5 years

Source: (Honeywell 2023a)

- *ATEX approved analysers. The generation of oxygen inside the housing, which must be vented is a serious limitation and currently, this is not technically possible. If a suitable sensor is available, then the following would be required. Likely steps and timescales are outlined in Table 19-14.*

Table 19-14: Lead-free ATEX approved analyser development timescale

Development stage	Time required
Sensor development	Up to 3-4 years
Analyser instrument development	3-4 years
Testing for compliance with applicable ATEX standards	1 year
Approvals by ATEX Notified Body	1 year
Total	8 – 10 years

Source: (Honeywell 2023a)

- *Vehicle exhaust analysis, SCUBA diving gases, Bio-ox and medical applications*

Table 19-15: Lead-free analyser development timescale

Development stage	Time required
Sensor development	Up to 4 - 5 years
Analyser instrument development	4 - 5 years
Instrument validation and approvals	2 years
Total	10- 12 years

Source: (Honeywell 2023a)

- *More technically difficult applications such as 0 – 2ppm O2*

Table 19-16: Lead-free analyser development timescale 0 – 2 ppm

Development stage	Time required
Sensor development	Up to 3 – 4 years
Analyser instrument development	5 years
Approvals	1-2 years
Total	Up to 11 years

Source: (Honeywell 2023a)

19.3. Critical review

19.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several uses of lead and lead compounds are listed in Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds. None of those entries are, however, relevant for the use of lead in the scope of exemption IV-1(b) (cf. section 4.2 on page 43 for details).

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

19.3.2. Adoption of the recommendation from the previous evaluation report

Exemption 1(b) was reviewed by (Deubzer et al. 2022) who recommended a renewal with the wording and scope reproduced in section 19.1.1 "History of the exemption" in Table 19-3.

At the time of the current review of exemption IV-1(b), the COM have not yet officially published their decision as to the adoption of the recommendations made by (Deubzer et al. 2022). Therefore, the COM wish the consultants to assess in this current review whether there are any substantial reasons in line with Art. 5(1)(a) against the adoption of the above recommendation for EEE of categories 8, 9 and 11.

During the review of the current exemption renewal request, the applicants were informed that if this review shows that the applicants' arguments justify the renewal of the exemption,

the consultants would recommend the wordings, scopes and expiry dates given in Table 19-17, adapted from the recommendations by (Deubzer et al. 2022).

Table 19-17: Renewal of exemption 1(b), adapted from (Deubzer et al. 2022)

No.	Exemption	Scope and dates of applicability
IV-1(b)	Lead anodes in electrochemical oxygen sensors.	Expires on 21 July 2021 for cat. 8 medical devices other than in vitro diagnostic medical devices
IV-1(b)(I)	Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and/or exhaled air for patients and that are consumables in medical devices put on the market before 26 May 2024.	Expires on 21 July 2025 for cat. 8 medical devices other than in vitro diagnostic medical devices
IV-1(b)(II)	Lead in galvanic oxygen sensors in instruments that are (a) designed for the measurement of oxygen in gases with a response time < 3 s (t95) and which are not handheld devices, and (b) designed for the measurement of dissolved oxygen in concentrations below 30 ppb.	Expires on - 21 July 2025 for cat. 9 monitoring and control instruments other than industrial monitoring and control instruments - 21 July [2025 **+ X***] for cat. 9 industrial monitoring and control instruments

*X can be a maximum of 6 years

When requested to comment on and explain any obstacles to the adoption of the above proposal for the requested exemption for category 9 IMCI, the applicants responded that they could not agree its adoption, based on the reasons summarized below.

- *(Alphasense 2023b) stated that the criteria of a response time of less than 3 seconds and having a sensitivity of 30 ppb are not applicable to capillary sensors. Rather, capillary sensors are able to measure to 20 ppb and have other critical performance characteristics which include the ability to operate at 0% oxygen, minimal response to temperature and pressure and wide operating temperature range. (Alphasense 2023b) also explain that technical differences between capillary sensors and those outlined in the recommended exemption IV-1(b)(II) are that the former permit the measurement of oxygen gas in fixed installations, personal monitoring devices and permeation measurements, all of which are not captured by 1(b)(II).*

- *(MOCON 2023) stated that the criteria of a response time of less than 3 seconds and having a sensitivity of 30 ppb are not applicable to Hersch sensors. Rather, Hersch sensors are able to measure to 200 ppt. The sensor response takes less than 8 minutes to 99 % full reading. (MOCON 2023) also explain that technical differences between Hersch cells and those outlined in the recommended exemption IV-1(b)(II) are that Hersch cells permit ultra-low detection of the absolute measurement of oxygen gas in the range of 200ppt to 70 ppm, critical to the production of pharmaceutical products, medical applications, assessment of the integrity of food packaging and solar panel lifespan calculations and improvements.*

- *(Dräger 2023b) stated that the recommended exemption wording does not cover the use of electrochemical sensors as consumables / spare parts in IMCI that will be put on the market before the expiry of the current exemption on 21st July 2024 or at the end of the requested exemption on 31st December 2025. (Dräger 2024a) added that sensors have a response time of well over 3 seconds and that the exemption wording would apply to their sensors if the restriction < 3 seconds response time was waived from the wording.*
- *(Honeywell 2023b) stated that the criteria of a response time of less than 3 seconds and having a sensitivity of 30 ppb are not applicable to galvanic IMCI sensors. The criteria are limited and not representational of the requirements of industrial monitoring and control instrumentation for safety, emissions, automotive, biogas, diving gas analysis and environmental applications.*

In the previous review of this exemption, the applicant JBCE had agreed to exclude sensors with a reaction time > 3 seconds from the exemption scope for oxygen gas senors. The applicants were asked to explain for which reasons their sensors require the exemption even if their reaction time is higher than 3 seconds.

- *(Alphasense 2024a) reiterated that lead is critical to achieving other required technical performance characteristics, for example, sensors which have minimal response to pressure, temperature and humidity, while having a short warm-up time and are self-powered. This provides unique functionality, which is not able to be offered without lead, and is critical to applications such as health and safety monitoring devices and automotive exhaust gas monitoring. Generally, Alphasense emphasize that the JBCE submission did not outline uses with relate to the industrial safety market, which is the main market for Alphasense device types.*
- *(MOCON 2024a) also reiterated that lead is critical to achieving the other technical performance characteristics, such as absolute oxygen measurement (measurement without the need for calibration) which allows the measurement down to concentrations as low as 200 ppt. MOCON added that Hersch devices are not used as handheld devices.*
- *(Honeywell 2024a) also stated that lead is critical to achieve the other technical performance characteristics. For example, it is self-powered and does not self-corrode or passivate under any conditions inside the sensor. They elaborated that the response time for an electrochemical oxygen sensor is determined by a number of factors, including the load resistor/electrical circuitry; the rate of diffusion of oxygen through the diffusion barrier (capillary or solid membrane); the bulk flow restriction of oxygen in capillary sensors; the diffusion rate of the oxygen through the electrode membrane and electrode structure; the electrolytic species (electrolyte material and concentration); the three phase interface (O_2, cathode catalyst and electrolyte); and the the cathode and anode material, structure, composition and activity. Due to these factors some sensor types cannot meet the 3 second response time, but still provide unique technical functionality which requires the use of the exemption. It is worthwhile noting that due to these fundamental characteristics listed above, various sensor designs have had response times greater than 3 secs since their conception in 1977.*

Further, the applicants during the previous review had agreed to exclude handheld devices from the scope, stating that these do not require the use of lead anodes. The applicants were asked to explain for which reasons handheld devices still require lead in their view.

- *(Dräger 2024a) also state that they have not used lead-containing oxygen sensors in portable gas detectors for decades and therefore agree that handheld devices do not require lead. They specify that these would be used exclusively for the personal protection of a worker. Ambient atmospheres consisting of saturated organic vapors in which the oxygen content must be lowered to prevent ignition simply do not occur in such cases. Once a portable measuring device has been in a harmful atmosphere for some time, it is taken out of this environment again by the worker and can regenerate in fresh air before being exposed to challenging atmospheres again.*

- *(Honeywell 2024a) reiterated that lead is critical in the functioning of capillary and membrane diffusion cells used in applications such as portable air monitoring applications; health and safety personal monitoring applications; exhaust monitoring applications; diving and bio-gas measurement. The rationale for the use of lead-based sensors in handheld devices includes that power consumption of sensors for use in portable monitoring instruments needs to be sufficiently low (ideally zero) so that the analyser can be powered by small lightweight batteries, ideally rechargeable types, for at least one working shift of 8 – 10 hours. This allows the device to be a suitable size and weight. Mechanical stability and short warm-up time after being switched off for 24 hours are also relevant factors. Environments where re-charging is not practical requires lead-based sensors, such as marine applications. Lastly, single gas use instrumentation with non-rechargeable batteries for continuous use for 1-2 years require lead.*

Given that Dräger had agreed that handheld devices did not require lead, Honeywell was asked to respond to their statement: (Honeywell 2024b) responded not to agree to Dräger's above statement, as Honeywell does not regard those as the main reasons to use lead in sensors in handheld devices. Honeywell assume that the alternative lead-free oxygen sensor that Dräger are referring to is an oxygen pump. This type of sensor can be affected by exposure to organic vapour and can take time to recover. The use case described by Drager only applies to a minority of use cases and is therefore not the main reason for why oxygen pump sensors are not widely used. According to (Honeywell 2024b), handheld devices need to be low power and small. This can preclude the use of oxygen pumps (which require power) and alternative lead-free anodes which are too large. Honeywell applications have to be able to operate in an array of challenging applications including extreme climate conditions, harsh environments, or remote locations (e.g., artic circle, sea, platform, refinery, landfill, facility, emission efficiency monitoring) where they are not able to be removed from the environment or location, due to access and/or lack of power.

Dräger were invited to comment on the above, and stated that they had been providing lead-free oxygen-sensors for portable devices for several decades. Through purposeful design of the sensors and gas measurement devices, it is well possible to reduce the power consumption to a degree that makes these sensors compatible with most of the above-described requirements (rechargeable device for an 8-10 hour shift, warm-up time within seconds). Concerning single gas units with run-times up to 2 years, Dräger Pac single gas detection instruments with oxygen sensors are lead-free and last for approximately 10 months without need for recharging or battery replacement. Afterwards, the costumer needs to replace the battery which we consider an acceptable inconvenience which does not justify further use of lead-based sensors. This period of time is valid for typical applications of

personal air monitoring devices, where ambient air with an oxygen-content of 20.9 vol% is present for most of the time. (Dräger 2024b) further specified to use three-electrode electrochemical amperometric oxygen sensors operated by a potentiostat in their portable gas measuring devices, rather than partial pressure / permeable membrane sensors.

JBCE, the applicant during the previous review by (Deubzer et al. 2022) were also invited to comment. (JBCE 2024a) provided the following statements:

- *The applications for the oxygen sensors for which JBCE requested the renewal of exemption IV-1(b) are gas measurements, and more specifically air pollution, factory emissions, automotive emissions, dissolved oxygen in water, etc. JBCE has no information on whether lead-free can or cannot be used in other applications. No additional information regarding lead-free solutions for handheld devices was provided.*

In the consultants' view, it seems plausible that the applications for which JBCE requested the renewal of exemption IV-1(b) overlap, but do not cover all applications for which the current applicants request the exemption, such as industrial safety applications. It appears plausible to the consultants that in different applications (use cases), different technical specifications are required to be fulfilled by the oxygen sensors, which may be different from fast response time and may justify the use of lead in some cases. The same applies to handheld devices, which, depending on their use case, may require certain specifications that are different from use cases and specifications required by JBCE. Differences between the viewpoints of Dräger and Honeywell are, at least in part, also likely due to differences in end use applications.

19.3.3. Scope clarification

The applicants were requested to provide information on the sensor technologies and their specifications in scope of the renewal requests, the results of which are reproduced in Table 19-18.

The consultants note that all sensor technologies in scope of the requests for renewal are for the measurement of oxygen concentration in gases rather than for dissolved oxygen in liquids. This is in contrast to the previous review of this exemption by (Deubzer et al. 2022), in which the applicant[106], JBCE, described both fields of application and differing technical requirements, which caused the consultants to recommend the exemption wording listed in Table 19-17(page 409) referring to oxygen gas and dissolved oxygen sensors separately.

The consultants further note that the applicants request the exemption for three different oxygen sensor technologies: capillary, membrane diffusion, and Hersch cells, which differ in their technology, specifications, and applications (use cases).

Table 19-18 also shows that even for the same sensor technologies, applicants request differring validity periods. This aspect is discussed further below in section 19.3.4.

[106] COCIR were another applicant but only for cat. 8 medical devices which are not relevant for this review.

Table 19-18: Overview on relevant specifications of the sensor technologies in scope of the exemption renewal requests

Sensor attributes	Alphasense (capillary)	Honeywell (capillary)	Honeywell (membrane diffusion)	Dräger (membrane diffusion)	MOCON (Hersch)
Sensor technology	Capillary	Capillary	Membrane diffusion / partial pressure	Membrane diffusion / partial pressure	Hersch (Pb / Cd)
Oxygen gas / dissolved oxygen	Oxygen gas	Oxygen gas	Oxygen gas	Oxygen gas	Oxygen gas
Main technical differentiator	Oxygen enters sensor through a small hole, not a membrane	Vented and non-vented O2 measurement	Vented and non-vented O2 measurement	The combination of the materials gold and lead results in an extremely stable operating point that can hardly be shifted by external influences. In addition, there is an encapsulated design without gas exchange through a porous membrane, which makes the sensor very robust in challenging technical environments (e.g. chemical industry, aerospace, process technology, etc.).	Absolute method of measurement (Coulometric), extremely low levels of detection
Applications / application examples for cat. 9 IMCI	Fixed installations, personal monitoring devices in mines, automotive emissions testing, anaerobic digestion/ biogas, permeation	Fixed installations and mobile; safety, emissions, automotive, biogas, diving gas analysis, env. applications	Fixed installations and mobile; automotive, medical, biogas, diving gas analysis, env. applications	Inerting processes, monitoring lower explosion limits of industrial processes	Permeability measurement of film, membranes, packaging in pharmaceutical, medical, food applications…

Sensor attributes	Alphasense (capillary)	Honeywell (capillary)	Honeywell (membrane diffusion)	Dräger (membrane diffusion)	MOCON (Hersch)
	measurements (to 20 ppb) in applications such as packaging of food and pharmaceutical packing.				
ATEX relevancy	Yes	Many designs: Yes	Many designs: Yes	Yes	No
Response time t90	< 15 s	Various: Typical safety applications require 10-15s	Various: Automotive: < 40 s (T99.5) Biogas: < 15 s Diving: < 30 s & < 7 s	< 40 sec. with dust filter	< 5 min
Init. output voltage	N/A	Typical capillary safety portable: 8-12 MV in air (100 ohms load resistor)	Typical membrane partial pressure: 9-13mV in 210mbar O2	Up to -20 mV	N/A
Init. output amperage	100 µA for standard 2 year sensor	Typical capillary safety portable device: 0.08mA – 0.12mA in air	55 to 85 µA in 21% O2 @ 20°C	I0 40 to 65 µA	N/A
Measurement range	0 – 30%	Volumetric oxygen: 0-30% or 0-1000 ppm	0 – 100%	0 - 100% Vol%	200 ppt – 70 ppm
Lower detection limit	20 ppb (cap. O_2 sensors for permeation measurements only)	Typically safety: 0.1-1% O_2.	Typically: 0.023-0.47% O_2.	5000 ppm	200 ppt
Operating temp. range	-30 to +50 ºC	-20°C to +50°C	-20°C to +50°C	-20°C to +40°C	30 to 43 ºC

Sensor attributes	Alphasense (capillary)	Honeywell (capillary)	Honeywell (membrane diffusion)	Dräger (membrane diffusion)	MOCON (Hersch)
Operating pressure range	80 – 120 kPa	Typically: 900-1100 hPA or 800-1200 hPa depending on specific sensor design	Typically: 500-2000 hPa	700 to 1300 hPa	530-1200 hPa
Sensor power requirements	Self-powered	Self-powered	Self-powered	Self-powered	Self-powered
Lifetime	1-3 years, standard is 2 years	1-2 years	1-2 years	1-2 years	1-4 years
Unique advantages over alternative technologies	Minimal response to pressure, temperature and humidity, while having a short warm-up time and are self-powered.	Section 4C of Honeywell request. Pages 8-9.	Section 4C of Honeywell request. Pages 8-9.	The sensor is resistant to poisoning by organic saturated vapor atmospheres (alkanols, esters, ketones) when monitoring ignitable air vapor mixtures.	Detection of trace quantities; absolute method of measurement (Coulometric) which removes the need for sensor calibration
Promising alternatives to lead (please highlight those only that justify further research)	There are no lead-free alternatives which offer the same technical performance as the lead capillary sensor	Section 6 of Honeywell request. Pages 10-20.	Section 6 of Honeywell request. Pages 10-20.		Different combinations of anode, cathode and electrolyte material are being tested, with screening testing identifying combinations to take forward for further testing. However, it should be noted that so far all possible substitute offers the same performance as lead and as such there

Sensor attributes	Alphasense (capillary)	Honeywell (capillary)	Honeywell (membrane diffusion)	Dräger (membrane diffusion)	MOCON (Hersch)
					is no certainty that a material with suitable technical performance can be identified.
Promising alternative sensor technologies (please highlight those only that justify further research)	There are no alternative technologies which offer the same technical performance as the lead capillary sensor		Section 6 of Honeywell request. Pages 10-20.	Technical solutions are being developed, but are not yet fully developed and are not protected by patents.	No alternative technologies exist with suitable technical performance
Renewal requested until	January 2027 for general applications; July for 2028 for ATEX rated products	July 2031	July 2031	December 2025	January 2028

From the provided information, among the three sensor technologies, Hersch cells seem technically more distinct. In contrast to the other two technologies, Hersch cells are capable of measuring absolute oxygen and much lower concentrations. However, differences and similarities in the technical capabilities and use cases of capillary oxygen sensors and permeable membrane (partial pressure) sensors were not immediately clear to the consultants. Upon request, (Honeywell 2024b) provided some additional information, summarized in Table 19-19 below. They also stated that both techniques allow the monitoring of oxygen, however volumetric measurements at 0-30% allows for a simpler design and faster responding sensor, i.e. capillary sensors, as opposed to a partial pressure (membrane diffusion) sensor. (Alphasense 2024b) confirmed that capillary lead oxygen sensors are less reactive to temperature and pressure, and are smaller. Partial pressure oxygen sensors are larger than the standard format capillary oxygen sensors.

Table 19-19: Comparison of capillary and partial pressure sensors

Aspect	*Capillary oxygen sensors*	*Partial pressure oxygen sensors*
Measurement range	*0 to 30 % and 0 to 2 ppm O_2*	*0 to 100 % O_2*
Advantages	*Faster; more robust for variable applications and conditions, including temperature, pressure, humidity, dirt, dust, vapours, chemical extremes) which could cause damage to the solid-state diffusion barrier; safety standard 4series size, operation temperature range -20 to 50°C, no passivation or H_2 evolution*	*Linear 0 to 100%, stable temperature onboard compensation, tolerant to CO_2, operation temperature range -20 to 50°C, no passivation or H_2 evolution*
Use cases	*Personal monitoring, confined space entry (fire safety, sewage, bilge tanks, tank inspection, food storage, manufacturing lines, mining), area monitoring, remote sensing, food packaging, leak detection. Emissions monitoring, boiler/burner domestic, burner efficiency commercial, landfill, outgassing, refinery*	*Exhaust measurement test equipment: exhaust measurement. Biogas, Industrial monitoring of gas generation/manufacture of bottled gas, in applications eg: Self-contained breathing apparatus*
Limitations	*Rapid temperature and pressure transients. Slightly non-linear. Intolerant to CO_2. Resolution at low O_2.*	*Output pressure sensitivity*

Source: (Honeywell 2024b)

(Honeywell 2024b) also noted that there are size considerations, stating that there is no alternative lead-free anode in the industrial safety standard size/format (4series 17 mm high, 20.4 mm diameter) as a drop-in replacement for instrument manufacturers (OEM), due to the fundamental chemistry limitations. Additional time will be required for design, development, recertification, approval, and intrinsic safety.

Interlinkage with exemption request IV-2022-2

Besides this renewal requests for exemption IV-1(b), covering sensors using lead anodes including Hersch cells, MOCON also requested a renewal for exemption IV-43, which permitted the use of cadmium anodes in Hersch cells. However, as the latter renewal request was submitted less than 18 months before the expiry date, it is considered as a new exemption request in this report (IV-2022-2) rather than a renewal request.

The consultants noticed inconsistencies between statements made in both exemption requests when the specifications of lead anodes in Hersch cells are discussed. For instance, in the request form for IV-2022-2, the applicants stated that lead is unsuitable for measurements in the parts per trillion (ppt) range, while (MOCON 2022) indicated lower detection limits of 200 ppt in the request for renewal for IV-1(b). Similarly, in the request for exemption IV-2022-2, the applicants had stated that lead does not provide the "Coulometric" (absolute) accuracy and characteristics of cadmium, while claiming the opposite in the renewal request for IV-1(b). When requested to clarify, (MOCON 2024a) provided the following explanation:

"The change in the statements relates to the change in our understanding which has been developing as testing for lead, and lead-free alternatives which has been ongoing. At the point that the cadmium renewal application was submitted, testing for lead had not yet started as investigations into RoHS compliant alternatives was on-going but not indicating the possibility of finding a viable alternative. Investigations into RoHS compliant alternatives was not halted, but lead was added to the scope of the work which was intended to provide an interim solution. By the time IV-1(b) renewal was submitted the investigations into lead were underway and reflect our change in understanding. It is important to note that while sensitivity has been maintained with the transition from cadmium to lead, there has been a reduction in manufacturability of the lead sensors (~20% reduction in sensors which meet performance criteria). Due to these manufacturing issues there is an increase in scrap of such sensors from this, and therefore an increase in the use of lead overall to meet the customer demand for sensors of this type."

When asked whether both variants of Hersch cells, with lead and cadmium anodes, were needed on the market and for which reasons, (MOCON 2024a) explained the following:

"The application for lead was submitted to ensure that Hersch cell devices, as MOCON is the only manufacturer worldwide of such devices, were able to be placed on the market. This is due to the consideration that the timeframe to renew the use for cadmium had passed and we were informed that this would be treated as a new application not benefiting from continued validity while the application was reviewed. The transition to lead ensures that the critical functions that Hersch cells provide are still able to be provided, although there are manufacturability concerns as outlined in our answer above."

When asked how the substitution of cadmium with lead was achieved and how long the process took, (MOCON 2024a) stated:

The properties of lead are the most similar to the original design of cadmium, however lead has distinct different technical parameters compared to cadmium. Importantly however it still offers the necessary technical performance, especially when compared to solutions that are free from RoHS-restricted substances. Work to develop a fully RoHS-compliant alternative is still on-going but requires more time. The process to move from cadmium to lead is expected to take 24-36 months in total, with the development of the lead sensor still on-going. It is important to note that due to the larger fundamental differences in properties

of RoHS restricted substances, the timeframe to qualify these substances is expected to be longer, and it is still not clear if they will be able to offer all of the necessary technical performance characteristics.

When first investigating a cadmium replacement, as well as RoHS compliant alternatives, an important item that must be considered is thermodynamic nobility. Thermodynamic nobility of any metal is assessed in contrast to the standard hydrogen electrode (0V). Metals with a higher equilibrium reaction potential are considered more noble thus being less likely to corrode and poor anode candidates. Lead's thermodynamic nobility is quite similar to that of Cadmium, with standard reduction potentials of (-0.58V) and (-0.81V), respectively. When first investigating a cadmium replacement, as well as RoHS compliant alternatives, an important item that must be considered is thermodynamic nobility. Thermodynamic nobility of any metal is assessed in contrast to the standard hydrogen electrode (0V). Metals with a higher equilibrium reaction potential are considered more noble thus being less likely to corrode and poor anode candidates. Lead's thermodynamic nobility is quite similar to that of Cadmium, with standard reduction potentials of (-0.58V) and (-0.81V), respectively.

(MOCON 2024a) summarize that throughout the investigation, alternatives free from RoHS-restricted substances have been investigated, but to ensure that the unique functionality of Hersch cells could still be offered a shorter term solution in lead was implemented.

19.3.4. Substitution and elimination of the restricted substances

All applicants have described the challenges of substituting lead used in oxygen sensor anodes with alternative metals. Honeywell was requested to elaborate on their testing efforts using alternative anode materials, using tin as an example that is repeatedly mentioned in the applicants' renewal request forms, and which had been claimed to self-corrode*. (Honeywell 2024a) elaborated that no specific testing has been undertaken to experimentally prove such an outcome, as the outcome is able to be predicted by basic theoretical understanding of device types. Certain anode materials that are less active than lead tend to passivate (form an insoluble oxide, so the sensor stops working), such as bismuth and antimony. One approach used to reduce the activity of tin is to alloy it with less active materials. However, this does not completely solve the issue. Such sensors still passivate before the whole anode is used up, because the more active material (tin) is consumed first then the remainder is passive. Tin alloys and bismuth can be used in some applications – for example medical sensors where there is a huge excess of anode (about 10x higher than is theoretically needed) and where the sensor current is very low. This approach is not practical for portable safety sensors, where the whole of the anode needs to be useable to achieve the necessary lifetime. In addition to this such applications which use tin anodes require a load resistor to meet the voltage requirements, but has the disadvantage that a lower sensor output current reduces resolution and accuracy, as well as increasing noise. As such it is not a viable solution in the applications considered in the renewal request.*

In the following, substitution and elimination are discussed individually for each of the three requested sensor technologies.

Capillary oxygen sensors

Lead-free permeable membrane oxygen sensors are available on the market, however, according to the applicants, lead-free variants of capillary sensors are not.

Alphasense stated that the capillary industrial market is expected to change to amperometric sensors when technical issues are resolved, for which they estimate a timeframe until January 2027 for general applications and July 2028 for ATEX-rated products. However, Honeywell requested a renewal of the exemption for capillary sensors for the maximum validity period.

When requested to provide argumentation for requesting the maximum validity period, (Honeywell 2023b) stated to agree, in principle, with the validity period requested by Alphasense at the sensor level. However, additional time will be required for instrument development and certification as outlined in the Honeywell derogation. (Honeywell 2024b) elaborated that Honeywell is a sensor manufacturer, as well as a Gas Instrumentation manufacturer (OEM). Honeywell uses gas sensor products, and as such, need to take into consideration both the timeframes needed to develop and validate a lead-free sensor (component), as well as the instrumentation (system) development, validation, and approvals. For example, the Alphasense application outlines a timeline for sensor development, however, it does not capture the need for instrument development. To the best of our knowledge, Alphasense do not offer instrumentation. From Honeywell's perspective it is the instrument redesign, development, intrinsic safety, and approvals through notified bodies (Atex, mining, EN, UKCA, AS/NZS, ANSI/ISA, BS EN) which will require the majority of the time.

In the consultants' view, the fact that Alphasense is capable of phasing out lead-based capillary oxygen sensors through elimination until July 2028 makes it likely that the manufacturers of instruments in which the sensors are used will also be adapted until that time, otherwise there would be no market for Alphasense's lead-free sensors. The evaluation by instrument manufacturer's is estimated to take 6 months or more, according to Alphasense. This casts some doubt onto whether the industry is dependent on a renewal by the maximum validity period to achieve the development and qualification of lead-free capillary oxygen sensors and their instruments, as requested by Honeywell. Potentially, a renewal shorter than the requested maximum validity period may have to reflect this.

Hersch cells

The technical differentiator of Hersch cells is their capacity to measure extremely low levels of oxygen concentrations, down to 200 ppt. (MOCON 2024b) confirmed that Hersch cells are exclusively used for the measurement of permeation, as described in their renewal request form. As MOCON are the only supplier of Hersch cells, they can determine with certainty that the only lead-free Hersch cells are their own variant that uses cadmium instead of lead.

MOCON have in the past made use of RoHS exemption IV-43 that covered Hersch cells with cadmium anodes, however, as MOCON had not submitted a request on time for a renewal, exemption 43 is set to expire on 15 July 2023 [107]. To ensure the availability of

[107] In parallel to this request for renewal of exemption IV-1(b), MOCON have submitted a parallel request to exempt cadmium for Hersch cells, which is labelled exemption IV-2022-2 in this report.

Hersch cells on the market despite the expiry of exemption IV-43, MOCON applied for renewal of exemption IV-1(b) to allow them to place a Hersch cell variant using lead as anode material on the EU market.

MOCON have described that only cadmium and lead meet the technical criteria to manufacture Hersch cells. The applicant has plausibly outlined that other sensor technologies are not capable of matching the technical specifications of Hersch cells. *(MOCON 2024a) explicitly confirmed that there are no other sensor technologies that perform absolute measurements at similarly low oxygen concentration ranges, stating that Hersch cells are a proprietary design and as such no other manufacturer of such devices, irrespective of the anode material, can produce them.*

When requested to provide more detail on the research and development of Hersch cells that do not rely on substances restricted by the RoHS Directive, (MOCON 2024a) confirmed to continue to research potential anode substitutes for both cadmium and lead based Hersch sensors. However, due to the demanding technical requirements of a Hersch cell, any change can have a detrimental impact on performance. For example, changing a single component in the cadmium version of the Hersch cell took 3 years to undertake and fully qualify. As a result, the development of a fully RoHS-compliant Hersch cell requires meticulous and time-consuming attention to detail. Additional theoretical and experimental work has been conducted to narrow down potential candidates. Based on theoretical cell potentials, only seven metals exhibit characteristics that could work inside a Hersch Coulometric Cell (Alkaline Electrolyte). Three of these have been the focus of ongoing experimental investigations as they have the most similarities to lead and cadmium. However, experiment results have still not led to a suitable substitute. Shifting to an acidic electrolyte could open new options, which will be studied if no encouraging progress is made with the current alkaline one. The move to an acidic electrolyte would trigger the need for more extensive testing and potentially design changes of the sensor. Overall this would have the impact of creating an even longer timeline to qualify a RoHS-substance free alternative, and why this has not been trailed at this point.

(MOCON 2024a) conclude that it is still uncertain whether a RoHS compliant alternative anode material will be able to offer the necessary technical performance they require of the Hersch Cell. Even with the most recent developments in technology, there are no other technologies which can detect oxygen to the very low concentrations which Hersch cells are able to detect.

When asked whether the renewal of exemption 1(b) was required in case their exemption request covering cadmium in Hersch cells (IV-2022-2) was granted by the COM, (MOCON 2024b) denied this, stating that as long as there is an exemption permitting the use of Hersch cells on a continuing basis, only one or the other exemption would need to be granted to cover the necessary uses. However, it is essential that the lead based exemption is not rejected until the cadmium based exemption is fully implemented, such that devices are able to be continually sold in the EU.

MOCON described that both variants perform equally well, but that cadmium is considered more toxic than lead. Asked whether, against this background, it would not be preferable to maintain lead-based Hersch cells while phasing out cadmium-based sensors, (MOCON 2024b) responded that it would be their preference that the exemption for cadmium be granted over lead due to the reduction in manufacturability of the lead sensors (~20% reduction in sensors which meet performance criteria). Due to these manufacturing issues there is an increase in scrap of such sensors from this, and therefore an increase in the use

of lead overall to meet the customer demand for sensors of this type. It is also worthwhile noting that there is a difference between the amount of RoHS-restricted substance required for a cadmium sensor and a lead sensor, so this should be considered when reviewing the potential environmental impact. The cadmium Hersch sensor uses at least 24% less material by weight than the lead Hersch sensor.

Relating to their request for exemption IV-2022-2, when asked to explain for which reason the requested wording includes a sensitivity threshold "below 100 ppm", when the wording of exemption IV-43 included a threshold of "below 10 ppm", (MOCON 2024b) stated that the useable range of the Hersch cell sensor is between 200 ppt and 70 ppm. As such, although both values are correct, it is most accurate to say that the sensor is able to measure to 100 ppm and below.

The consultants agree that setting at 100 ppm appears more suitable to cover Hersch sensors that measure the given range, while 10 ppm might lead to some uncertainty. In practice, if a potential exemption wording included the term "Hersch" cell or sensor as was requested by the applicant, the scope of the exemption would not differ with either value.

When asked whether differing wording was required for both requested exemptions, (MOCON 2024b) stated that the differences in requested exemption wording is a reflection of our thinking at the time in which the exemptions were submitted and not a reflection of technical differences. As such, either wording would cover MOCON applications.

In the consultants' view, the information provided by the applicants plausibly demonstrate that only Hersch cells are capable of measuring the extremely low oxygen concentration ranges, and that, thus far, only lead- and cadmium-based anodes are capable of achieving this. Therefore, it seems reasonable to the consultants that the substitution and elimination are technically and scientifically not yet practicable. Further, to ensure that Hersch cells continue to be available on the market, it appears reasonable to renew exemption 1(b) to cover lead-based Hersch cells until a new exemption for cadmium-based Hersch cells can be granted.

Permeable membrane / partial pressure oxygen sensors

Lead-free permeable membrane / partial pressure oxygen sensors have been available on the market for several years, as had already been discussed in the previous review of exemption 1(b) by (Deubzer et al. 2022). At the time of the previous review, remaining uncertainty regarding the performance and reliability of lead-free alternatives had been discussed.

For the current review, Dräger requested a renewal of this exemption for permeable membrane oxygen sensors until the end of 2025, and the maximum validity period for oxygen sensors as spare parts. Honeywell requested a renewal for permeable membrane oxygen sensors for the maximum validity period.

When requested to explain whether the membrane diffusion cells are identical in technology to those in Dräger's renewal request, (Honeywell 2024a) elaborated that they are in fact identical technologies but, utilised across different applications, stating that it is important to note that due to the difference in end applications, the testing requirements to qualify alternatives in each application are likely to differ and hence explain the difference in the need for different validity periods requested. (Honeywell 2024b) added that from the publicly accessible information which Drager submitted, there is no breakdown of the timeline which

they requested. As such it is assumed that they also do not have a need for instrument redesign, development, intrinsic safety and approvals through notified bodies. However, this is an assumption made on publicly available information and additional information should be shared to confirm this.

When asked how the phasing out of lead-based partial pressure sensors will be achieved, (Dräger 2024b) explained that their strategy does not require redesigning analyser instruments, but adapting an existing lead-free sensor to also be operated in an existing measuring head. The new sensors are still electrochemical amperometric gas sensors, but with a three or four-electrode design and will be operated by a potentiostat in order to obtain the required driving force to reduce oxygen. When asked about the applications of their sensors, (Dräger 2024b) responded that while monitoring the lower explosion limit is probably the most technically demanding, the sensors are also used in other inerting applications, especially where light gases (such as hydrogen or helium) can also occur. Oxygen displacement by these gases can only be reliably detected with a membrane-covered oxygen sensor. The exemption sought by Dräger relates only to stationary measuring heads in various industrial applications, generally to ensure occupational safety for our customers' employees. (Dräger 2024b) also added that in their perception, any future-oriented company should have been able to develop suitable alternatives to lead-based oxygen gas sensors within the last years.

Maxell, a supplier of lead-free permeable membrane oxygen sensors was invited to comment on their view whether the exemption for lead was still needed for permeable membrane oxygen sensors. *(Maxell 2024) stated to have released a galvanic cell type lead-free oxygen sensor in 2019, based on a tin alloy anode and a weak acid electrolyte consisting mainly of citric acid. These allowed the reaction to proceed without passivating the tin, and achieved characteristics equivalent to those of leaded oxygen sensors. It has been used in mass-produced equipment, switching from leaded oxygen sensors, and has not caused any problems in the market. Differences in characteristics and appearance between sensor manufacturers can be accommodated by the software and hardware of the device. In addition, Maxell's lead-free oxygen sensors are similar to leaded oxygen sensors in both characteristics and end-of-life behavior, making the switch relatively easy in their opinion. However, since no formal decision has been made after the report on RoHS Pack 21 by (Deubzer et al. 2022) was released, many customers are still trying to continue using leaded oxygen sensors. On the other hand, Maxell have determined that their lead-free oxygen sensors are technically ready to replace leaded oxygen sensors, which led them to decide to discontinue lead oxygen sensors in March 2025, after which Maxell will sell only lead-free sensors.*

Maxell referenced a press statement[108], in which they announced to discontinue the sale of their KE series leaded galvanic cell-type oxygen sensors after 35 years, with last orders accepted until September 2024, to switch to their successor, the KE-LF series lead-free galvanic cell-type oxygen sensors. Examples for applications include combustion gas monitoring and oxygen concentration measuring devices (oxygen monitors). Further application examples mentioned on their website include health and safety, biotechnology,

[108] Maxell press release “Discontinuation of KE series leaded galvanic cell-type oxygen sensors, available: https://ssl4.eir-parts.net/doc/6810/ir_material22/209430/00.pdf (accessed 28 January 2024)

medical devices and health equipment, food storage, and education. Some of the sensors' specifications are reproduced in the Table 19-20.

Table 19-20: Specifications of lead-free galvanic oxygen sensors from Maxell[109]

Model	KE-25LF/KE-25F3LF	KE-12F3LF	KE-50LF	KE-25F3LFM
Features	Standard product	Fast response time	Long life	Measurable up to 100 % O_2
Measurement range	0 ~ 30 % O_2			0 ~ 100 % O_2
Initial output voltage	10~15.5 mV	9~15 mV	4.5~7.5 mV	5~8 mV
Operating temperature range	5 ~ 40 ℃			
Operating pressure range	811~1216 hPa			
90% response time	Approx. 15 sec.	Approx. 8 sec.	Approx. 60 sec.	Approx. 15 sec.
Power	Self-powered			
Lifetime	Approx. 5 years	Approx. 3 years	Approx. 10 years	Approx. 6 years

Source: Maxell[109]

Maxell were also invited to comment on specific arguments provided by the applicants to justify the renewal of this exemption, to which (Maxell 2024) provided the following information:

- *Measurement of extremely low oxygen concentrations: Maxell's lead-free oxygen sensors cannot measure extremely low oxygen concentrations at the moment.*
- *Measurement in the subzero temperature range: Maxell's lead-free oxygen sensors can measure even at -20°C because the electrolyte solution does not freeze. A sensor that can be used at -30°C is currently under development.*
- *Temperature- and pressure-dependence: According to (Maxell 2024), these are the features of the capillary type. Maxell's lead-free sensors, which are membrane type, can be used if instruments are adjusted accordingly while they are affected by temperature and pressure.*

[109] Website of Maxell for lead-free oxygen sensors (O2 sensors), available: https://biz.maxell.com/en/tokki/oxygen_sensors.html (accessed 28 January 2024)

- *Lead-free sensors are affected by the presence of CO_2: All of Maxell's lead-free oxygen sensors use originally developed weak acidic electrolyte solution, so they are unaffected by CO_2 as disclosed in the KE-25 F3LFM news release[110].*
- *No lead-free sensors have been ATEX approved: According to (Maxell 2024), both Maxell's lead-free and leaded oxygen sensors have the same sensor current. The current flowing to the sensor at 1 atmosphere pressure (atm) in air is less than 15 μA for standard models, so the sensor cannot be a source of ignition. Maxell believe that the explosion-proof design of the device itself is the critical issue, while whether the sensor could be a source of ignition is not the reason for extending the exemption.*

In conclusion, (Maxell 2024) state that in their view, customers using oxygen sensors still tend to continue using leaded oxygen sensors. (Maxell 2024) believe that, depending on the outcome of the review, the shift to lead-free products in the industry can be accelerated.

The applicants were requested to provide arguments for why the exemption is needed while lead-free permeable membrane oxygen sensors are available on the market.

(Honeywell 2024b) stated that the alternative lead-free anode options from Honeywell and other manufacturers are dimensionally larger compared to the current industrial safety standard size/format (4series 17mm high, 20.4mm diameter) at 47.3mm/50mm high and 28mm/22.7mm diameter respectively. Currently there are no alternative lead-free anode options available as a drop-in replacement for the instrument manufacturers (OEM), due to the fundamental chemistry limitations. There is no backwards compatible sensor, form, fit or function for the industry.

(Honeywell 2024b) further stated that technical characteristics that would require a lead based sensor compared to the lead-free variant will be specific to the application and environmental conditions e.g., temperature, pressure, humidity, and other external environmental factors. Such factors may limit usage in exhaust measurement test equipment, biogas, and industrial monitoring of gas generation/manufacture of bottled gas and in applications such as self-contained breathing apparatus.

Dräger had described that commercially available oxygen sensors using tin anodes in a caesium carbonate electrolyte are being sold in the EU, however that an evaluation of these sensors found that they do not meet their specifications when used with existing designs of analysing instruments. When asked to elaborate on which specifications could not be met, (Dräger 2024b) explained that the commercially available oxygen sensors that they had tested so far did not meet the requirements of a typical application of a Dräger customer. They either observed several sensor failures already at the very beginning of their evaluation tests, indicating insufficient sensor quality, or the sensors did not meet the required specifications in the first place and the suppliers were not willing or able to adapt the sensor specifications to their needs. One example is a sensor that was developed for the medical market in the same way as Dräger lead-containing oxygen sensors, but only has a lower temperature limit of 0°C. As temperatures down to -20°C are also required and

[110] Maxell press release on lead-free galvanic cell-type oxygen sensors suitable for medical use: https://biz.maxell.com/en/tokki/20210413NR_LFo2sensors_en.pdf (accessed 1st March 2024)

are also used by customers, this sensor is not suitable to be qualified as a 1:1 replacement for our current sensor.

(Dräger 2024a) added that they have had lead-free oxygen sensors in their portfolio for over 30 years, which is significantly longer than the RoHS II directive requires the replacement of lead in oxygen sensors. Hundreds of thousands of sensors are now manufactured every year using lead-free technology, compared to a few thousand sensors that still contain lead. There are several reasons why this lead-containing type of sensor is being retained. Firstly, this is due to the robustness and durability of Dräger gas measurement transmitters, which are often used by their customers for decades and regularly require replacement sensors. For reasons of sustainability in the use of valuable resources, they do not consider it necessary to replace fully functional gas measuring transmitters prematurely. On the other hand, it is also due to the extremely demanding measuring task that the sensors have to fulfil in practice. The transmitters that require this type of sensor operate under extremely harsh conditions, which currently only the leaded version of Dräger's oxygen sensor can survive in the long term. The development of a lead-free oxygen sensor for these harsh conditions is accompanied by extreme challenges, as lead-free sensors, for example, have to be much more open to their environment, as they generate O_2 in their interior as so-called oxygen pumps, which must be continuously dissipated. At the same time, however, interfering substances such as organic vapors must be prevented from penetrating the sensor and causing malfunctions.

(Dräger 2024a) stated to be confident that they will be able to achieve this with great effort for the remaining applications of lead-containing sensors, but cannot explain this in more detail at this point due to the lack of patent protection. The fact is that the vast majority of industrial applications are currently served by lead-free oxygen sensors and they still need some time to achieve this for the remaining sensors.

In the consultants' view, it can be concluded that lead-free permeable membrane sensors are technically practicable, as has been demonstrated by market-available products. Further, as was explained by Dräger, permeable membrane oxygen sensors can be eliminated by using alternative, lead-free technologies, such as amperometric sensors featuring three or four electrodes, although not all technological challenges have yet been overcome for a complete transition.

The applicants argue that available lead-free solutions are not drop-in replacements for existing instruments, due to technical differences in form, fit, and function, requiring more time for the redesign of instruments that use the oxygen sensors. Dräger reported to have found a workable solution that can be fully implemented until the end of 2025. Honeywell state to require the maximum validity period of 7 years to continue the process. The consultants acknowledge that the applications for which Dräger and Honeywell manufacture their sensors and instruments may be different, which may be a determinant of the differing timelines.

(Dräger 2023a) requested a renewal of this exemption for new instruments that use electrochemical oxygen sensors and for the maximum validity period for oxygen sensors that are spare parts for instruments placed on the market until the end of 2025. *(Dräger 2023b) confirmed that their intention is to continue servicing those instruments that were designed to work with type of a sensor for which the exemption is requested beyond 2025 and that after the end of 2025, Dräger will no longer put onto the market lead containing sensors.*

In the consultants' view, RoHS Art. 4(4)(f) postulates that the substance restrictions stipulated by RoHS Art. 4(1) do not apply to 'spare parts' for EEE which benefitted from an exemption and which was placed on the market before that exemption expired. When asked whether Dräger consider replacement oxygen sensors to be 'spare parts' in the sense of the definition under RoHS Art. 3(27), *(Dräger 2023b) confirmed this to be the case, stating that Electrochemical sensors used in our industrial monitoring and control instruments have a life span of maximum one year. After this period, the sensor must be replaced for the device to continue functioning as intended. In the absence of the replacement sensor, the device will be rendered non-functional.*

Stakeholder contribution of COCIR

The consultants agree that the intention of the wording of for the recommended exemption IV-1(b)(I) was to include both oxygen sensors sold as consumables as part equipment as well as consumables sold as sensors to replace spent sensors. Therefore, introducing the changed wording proposed by COCIR should increase the clarity of what is covered by the exemption. The consultants do not consider any risk that the scope of the proposed exemption is broadened by such a change.

19.3.5. Environmental, health, safety, and socio-economic impacts

Given that lead-free sensors seem to be able to cover many, but not all applications (use cases), it is conceivable that at least some of the impacts described by the applicants may occur in case the exemption was not renewed as requested.

19.3.6. Summary and conclusions

Four applicants requested the renewal of this exemption, requesting different wording and validity periods, for industrial monitoring and control instruments of RoHS EEE category 9. The applicants describe three distinct oxygen sensor technologies that require the exemption:

- capillary oxygen sensors (Alphasense and Honeywell),
- Hersch cell oxygen sensors (MOCON), and
- permeable membrane / partial pressure oxygen sensors (Honeywell and Dräger).

These differ in their technology, technical specifications, and applications (use cases). All sensors for which the renewal is requested measure oxygen in gases, rather than dissolved oxygen in liquids.

During the last review of this exemption, (Deubzer et al. 2022) recommended to narrow the exemption wording to adapt to the scientific and technical progress. For sensors measuring oxygen in gases, the applicants at that time, JBCE, agreed to include two criteria in the exemption wording to achieve this: Handheld instruments and sensors with a reaction time above 3 seconds (t95) were found to not require lead and thus were excluded from the scope of the recommended wording. However, all applicants during the current review of exemption IV-1(b) stated that these criteria do not apply to their technologies and applications, and that lead is still needed in sensors and instruments that would be excluded

if the two criteria were included in the exemption wording. Their sensors rely on different technologies, have different specifications are applied in different use cases, which cannot all be covered using lead-free alternatives.

Capillary oxygen sensors

Oxygen enters capillary oxygen sensors through a small hole that restricts the flow of oxygen, by which the consumption of the anode is slowed and thereby the lifetime of the sensor is extended. In contrast to partial pressure / permeable membrane sensors, they are smaller, measure only lower oxygen concentrations up to 30 % (rather than 100 % like partial pressure sensors), and are used for different applications, including personal monitoring.

No lead-free capillary oxygen sensors have been stated to be available on the market. Alphasense requested a renewal until January 2027 for general applications and until July 2028 for ATEX-rated products. Honeywell requested a renewal for the maximum validity period of 7 years, i.e. until 21 July 2031.

Alphasense explained to transition to lead-free amperometric sensors, which they also stated is expected for the majority of the capillary industrial market, once the remaining technical issues are solved. This transition would be possible within the requested validity period of three and four years for specified uses. Honeywell refer to the fact that they need to account for adaptation of their instruments in addition to adaptation of the sensors, thus requesting a longer validity period.

Both applicants did not agree that the recommendations made by (Deubzer et al. 2022) after the last review of exemption 1(b) could be adopted for applications falling under category 9 IMCI. One difference to the applications for which the previous applicant, JBCE, had requested the exemption, according to Alphasense, is that JBCE did not outline uses of their sensors in the industrial safety market, which is the main market for the Alphasense sensors.

In the consultants' opinion, as Alphasense have described that the majority of the capillary oxygen sensor industry is expected to shift to lead-free amperometric sensors after technical challenges have been solved, it may be possible to phase out lead-containing capillary oxygen sensors sooner than the maximum validity period requested by Honeywell. Although Honeywell has described amperometric sensors as having different form, fit, and function and so are not drop-in replacements for lead-based capillary oxygen sensors, requiring the redesign of the relevant instruments, the consultants consider that the maximum validity period may not be needed for all stakeholders in the industry. Honeywell argued that Alphasense only manufactures sensors, not oxygen sensor instruments, however, the consultants consider that Alphasense would not be able to phase out their lead-based sensors in favour of lead-free alternatives if their customers, being instrument manufacturers and end users, were not ready for it. Therefore, it appears sensible to the consultants to renew the exemption for capillary oxygen sensors not for the maximum validity period until 2031, but until July 2028 as requested by Alphasense. Suppliers of capillary oxygen sensors who still require the exemption thereafter will need to specify at that time for which reasons they have not yet been able to make the transition, while competitors in the same market have.

Hersch cells

Hersch cells using lead anodes are developed by MOCON as it became clear that their renewal request for exemption IV-43, covering Hersch cells using cadmium anodes, was submitted too late for a renewal and would be considered a request for a new exemption (exemption IV-2022-2). This means that exemption IV-43 expired on 15 July 2023, effectively banning Hersch cells using cadmium anodes from the EU market.

MOCON also rejected the consultants' proposal to adopt the recommendations made by (Deubzer et al. 2022) for their equipment in scope of cat.9 IMCI on the basis that Hersch cells are capable of absolute measurements and measurements of extremely low oxygen concentration ranges, which no alternative technology can achieve, but their response time is not within 3 seconds.

MOCON have provided plausible arguments that lead and cadmium are the only materials that are currently capable to achieve the technical specifications required of Hersch cells, including extremely low detection limits. These cannot be matched by other oxygen sensor technologies either. Therefore, in the consultants' view, a renewal of the exemption for Hersch cells appears to be justified.

MOCON requested a renewal of exemption IV-1(b) until January 2028 to cover lead-based Hersch cells. In parallel, MOCON requested an exemption (IV-2022-2) to cover cadmium-based Hersch cells for the maximum validity period of 7 years. Given the lack of substitution and elimination opportunities at the current time, the consultants consider the timeframe justified.

Permeable membrane / partial pressure oxygen sensors

Dräger requested a renewal of this exemption for permeable membrane oxygen sensors in new instruments only until the end of 2025, after which they stated to be able to transition fully to lead-free amperometric oxygen sensors. Honeywell requested the exemption for the maximum validity period, citing different end uses (applications).

Neither applicant agreed to the adoption of the recommendations made by (Deubzer et al. 2022) for their equipment in scope of cat. 9 IMCI. Both applicants claim that their sensor technology does not meet the criterion to have a response time below 3 seconds. While Dräger highlight that handheld devices do not require lead, Honeywell highlight that handheld devices for different end uses do. Under these circumstances, the consultants note remaining uncertainty regarding whether handheld devices require the exemption or not. A focus on substituting or eliminating lead-anodes in all applications may be more promising in this case.

Lead-free permeable membrane oxygen sensors have been available on the market for years. Suppliers like Maxell have announced to fully phase out their lead-based oxygen sensors in favour of a series of lead-free variants.

For these reasons, the consultants do not consider it necessary to renew the exemption for permeable membrane oxygen sensors for the maximum validity period as was requested by Honeywell. A shorter validity period would signal to the industry at large that the transition to lead-free is becoming both increasingly feasible and urgent.

The consultants note that Dräger had requested the exemption renewal for oxygen sensors in new instruments until the end of 2025, and for oxygen sensors as spare parts placed on the market before 1 January 2026 for the maximum validity period, i.e. 7 years. However,

in the consultants' view, RoHS Art. 4(4)(f) postulates that the substance restrictions stipulated by RoHS Art. 4(1) do not apply to 'spare parts' for EEE which benefitted from an exemption and which was placed on the market before that exemption expired. Therefore, the consultants do not consider it necessary to reflect spare parts in the exemption wording.

Further conclusions

In the consultants' opinion, one challenge during the review of this exemption has been to identify which of the arguments provided by the applicants apply to which of the oxygen sensor technologies in scope of the multiple renewal requests. Differentiating the technical specifications and application requirements for each technology should, in the consultants' view, make it more practical to specifically discuss the progress that has been made regarding substitution and elimination of RoHS-restricted substances. Therefore, the consultants consider it advisable to specify the exemption wording further to reflect the different technologies in scope of exemption 1(b).

Whether handheld instruments featuring lead-free sensors can cover all relevant use cases could not be fully clarified during this review. It is therefore seen as advisable that potential future reviews of the exemption request additional evidence from applicants on this aspect.

19.4. Recommendation

The consultants recommend the renewal of exemption IV-1(b), however, the wording and scope recommended by (Deubzer et al. 2022) was not found to be applicable to the equipment in scope of the cat. 9 IMCI for which the requested renewal is discussed in this review, and therefore requires adaptation. If the COM decides to follow the consultants' recommendations, it is proposed to further split exemption 1(b) with the numbering, wording, scopes, and validity periods as displayed in the table below, to adapt it to technical and scientific progress:

No.	Exemption	Scope and dates of applicability
IV-1(b)	Lead anodes in electrochemical oxygen sensors	Expires on - 21 July 2021
IV-1(b)(I)	Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and/or exhaled air for patients and that are intended to be used as consumables in medical devices put on the market before 26 May 2024.	Applies to cat. 8 medical devices other than in vitro diagnostic medical devices. Expires on - 21 July 2025
IV-1(b)(II)	Lead in galvanic oxygen sensors in instruments that are designed for the measurement of dissolved oxygen in concentrations below 30 ppb.	Applies to cat. 9 including industrial monitoring and control instruments. Expires on - 21 July 2025
IV-1(b)(III)	Lead anodes in galvanic capillary oxygen sensors in instruments that are designed for the measurement of oxygen in gases.	Applies to cat. 9 industrial monitoring and control instruments. Expires on

		- 21 January 2027 for general applications - 21 July 2028 for ATEX-rated products
IV-1(b)(IV)	Lead anodes in galvanic Hersch cells for oxygen sensors where sensitivity below 100 ppm is required.	Applies to cat. 9 industrial monitoring and control instruments. Expires on - 21 January 2028
IV-1(b)(V)	Cadmium anodes in galvanic Hersch cells for oxygen sensors where sensitivity below 100 ppm is required.	Applies to cat. 9 industrial monitoring and control instruments and expires on [7 years after official publication of the COM's decision]
IV-1(b)(VI)	Lead anodes in galvanic permeable membrane oxygen sensors in instruments that are designed for the measurement of oxygen in gases.	Applies to cat. 9 including industrial monitoring and control instruments. Expires on - 31 December 2025

The recommendation by (Deubzer et al. 2022) to expire exemption 1(b) with the previous wording "lead anodes in electrochemical oxygen sensors" can be upheld. The wording and scope of the recommended exemption 1(b)(I) can also be upheld. From the recommended exemption 1(b)(II), only clause (b) on oxygen sensors in instruments designed to measure dissolved oxygen can be upheld, while clause (a) on sensors in instruments that measure oxygen in gases is omitted. In its place, the newly recommended exemptions 1(b)(III) through 1(b)(VI) more specifically address individual oxygen sensor technologies and reflect the status of technical and scientific practicability of substitution and elimination via differing validity periods.

The consultants further recommend that the COM ensures sufficient time between the official publication of the COM's decision and the expiry date of the exemption to allow for the preparation and timely submission of renewal requests 18 months prior to the expiry of the exemption.

The consultants note that the proposed exemption IV-1(b)(V) is equivalent in wording and scope to the exemption IV-X that is proposed as a result of the review of MOCON's exemption request IV-2022-2. The COM may decide to grant the exemption as a new exemption or under exemption 1(b), should they decide to follow the consultants' recommendations.

Finally, with a view to possible future renewal requests for the above recommended exemptions, it could be seen as preferable to align the expiry dates to reduce the required effort for future reviews. Such an aligned expiry date could be 21 July 2028. This would not affect the recommended expiry date of exemption 1(b) on 21 July 2021.

Applicants' feedback on the recommendations

(Alphasense 2024(c)), (Dräger 2024(c) and (MOCON 2024c) stated to agree with the above recommendations. (Honeywell 2024c) agree to the proposed scope of the exemption 1(b)

but maintain their request for the maximimum validity period for necessary sensor developments and their system level qualifications.

The consultants are confident that they considered all relevant arguments made available by applicants and stakeholders during the review, and that the arguments have been evaluated taking into account the requirements of Art. 5(1)(a).

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20. Exemption 1(c) of Annex IV: Pb, Cd and Hg in infrared detectors

The below Table 20-1 shows the wording, scope and expiry dates of the exemption.

Table 20-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
IV-1(c)	Lead, cadmium and mercury in infra-red light detectors.	Applies to categories 8 and 9. Expires on - 21 July 2021 for category 8 other than in vitro diagnostic medical devices and for category 9 other than industrial monitoring and control instruments. - 21 July 2023 for category 8 in vitro diagnostic medical devices. - 21 July 2024 for category 9 industrial monitoring and control instruments.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

Bruker	Bruker Optics GmbH&Co.KG
Cat.	Category, referring to the categories of EEE specified in Annex I of the current RoHS Directive 2011/65/EU
Cd	Cadmium
COM	European Commission
EEE	Electrical and electronic equipment
EU	European Union
FTIR	Fourier transform infrared
Hg	Mercury
IMCI	Industrial monitoring and control instruments

IVD	In-vitro diagnostic medical devices
LIRS	long-wavelength infrared spectrum (8µm to 14µm)
MCT	mercury cadmium telluride
MIRS	medium wavelength infrared spectrum (3µm to 8µm)
NIRS	near infrared spectrum (0.78µm to 3µm)
Pb	Lead
PPTF	Polish Technological Platform on Photonics
RoHS 1	Directive 2002/95/EC
RoHS 2, RoHS	Directive 2011/65/EU
VLIRS	very long wave IR spectrum (14µm to 30µm)

20.1. Background and technical information

Bruker Optics GmbH & Co. KG (Bruker 2023a) (on 17 January 2023) and the Polish Technological Platform on Photonics (PPTF 2023, on 20 January 2023) requested the renewal of exemption IV-1(c) as displayed in the below table for EEE of category (cat.) 9 industrial monitoring and control instruments (IMCIs).

Table 20-2: Requested exemption renewal

No.	*Requested exemption*	*Requested scope and dates of applicability*
IV-1(c)	*Lead, cadmium and mercury in infra-red light detectors*	*Applies to category 9 industrial monitoring and control instruments.* *Expires on 21 July 2031 (2024 +7 years)*

(trinamiX 2023) contributed to the stakeholder consultation in support of the renewal of the exemption for mercury-cadmium-telluride (MCT) sensors and for lead-sulphide and lead-selenide sensors. (PPTF 2023) did not answer the clarification questionnaire even upon repeated request to do so. Their renewal request was therefore not reviewed.

20.1.1. History of the exemption

The COM followed the recommendation of (Goodman 2006) and listed exemption 1(c) on Annex IV of RoHS Directive 2011/65/EU (2011) (RoHS 2) when it was officially published in 2011. Due to its expiry for EEE of cat. 8 other than in-vitro diagnostic medical devices (IVD) and cat. 9 other than industrial monitoring and control instruments (IMCI) on 21 July 2021, requests for the renewal of exemption 7(c)(I) were submitted, which included the renewal of the exemption for cat. 8 IVD and cat. 9 IMCI despite their expiry on 21 July

2023/2024 respectively. (Deubzer et al. 2022) reviewed the exemption renewal requests and recommended an amendment of the wording according to Table 20-3.

Table 20-3: Renewal of current exemption IV-1(c) recommended by (Deubzer et al. 2022)

No.	Exemption	Scope and dates of applicability
1(c)-I	Cadmium and mercury in mercury cadmium telluride (MCT) of infrared light detectors	Applies to categories 8 and 9 Expires on 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices, and for category 9 monitoring and control instruments incl. industrial monitoring and control instruments.
1(c)-II	*Lead in lead sulphide (PbS) and lead selenide (PbSe) of infrared light detectors*	Applies to categories 8 and 9 Expires on 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices, and for category 9 monitoring and control instruments incl. industrial monitoring and control instruments.
1(c)-III	Lead in PZT ceramics of infrared light detectors	Applies to categories 8 and 9 Expires on 21 July 2027 for category 8 medical devices including in-vitro diagnostic medical devices, and for category 9 monitoring and control instruments incl. industrial monitoring and control instruments

Source: (Deubzer et al. 2022)

20.1.2. Focus of the review

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status January 2024). In January 2023, (Bruker 2023a) therefore applied for the renewal of the current exemption 1(c) for cat. 9 incl. industrial monitoring and control instruments since it was earmarked for expiry on 21 July 2024 for this subcategory of cat. 9 EEE. The exemption thus became due for review even though the recommendation for the renewal of exemption 1(c) of (Deubzer et al. 2022) included cat. 9 IMCI.

The COM asked the consultants to assess in their review of the exemption renewal request at hand whether and how far the recommendation of (Deubzer et al. 2022) can be adopted to cat. 9 IMCI in line with Art. 5(1)(a). A re-evaluation of the previous review by (Deubzer et al. 2022) is not intended. The consultants will rely on the critical review conducted by (Deubzer et al. 2022) and on the resulting conclusions and recommendation unless the renewal request or stakeholder contributions give reasons to reassess the state of science and technology.

20.1.3. Summary of the requested exemption

According to (Bruker 2023a) this exemption request relates to the substances mercury and cadmium which are integral material components of photon sensitive semiconductor elements in light detectors (HgCdTe or, simplified, MCT detectors) designed for operation in the mid-infrared spectral range. Bruker Optics manufactures FTIR spectrometer systems which use this detector type as an indispensable detecting component for mobile, advanced and research applications in the field of mid-infrared spectroscopy.

In the mid-infrared spectral range (400cm^{-1} … 4000cm^{-1}), and, particularly, in the so-called fingerprint range (~ 1500cm^{-1} - 700cm^{-1}), there is no suitable substitute available to replace MCT detectors regarding the following combination of unique features:

- *The sensitivity has its peak in the spectral range below 1500cm-1 and is at least of the order 10^{10}…10^{11} Jones (when cooled at liquid nitrogen temperature). In addition, the sensitivity can be further spectrally fine-tuned by the relative material composition of the detector element to be optimal for the corresponding spectroscopic application.*
- *The detector allows for high interferometer scanning velocities and can provide a time resolution with a rise time down to the nanosecond range.*

Infrared spectroscopy with FTIR instruments is a widely used technique in many fields, e.g., life and material science, chemistry, pharma, forensics. The extension of the existing exemption, which Bruker Optics applies for in this form, would make possible to retain the high level of quality in this research fields within the EU for the upcoming years.

Furthermore, according to (PPTF 2023) infrared measurement technology has various advantages over different techniques - it is highly sensitive, selective and very fast, allowing for real-time measurement of various substances, gases and fluids. The most common measurement technique is infrared spectroscopy. It covers a range of techniques, mostly based on absorption spectroscopy. As with all spectroscopic techniques, it can be used to identify and study chemicals.

Especially the MWIR (3-8µm) and LWIR (8-14µm) IR spectra are useful for analytical purposes:

- *Many gases have only in the MWiR significantly strong absorption features.*
- *The fundamental absorptions of many gases are much stronger in the MWIR than the overtone bands in the SWIR (e.g., CO2 and CH4).*
- *Separation of the absorption "fingerprints" of different molecules is easier in the MWIR and LWIR.*

The most sensitive IR devices are based on photon detectors – i.e. compound semiconductors using II-VI, III-V and IV-VI compounds. The variable band gap Hg1-xCdxTe (also called in short HgCdTe or MCT) has been undeniably the champion among the large variety of material systems, offering 2x up to 100x better detectivity levels in the MWIR and especially LWIR spectrum.

There are possible substitutes used in less demanding measurement applications – III-V compound semiconductor detectors. However, despite many years of development there have not yet been any commercially available detectors matching MCT detectors in terms of detectivity.

20.1.4. Technical description of the exemption and use of the restricted substance

Like in 2020 (cf. Deubzer et al. 2022), the renewal of the current exemption IV-1(c) is requested. (Bruker 2023a; PPTF 2023; Deubzer et al. 2022) provide technical descriptions of the exemption. They mention only applications and restricted substances that were in the scope of the last review of the exemption by (Deubzer et al. 2022), namely mercury-cadmium-telluride (MCT) detectors for application in Fourier transform infrared (FTIR) instruments.

20.1.5. Amount(s) of restricted substance(s) used under the exemption

According to (PPTF 2023) mercury and cadmium are the basic components of mercury cadmium telluride (HgCdTe), the variable band gap semiconductor used for infrared photodetectors. The concentration of mercury in a typical infrared detector single element chip is approximately 0.7 % of chip weight. The concentration of cadmium in a typical infrared detector single element chip is approximately 0.5 % of chip weight.

(PPTF 2023) state that there is no accurate data available to quantify the amount of mercury and cadmium entering the EU market annually through the application in the scope of exemption IV-1(c). It is estimated that the annual global production of MCT detectors for commercial applications is approximately 20,000 units per year. The weight of a single pixel detector chip is approximately 0.005g ($5*10^{-3}$ g). Typical detector contains 0.0000314g ($3.14*10^{-5}$ g) of mercury and 0.0000235g ($2.35*10^{-5}$ g) of cadmium. Therefore, the total global amount of mercury in MCT detectors per year is about 0.6g, and 0.5g of cadmium.

The calculation of the annual amount of Cd and Hg placed on the EU market provided by (Bruker 2023a) is confidential. They state that it is less than 0.1 g mercury per year and less than 1g of cadmium per year.

20.2. Justification of the requested exemption

20.2.1. Substitution and Elimination of the restricted substance

A detailed justification for the renewal of exemption IV-1(c) after 2021 and the applicants' current justification is provided by (Bruker 2023a; PPTF 2023; Deubzer et al. 2022)

20.2.2. Environmental, health, safety and socioeconomic impacts

(Bruker 2023a; PPTF 2023; Deubzer et al. 2022) describe the environmental, health, safety and socio-economic impacts.

20.2.3. Roadmap towards substitution or elimination of the restricted substance

(Bruker 2023a) state that Bruker does not develop detectors but integrates these essential components in its own spectrometer systems. Therefore, Bruker depends on what is

available on the market which is regularly observed. The standard mid-infrared detector is the RoHS compatible DLaTGS pyroelectric detector. MCT detectors are only used for dedicated applications where the performance of an MCT detector is needed.

Furthermore, (Bruker 2023a) elaborated the stages that are necessary for establishment of possible substitutes. Substitute detectors must match the current MCT detectors regarding the following properties:

- *They should offer an at least comparable performance within the same spectral range which a MCT detector can cover. In particular, the low wavenumber range including the so-called fingerprint below 1500 cm^{-1} is of essential importance in infrared spectroscopy.*
- *They should offer an at least comparable fast response for applications in time resolved spectroscopy.*
- *They should not be significantly more expensive.*

From the point of view of (Bruker 2023a), which is the point of view of a customer of detector manufacturers, it is difficult to assess the time frame needed for having such a substitute detector in sufficient quantities commercially available. According to (Bruker 2023a), the industry is working on replacement types, but they expect that it will take at least 5 more years to realise a commercial replacement.

(PPTF 2023) state that the establishment of substitutes for the RoHS regulated substances would require:

- *Improved design of the InAs/InAsSb detector heterostructures taking into account unavoidable limitations of the MBE and MOCVD epitaxial techniques*
- *Refinement of the growth procedures to reduce concentration of residual uncontrolled dopants, SR centers and density of dislocations in the InAs/InAsSb SL-based detector heterostructures*
- *Growth and characterization of the heterostructures for several types of photodetectors.*
- *Processing, packaging and characterization of the several types of photodetectors for medical applications*
- *Iterative corrections of the design and growth procedures of detector heterostructures.*
- *Development of fast and sensitive devices with the use of plasmonic enhanced absorption of IR radiation*

The above mentioned stages require a lot of effort in development and refinement of epitaxial growth techniques – where actual results are visible in nanoscale and are quite difficult to be measured. (PPTF 2023) estimates that it would take another 5-7 years to introduce new type of III-V detectors with detectivity and reliability levels of MCT.

20.2.4. Stakeholder contributions

(trinamiX 2023) provided answers to the consultation questionnaire. (trinamiX 2023) agree to the argumentation of (Bruker 2023a) that exemption IV-1(c)-I (cf. Table 20-3) would cover their applications of cadmium and mercury in EEE of category 9 industrial monitoring and control instruments provided that the exemption would remain valid for four years, i.e. until 2028 as recommended by (Deubzer et al. 2022). Furthermore (trinamiX 2023) agree that the specifications of many mercury-free, cadmium-free and lead-free IR detectors on the market are still not competitive and that since the review of (Deubzer et al. 2022) no breakthrough in Hg, Cd and Pb free IR detectors has happened. It is still unclear if materials with comparable properties can be developed. (trinamiX 2023) also agreed with the statements made by (Bruker 2023a) in their socioeconomic analysis related to cadmium and mercury in Fourier-Transform Infrared Spectroscopy.

20.3. Critical review

20.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several restrictions of cadmium and its compounds are listed on Annex XVII (cf. section 4.1 on page 48). None of those, however, is applicable to the use of cadmium and cadmium compounds in the scope of exemption 1(c).

Further on, uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds. None of those entries are relevant for the use of lead and lead compounds in the scope of exemption IV-1(c) (cf. section 4.2 on page 51 for details).

Finally, Annex XVII contains several restrictions for the use of mercury and its compounds. None of those entries are relevant for the use of mercury and mercury compounds in the scope of exemption IV-1(c) (cf. section 4.3 on page 54 for details).

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

Cadmium

Cadmium and several of its compounds are substances of very high concern but so far are not adopted to Annex XIV as substances that require authorisation for use.

With regards to Annex XVII, cadmium is mentioned in a few of the listed restrictions.

Paragraph 1 of entry 23 of Annex XVII refers to cadmium and several of its compounds including cadmium telluride. Under this entry, several restrictions are mentioned for cadmium and the compounds, among others:

1. A list of various polymers in which Cd may not be used unless required in colour for safety reasons.
2. Shall not be used for cadmium plating[111] metallic articles or components of articles used in equipment and machinery in certain branches and applications, e.g. cooling and freezing, food production, etc.
3. Shall not be used in brazing fillers unless used for safety reasons
4. 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 metal beads and other metal components for jewellery making, or metal parts of jewellery and imitation jewellery articles and hair accessories, e.g. in wristwatches.

In the scope of the requested exemption, Cd is neither used in polymers or jewellery or for plating, nor as brazing filler. The above stipulations are therefore not applicable to the use of cadmium in the requested exemption.

Due to their carcinogenicity, entry 28 of Annex XVII does not allow the placing on the market, or use of various substances as such, as constituents of other substances, or in mixtures. Various compounds are mentioned in this respect, including among others cadmium sulphide and cadmium nitrate.

The use of cadmium in the scope of the requested exemption cannot be considered placing on the market cadmium or cadmium compounds in the sense of the above since cadmium is used in an article.

Entry 72 lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It stipulates that the substances listed in column 1 of the table in Appendix 12 shall not be used in textiles, clothing and footwear. The table lists cadmium and its compounds as listed under entries 28, 29 and 30. Like entry 28, this entry does not address the use of cadmium in the scope of the requested exemption.

To conclude, none of the entries currently listed under REACH would apply to the case at hand. The use of Cd in the scope of the requested exemption cannot be considered to weaken the protection afforded by REACH. The exemption can therefore be renewed if the relevant stipulations of Art. 5(1)(a) apply.

Mercury

Annex XVII of the REACH Regulation contains several entries restricting the use of mercury and of mercury compounds. *Entry 18 restricts*[112] *placing on the market, or use, as substances or in mixtures mercury compounds where the substance are intended for certain*

[111] 'Cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface

[112] ECHA, https://echa.europa.eu/documents/10162/5a7222b0-9d3a-4a90-9e55-258149e92b1a

uses, e.g. in treatment of industrial sewage or for the impregnation of heavy-duty industrial textiles and yarn.

Mercury in the applications in scope of the requested exemption is not used for any of the above applications, and the restrictions are therefore not applicable.

Entry 18a restricts the use of mercury[113]*:*

- in fever thermometers;
- in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers);
- in a number of specified measuring devices intended for industrial and professional uses, in particular barometers, hygrometers, manometers, sphygmomanometers114, strain gauges to be used with plethysmographs115, tensiometers, thermometers and other non-electrical thermometric applications, mercury pycnometers and mercury metering devices for determination of the softening point.

To the consultants' best knowledge, the applications in scope of the requested exemption do not include the use of mercury in any of the above products/articles so that the above restrictions do not apply.

Entry 62 lists several phenylmercury compounds[116], which are, however, not related either the use of mercury in the applications in the scope of the requested exemption.

No other relevant entries in regard to the use of mercury could be identified in Annex XIV and Annex XVII. Based on the current status of these Annexes, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

Mercury is also restricted in certain applications through the Mercury Regulation 2017/852 implementing the international Minamata Convention on Mercury of 2013. The Mercury Regulation refers to the RoHS Directive in Article 8(1) on *"New mercury-added products and new manufacturing processes"* and stipulates that *"Economic operators shall not manufacture or place on the market mercury-added products that were not being manufactured prior to 1 January 2018 ('new mercury-added products') unless authorised to do so by means of a decision taken pursuant to paragraph 6 of this Article or allowed to do so under Directive 2011/65/EU of the European Parliament and of the Council"*.

If the COM grants the renewal of the requested exemption the use of mercury would be allowed under Directive 2011/65/EU so that the above restriction would not be applicable.

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[113] ECHA, https://echa.europa.eu/documents/10162/dbcaaec7-bd5b-4a7d-b164-23fa97950a86

[114] Device used to measure blood pressure.

[115] Device for measuring changes in volume within an organ.

[116] ECHA, https://echa.europa.eu/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

Additionally, exemption IV-1(c) was listed on RoHS Annex IV when it was published in 2011. The mercury-added products in the scope of exemption IV-1(c) thus have been manufactured and placed on the market before 1 January 2018. The coherence with the Mercury Regulation is therefore established.

Based on the current status of the REACH annexes, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

20.3.2. Substitution and elimination of the restricted substance

(Deubzer et al. 2022) proposed the renewal of the exemption as displayed in Table 20-3 on page 437 stating that substitution or elimination of cadmium, lead and mercury in the applications in scope of the renewed exemption IV-1(c) are scientifically and technically not yet practicable so that granting the recommended exemption would be justified by Art. 5(1)(a).

According to (Bruker 2023a; trinamiX 2023) no new materials for substitution or technologies for elimination of the restricted substances were identified since the last review of exemption IV-1(c) by (Deubzer et al. 2022).

These statements are in line with the findings of (Deubzer et al. 2022) for the use of cadmium and mercury in mercury-cadmium-telluride (MCT) detectors, and for the use of lead in lead-selenide (PbSe) and lead-sulphide (PbS) detectors. Substitution or elimination of these substances in these detectors were neither practicable at the time of the review nor foreseeable for the time period until July 2028 for which the exemption was recommended to be granted. This was different for lead in PZT infrared detectors for which the expiry was hence recommended for 21 July 2027.

The applications of the restricted substances in MCT are the same like in the previous review by (Deubzer et al. 2022), and scientific progress towards substitution or elimination of the restricted substances has neither happened nor did the previous reviewers expect it to happen in the coming years. the consultants therefore asked the applicant to agree to adopt the recommendation of (Deubzer et al. 2022) illustrated in *Table 20-3*. *(Bruker 2023b) agreed provided that the exemption remains valid for four years (until 2028). (trinamiX 2023) as well confirmed their agreement (cf. section 20.2.4 on page 441).*

PPTF neither answered the clarification questionnaire despite of repeated request to do so nor did they contribute to the stakeholder contribution. Their renewal request was therefore not reviewed further.

20.3.3. Summary and 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 consultants could not find any technical evidence to deviate from the technical conclusions in the last review and to recommend a different exemption for cat.9 IMCI. The recommended expiry date of 21 July 2028 does not need to be adapted in view of the applications received.

Bruker and trinamiX agree to the adoption of the recommendation of (Deubzer et al. 2022) for the renewal of exemption IV-1(c). The consultants therefore conclude that the exemption III-1(c) can be renewed as recommended by (Deubzer et al. 2022).

20.4. Recommendation

The consultants recommend the renewal of the exemption like proposed by (Deubzer et al. 2022).

No.	Exemption	Scope and dates of applicability
1(c)-I	Cadmium and mercury in mercury cadmium telluride (MCT) of infrared light detectors	Applies to categories 8 and 9 Expires on 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices, and for category 9 monitoring and control instruments incl. industrial monitoring and control instruments.
1(c)-II	*Lead in lead sulphide (PbS) and lead selenide (PbSe) of infrared light detectors*	Applies to categories 8 and 9 Expires on 21 July 2028 for category 8 medical devices including in-vitro diagnostic medical devices, and for category 9 monitoring and control instruments incl. industrial monitoring and control instruments.
1(c)-III	Lead in PZT ceramics of infrared light detectors	Applies to categories 8 and 9 Expires on 21 July 2027 for category 8 medical devices including in-vitro diagnostic medical devices, and for category 9 monitoring and control instruments incl. industrial monitoring and control instruments

Applicants' feedback on the recommendation

(Bruker 2023a) (applicant) and (trinamiX 2023) (contributor to the stakeholder consultation) agreed to the above proposal.

The second applicant did not react on questions during this review of exemption 1(c)(I).

20.5. References

Bruker (2023a): Request for renewal of exemption IV-1(c). RoHS Pack 27. Retrieved from https://rohs.biois.eu/RoHS_V_Application_Form-final.pdf, Last updated 26.02.2024.

Bruker (2023b): Answers to questionnaire 1 (clarification questionnaire) sent via e-mail by Michael Jütte, Bruker, to Alexandra Morozov, Fraunhofer IZM. RoHS Pack 27. Retrieved from https://rohs.biois.eu/Ex_IV_1c_Bruker_Questionnaire-1_Clarification.pdf, Last updated 26.02.2024.

Deubzer et al. (2022): Study to assess requests for renewal of 16 exemptions to Annex IV of Directive 2011/65/EU. 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. Amended Final Report. In cooperation with Dr. Deubzer, Otmar, Fraunhofer IZM und UNITAR, Saskia Huber, Jana Rückschloss, Fraunhofer IZM, UNITAR Christian Clemm und Bio I. S. Shailendra Mudgal. Hg. v. Publications Office of the European Union. European Commission (RoHS 26, Pack 21). Retrieved from https://op.europa.eu/en/publication-detail/-/publication/f46d5d27-2d8d-11ed-975d-01aa75ed71a1, Last updated 26.02.2024.

Goodman, Paul (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 - Final Report (amended). ERA Report 2006-0383. In cooperation with Chris Robertson. Retrieved from https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf, Last updated 26.02.2024.

PPTF (2023): Request for renewal of exemption IV-1(c). RoHS Pack 27. Retrieved from https://rohs.biois.eu/RoHS_V_Application_Form%202022_final.pdf, Last updated 28.02.2024.

trinamiX (2023): Answers to consultation questionnaire by trinamiX. Retrieved from https://rohs.biois.eu/trinamiX.pdf, Last updated 28.02.2024.

21. Exemption 4 of Annex IV: Lead in glass frits of X-ray tubes, etc.

The below Table 21-1 shows the wording, scope and expiry dates of the exemption.

Table 21-1: Current wording of the exemption

No.	*Exemption*	*Scope and dates of applicability*
IV-4	*Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons.*	*Applies to category 8 and 9.* *Expires on* - *21 July 2021 for category 8 medical devices other than in vitro diagnostic medical devices, and for cat. 9 monitoring and control instruments other than industrial monitoring and control instruments* - *21 July 2023 for cat. 8 in vitro diagnostic medical devices* - *21 July 2024 for cat. 9 industrial monitoring and control instruments*

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

Cat.	Category, referring to the categories of EEE specified in Annex I of the current RoHS Directive
COM	European Commission
EEA	European Economic Area
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instrument
Lead-free	Not containing lead in the applications in scope of the exemption to be reviewed
SEA	Socioeconomic analysis

21.1. Background and technical information

On 20 January 2023, (TMC 2023a) requested the renewal of the above exemption for category (cat.) 9 industrial monitoring and control instruments (IMCI) with the wording, scope and validity period shown in the table below.

Table 21-2: Requested exemption renewal

No.	Requested exemption	Requested scope and dates of applicability
IV-4	*Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons.*	*Applies to category 9 industrial monitoring and control instruments.* *Expires on 21 July 2031 (= 2024 +7 years) for category 9 industrial monitoring and control instruments.*

(EPPA 2023) submitted a socioeconomic analysis (SEA) along with the renewal request of (TMC 2023a).

21.1.1. History of the exemption

(Goodman 2006) recommended exempting the types of EEE covered by the current exemption IV-4 if EEE of cat. 8 and cat. 9 were included in the scope of the RoHS Directive. Consequently, the current exemption 4 was listed in Annex IV of (Directive 2011/65/EU 2011) (RoHS 2) when it was published and enacted in 2011. (TMC 2023a) requested the renewal of the exemption for category (cat.) 9 IMCI to avoid its expiry on 21 July 2024 so that the exemption is due for review for the first time since its adoption to Annex IV.

21.1.2. Focus of the review

The European Commission (COM) have not yet officially published their decision as to the adoption of the above recommendation (status January 2024). On January 2023, (TMC 2023a) applied for the renewal of the current exemption 4 for cat. 9 since it was earmarked for expiry on 21 July 2024 for this subcategory of cat. 9 EEE.

21.1.3. Summary of the requested exemption

(TMC 2023a) explain that precision lasers with high spectral purity are manufactured with a borosilicate glass rod with glass frit containing lead oxide (PbO). PbO glass frit has a low melting point and excellent wetting characteristics, which achieves a thermally matched bond of the glass rod to other components in the manufacture of precision lasers without damaging or distorting the glass. The materials and heat cycle for attaching glass to metal must be precisely controlled to avoid stresses caused by thermal expansion differences.

(TMC 2023a) state that the unique characteristics of lead make the substance a necessary part of the functioning of glass frit, which cannot be substituted with other substances. The Test & Measurement Coalition therefore applies for a renewal of exemption 4 (IV) for the maximum validity period.

A Socio-Economic Analysis (SEA) (EPPA 2023) was conducted in addition to the technical assessment and attached to the exemption request submission. Overall, the analysis concludes that the total impact of non-renewal of this exemption is monetized in the range of 15 million EUR and 40 million EUR (conservative lower bound estimate).

21.1.4. Technical description of the exemption and use of the restricted substance

(TMC 2023a) explain that the exemption is relevant for the following EEE or components within Cat.9:

- *Laser Interferometers and Calibration Systems (Monolithic Laser Combiners & Precision Optics).*
- *Application-Specific Test Systems and Components.*
- *Used Equipment in the above categories.*

According to (TMC 2023a), these instruments are used in research, for quality control and testing laboratories (including field testing) in universities, manufacturing and clinical facilities and by governmental agencies for conformance verification and environmental testing. They are employed to ensure the good functioning of electronic communications networks, heavy industrial processes such as steel manufacturing, the testing of vehicles for compliance with emissions standards, and the monitoring of complex and critical systems of all types.

They are also employed in the manufacturing of semiconductors, as lithography using lasers create patterns down to the nanometre scale. Lasers are used for precision measurement of the alignment of etched layers, critical to integrated circuit manufacturing. The measurement uses interferometry, a technique that uses the interference of 2 light beams of very stable wavelength to make nanometre-scale measurements.

Precision lasers with high spectral purity are manufactured with a frit made of borosilicate glass containing lead oxide (PbO) to connect this glass to the metal pieces of the assembly. In highly precise, spectrally pure lasers, a heating element is attached to the glass rod to adjust the rod length to allow tuning; this attachment also uses a PbO-based glass frit. (TMC 2023a) state that PbO is used in glass frit in lasers due to its technical advantages, including:

- *Melting point below 490 °C, allowing usage with borosilicate glass which has a maximum processing temperature of 500 °C, and avoiding damage to the sensitive optics.*
- *Good match for coefficient of thermal expansion, which reduces stresses and prevents cracking of the seal or the glass. Heating of the laser rid tunes the cavity*

length. Thermal expansion and contraction of the heating element/glass frit/glass rod must be closely matched to allow for this tuning and to prevent damage.

- *Good wetting, allowing penetration into tighter spaces and effective sealing.*

21.1.5. Amount(s) of restricted substance(s) used under the exemption

According to (EPPA 2023), the content of substance in homogeneous material is approximately 90 % of lead (Pb) by weight. The amount of Pb entering the EU market annually through the application for which the exemption is requested would be approximately 5.8 kg of Pb, based on the replies provided by the TMC members.

Since not all producers of cat. 9 IMCI are members of TMC, the actual amounts of lead placed on the EU market under the exemption can be assumed to be higher.

21.2. Justification of the requested exemption

21.2.1. Substitution and Elimination of the restricted substance

(TMC 2023a) state that alternatives to lead (Pb) that have been suggested or tried are barium oxide (BaO) with a melting point of 1923 °C, and strontium oxide, with a melting point of 2531 °C. These alternatives require processing at conditions well above the maximum workable temperature for borosilicate glass and coefficients of expansion are too different to be usable. Other alternatives, such as Bi-based frit, melt at 540 °C or higher, and Bi-based frit flows poorly below 540 °C. PbO, on the other hand, melts at 880 °C and when used as a flux in the joining of glass to other materials, it can be processed below 500 °C.

(TMC 2023a) conclude that there are currently no suitable lead-free alternatives that meet RoHS exemption criteria on the EU market for cat. 9 IMCI and that re-designing cat. 9 IMCI could take approximately four years if an alternative is found. The unique characteristics of lead make the substance a necessary part for the proper functioning of glass frit, which cannot be substituted with other substances.

21.2.2. Environmental, health, safety and socioeconomic impacts

(EPPA 2023) identify the main potential negative consequences that the EU society at large would face in the framework of the potential restriction of non-renewal of Annex IV, exemption 4. The results are based on a survey focused on the EU test and measurement equipment industry, with market share coverage of approximately 70 % of the EU market. It therefore provided sufficiently reliable data for a representative extrapolation of the EU market.

(TMC 2023a) conclude that the total impact of a non-renewal is monetized in the range of 15 million EUR and 40 million EUR (conservative estimates in net losses; potential gains for suppliers of other components have been already taken into account), consisting of: economic impacts (EBIT loss) on test and measurement industrial type products' manufacturers; substitution costs and social impacts (i.e., unemployment in the EU-27).

From the environmental and health perspective, (EPPA 2023) state that under normal conditions of equipment use, lead is encapsulated within the equipment enclosure. As this equipment is sold for professional/industrial use only, when the equipment reaches the end-of-life, it will be appropriately processed by professional recyclers who are obligated to have suitable controls to avoid any environmental releases and are notified of the presence of the substance under the producers' obligation to provide a SCIP notification.

From a socioeconomic perspective, (EPPA 2023) state that the revocation of the exemption could lead to certain market distortions in the EU market. As the vast majority of sales into the EEA relating to equipment utilizing lead in glass frit is sold to EEA producers of semiconductor lithography, if the exemption is not renewed it would have a direct impact on a critical tool in the production of silicon chips from within the EEA. (EPPA 2023) expose the risk of customers of test and measurement equipment being forced to move operations to other areas, outside the EEA, hampering the EU's position as a relatively important exporter and trading partner. TMC manufacturers also declared that this would very likely lead to unemployment within the companies.

(EPPA 2023) state that if the exemption is not renewed, there would be little economic impact on frit suppliers as sales corresponding to this application are small and infrequent. A substantial impact on chip producers is anticipated though, due to the non-availability of semiconductor lithography products (incorporating test equipment) exclusively needed for this sector. It also states that the revocation would also have wider impacts on innovation in Europe and a direct negative impact on the research and innovation output within the EEA, as a major use of the Category 9 products is for industrial research and development processes, both within private companies and for state-sponsored research.

21.2.3. Roadmap towards substitution or elimination of the restricted substance

(TMC 2023a) state that, to their best knowledge, there are no suitable lead-free alternatives that meet the physical and technical performance criteria, and that fulfil RoHS exemption criteria on the EU market for test & measurement industrial-type products. As stated before, certain alternatives have been tested, but cannot be considered viable alternatives as their melting points require processing above the maximum workable temperature for borosilicate glass.

(TMC 2023a) report that if an alternative is found re-designing of the test & measurement equipment could take approximately four years.

21.3. Critical review

21.3.1. REACH compliance – Relation to the REACH Regulation

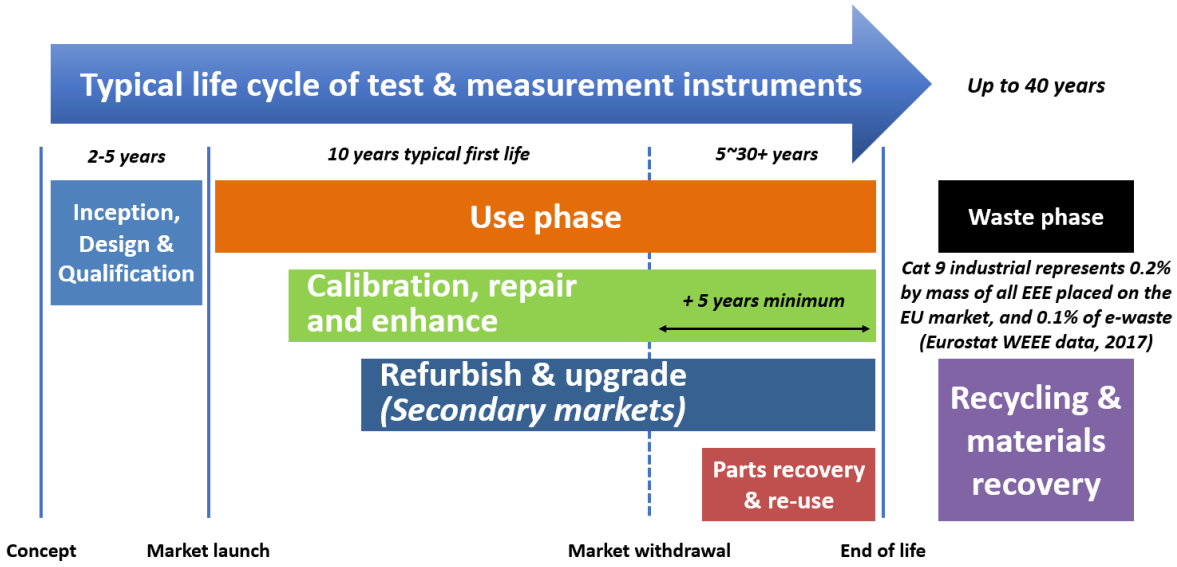
Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "provided that such inclusion does not weaken the environmental and health protection afforded by" 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 consultants as a threshold criterion: an exemption could not

be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

21.3.2. Relevance of the exemption for reuse of EEE

(TMC 2023a) point out that the exemption is relevant for used equipment. (TMC 2023b) added that due to the extended life and asset value of equipment, when customers no longer need the equipment, it is frequently procured back from them within or outside the EU. The equipment is then refurbished and made available as used in the market. (EPPA 2023) present the below life cycle of cat. 9 EEE. Figure 21-1 shows the lifecycle of this equipment.

Figure 21-1: Life cycle of cat. 9 IMCI



Source: (EPPA 2023)

The above explanation is not fully correct. For EEE placed on the European Economic Area (EEA) market, RoHS Art. 4(4) stipulates that substance restrictions do not apply to spare parts for the repair, reuse, updating of functionalities or upgrading of capacity of EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.

For the same EEE placed on the market outside the EEA, Art. 4(4) actually would apply from the point in time on when the EEE is placed on the EEA market, for example as reused equipment. The EEE would not be RoHS compliant if the exemption expired before placing on the EEA market of this EEE as reused equipment.

If exemption IV-4 expires on 21 July 2024 without allowing time for its renewal, equipment that was placed on a market outside the EEA prior to the expiry of the exemption would be blocked from entering the EEA market as used equipment from 22 July 2024 on. Renewing exemption IV-4 would prevent this situation.

21.3.3. Scope of the renewal request

The applicant was asked to describe the EEE covered in the exemption wording (X-ray tubes, image intensifiers, gas lasers, and vacuum tubes) in more technical detail, as well as the applications of such (parts of) equipment.

(TMC 2024a) stated that *their members do not know specifics beyond their applications in HeNe gas lasers which they claim to have explained in the exemption application and SEA.*

As to the other types of EEE covered in the exemption wording (image intensifiers, X-ray tubes, and vacuum tubes) (TMC 2024a) replied that *such devices are not used or produced by their members, and therefore they cannot provide feedback.*

(TMC 2023a) had applied for the renewal of the exemption in its current wording. The consultants conclude from the applicant's above statement that the exemption nevertheless is only required for gas lasers.

A potential to narrow the scope of the exemption has been identified, as it was concluded from the renewal request that among the equipment named in the original wording, the exemption is only required for HeNe gas lasers. There is a further potential to narrow the scope, specifying the use of heterodyne interferometry and the applications of the HeNe gas lasers.

21.3.4. Substitution and elimination of the restricted substance

Substitution of lead by lead-free glasses

(TMC 2023a) *suggested alternatives to Pb in glass frit. These are barium oxide (BaO) with a melting point of 1923 °C, strontium oxide, with a melting point of 2531 °C, and Bi-based frit, with a melting point of 540 °C which flows poorly below 540 °C. PbO, on the other hand, melts at 880 °C and when used as a flux in the joining of glass to other materials, it can be processed below 500 °C.* When asked if other alternatives have been investigated and the status of the substitution efforts, (TMC 2024a) stated that *producers continue to assess the availability of new substances that may be potential substitutes for the use of lead in this application. To date, there have been no usable alternatives found.*

Argon and Krypton lasers use lead in seal frits of window assemblies in line with exemption III-32, which was reviewed and recommended for renewal by (Baron et al. 2022c) until 21 July 2026. The reviewers concluded that substitution of lead in these glass frits was scientifically and technically still impracticable. (TMC 2024a) confirmed that *the use of lead in a frit seal described in their application is consistent with the justifications recommended for the renewal of exemption III-32 where a gas-tight seal is required between glass and metal materials of the laser tube. The exemption is, however, limited to Argon and/or Krypton laser tubes and does not include Helium-Neon lasers.*

The above information suggests that substitution of lead in the glass frits is actually scientifically and technically still impracticable.

The applicant was asked if the current exemption 7(c)(I) or one of the subclauses of the recommended renewed exemption 7(d)(V) cover the various uses of lead in the scope of the current exemption IV-4. (TMC 2023b) replied that g*iven the likelihood of more frequent changes to Annex III exemptions, particularly in the narrowing of scope and/or limited*

durations, it would not be appropriate to attempt to align with the AIII 7(c)-I or 7(c)-V as recommended by (Baron et al. 2022a).

Since the COM decided to place this exemption on Annex IV specifically for use in cat. 8 and cat. 9, it would be consistent with this approach to maintain exemption IV-4 as a separate exemption on Annex IV. The scope of a renewed exemption IV-4 should be excluded from the scope of exemption III-7(c)(I) and its renewed versions to avoid scope overlaps.

Exemption IV-4 could also be merged with exemption III-32 since both exemptions are based on the vacuum tube technology that uses the leaded glass frits to seal the evacuated tube. This would imply a transfer of exemption IV-4 from Annex IV to Annex III even though the exemption, differently from exemption III-32, is only relevant for cat. 8 and cat. 9. Like in the above case related to the integration of exemption IV-4 into III-7(c) exemptions, it would be consistent with the COM's original approach to have two separated annexes whereas the second is dedicated for specific EEE categories.

Elimination of lead by DPSS lasers

The applicant does not mention alternative technologies to eliminate the use of lead in their application, and it was asked whether, for example, diode-pumped solid-state (DPSS) lasers could replace those whose manufacturing requires lead. (TMC 2024a) replied that *alternative technologies, such as diode-pumped solid-state lasers, do not have the necessary specifications to perform the aforementioned applications. For instance, the necessary precision, power, and quality of the beam necessary for manufacturing semiconductors are only achievable with temperature-stabilized gas lasers.* According to (TMC 2024a), *the main deficit of DPSS lasers has to do with the beam quality. The HeNe gas laser light is extremely monochromatic with high "temporal coherence", meaning as you travel along the direction of propagation, the components of the electric field continue to oscillate like a sine-wave with a single wavelength, amplitude, and phase. The distance over which the waveform remains similar to a sine-wave is called the coherence-length of the beam and can be more than 100 m. Along with excellent coherence-length, the sine wave is frequency stable.*

(TMC 2024a) further stated that *coherence length is the most difficult and expensive quality to achieve with a diode laser. The most popular way of ensuring high coherence length and very stable central wavelength is to apply external cavity designs (ECDL – external cavity diode laser) by using Bragg gratings. This solution requires stable power and thermal controls, safety controls due to high power, and has a limited lifespan compared to the HeNe laser tube. Consequently, even where the performance of DPSS of devices approaches that of HeNe laser sources, their reliability is not ensured.* When asked about the difference in expected lifespan between HeNe lasers and DPSS lasers, (TMC 2024b) stated that *HeNe laser heads produced by our members are warranted to meet all published specifications for 3 years of continuous operation (~26, 000 hours) with a typical lifespan over 5 years, and a published MTBF value is >50,000 hours. By comparison, internet searching found the typical expected lifespan of a DPSS laser is approximately 20,000 hours. While this can be extended to more than 100 K hours if operated well below maximum power, these figures reflect typical use models of intermittent operation with anticipated duty cycles where the output is off.*

In the consultant's opinion, a shorter lifetime does not show that reliability is not ensured or that a DPSS laser cannot be used for the requested applications. DPSS lasers can still operate reliably for ~20, 000 hours, and a shorter lifetime would not per se be a reason to grant the exemption unless sub-clause 3 of Art. 5(1)(a) would be applicable (cf. section 21.3.7 on page 458).

The consultants have found DPSS lasers on the internet with a coherence length greater than 100 m[117], matching the coherence length of HeNe lasers. Furthermore, these lasers' applications are, among others, interferometry, semiconductor inspection, wafer fabrication, and lithography. These DPSS lasers can thus be used for those applications for which TMC claim that they do not have the specifications needed. Based on this, the applicant was asked about the potential substitution of HeNe lasers by such DPSS lasers.

(TMC 2024b) replied that *in the HeNe laser applications, knowing the exact position of the stage holding the semiconductor wafer down to the picometer regime is critical. Because of the extensive history of HeNe lasers in industry, the install base of semiconductor tools has optics coated specifically for 632 nm wavelength. There are no alternate 632 nm laser sources that meet all of these requirements readily available in the market.* The consultants have not found a DPSS laser with a 632 nm wavelength in their research, and it was asked why the 632 nm wavelength is required for the applications described.

(TMC 2024c) replied that *system aspects have been optimised for the 632 nm wavelength specific to HeNe laser sources, including optical properties of the interferometer optics, the required optical materials and coatings, and the performance specifications of photoreceivers regarding bandwidth, dynamic range, and wavelength sensitivity. In the case of using a different wavelength, it's crucial to assess whether the phase measurement electronics hardware, firmware, and software can effectively accommodate the new wavelength "ruler." Achieving a thorough understanding of the laser's required performance demands extensive system-level study and experimentation*. (TMC 2024d) stated that *shorter wavelengths, such as 394 nm in the ultraviolet range, are absorbed by the glass which attenuates the beam and heats up the glass, leading to inaccuracies.*

From these statements, it is understood that the laser's longer wavelength (632 nm) is relevant for the functioning of the overall system. Nevertheless, 394 nm DPSS lasers are offered on the market for the same tasks as the 632 nm gas lasers.

The critical characteristic for precision positioning in semiconductor manufacturing is the lasers' accuracy. (TMC 2024b) stated that *the approach taken to meet the needs of these applications is the heterodyne interferometry method, which allows high wavelength stability, long coherence length, and a long lifetime. The heterodyne interferometry method achieves the measurement accuracy and precision crucial for high-end tools, and other position measurement methods have yet to prove this capability*. *Heterodyne interferometry, in comparison to homodyne interferometry, uses phase measurement instead of signal amplitude measurement which greatly improves signal-to-noise characteristics of interferometer systems.* (TMC 2024d) further explained that *heterodyne interferometry requires two different frequencies with orthogonal polarizations, meaning that HeNe lasers produce light of two different wavelengths at the same time. With the differences depending on the characteristics desired; these frequencies are frequency-locked and in phase. The*

[117] Cf. Skylark, https://www.skylarklasers.com/product/349-nx

stability in the difference of the frequencies is another key feature for stable measurement capability, the heterodyne method uses a stabilized HeNe laser to achieve accuracy which is also more configurable for multiple axes of measurements. DPSS lasers, regardless of frequency, are single frequency beams (homodyne interferometry) and while locking the frequency of two DPSS lasers is theoretically possible, it has not been demonstrated and is not commercially reproducible. Homodyne interferometry is less precise, known homodyne systems have an accuracy of ~0.5 ppm (parts per million), while heterodyne systems have an accuracy of ~0.5 ppb (parts per billion) – a difference of 1000x.

(TMC 2024b) shared the technical overview of a HeNe laser, where the vacuum wavelength stability is stated as ±0.002 ppm typical (one hour) and ±0.02 ppm typical (lifetime)[118]. This wavelength stability is unmatched by the DPSS laser with a coherence length greater than 100 m found by the consultants. The consultants asked if the performance criteria described for the applications at 632 nm (wavelength stability) are identical for a laser with a different wavelength, or if they vary with the wavelength. (TMC 2024c) replied that *a comprehensive analysis of the system's performance must encompass the characteristics and limitations of the laser itself, the interferometer optics, and the electronics. This includes wavelength sensitivity.* When asked for the specific case of a 349 nm wavelength, (TMC 2024d) further explained that *while a 2x decrease in wavelength provides a 2x improvement in resolution if all else is equal, the smaller wavelength is absorbed by the glass optics of the interferometer, requiring higher power to compensate and resulting in heating of the glass leading to poorer accuracy.*

(TMC 2024d) state that *DPSS lasers are much less expensive and widely available than gas lasers. These lasers are a good option for applications that tolerate homodyne-level performance, but they have less wavelength accuracy (1 decimal place vs 5) and worse spectral stability (0.2 picometers vs 0.06 picometers). They are also less easily configurable for different axes.*

In the consultant's opinion, the information made accessible during the review suggests that the DPSS lasers with similar features and applications rely on homodyne interferometry. Heterodyne interferometry as enabled by the HeNe lasers still seems to be needed to ensure the accuracy required for precision positioning and calibration.

Elimination of lead by malleable metal seals

(Baron et al. 2022c) mention in their review of exemption III-32 an alternative sealing mechanism based on malleable metals as a promising alternative technology to eliminate the use of lead in glass seal frits. Coherent, a manufacturer of argon lasers, confirmed that the use of malleable metals will be investigated in the coming years. Coherent believe this technology to be fully qualified by 2025 so that the leaded glass frits can be replaced by a mechanical metal seal by 2025. The solution would also be applicable for krypton lasers. (Baron et al. 2022c) recommend assessing the status of the development of this alternative in the next review.

[118] Optics and Laser Heads for Laser-Interferometer Positioning Systems | Keysight

(TMC 2024a) confirmed that the use of lead under exemption III-32 is consistent with the justifications for the renewal of exemption IV-4 for HeNe-lasers where a gas-tight seal is required between glass and metal materials of the laser tube.

This statement raises the question of whether the lead-free malleable metal seal would not be useable for HeNe-lasers as well.

(TMC 2024h) reply that they are unaware of any capability for "malleable metals" to be used as a substitute for the lead frit seal in their HeNe laser application. The only similarity between the Coherent Inc. application and the frit seal in the TMC application is both are gas lasers. It must be noted that there is no publicly accessible information regarding the potential transition to using "malleable metals" as an alternative to a lead frit seal for the Coherent Inc. application. (TMC 2024h) concluded that the application may be proprietary and not commercially available to other producers. Even if such a solution were to become commercially available in the future, the reliability of substitution would still have to be proven in the HeNe Laser applications. Consequently, they conclude that substitution or elimination of lead in the frit seal of HeNe gas lasers remains scientifically and technically impracticable, and so it is not possible to determine today the reliability of substitutes.

In the consultant's opinion, the above aspects should be clarified with view to the scientific and technical practicability of lead elimination in HeNe-lasers with the malleable metal solution. The consultants therefore recommend a joint review of exemptions III-32 and IV-4 which requires an alignment of the expiry dates.

21.3.5. Wording of the exemption

A potential to narrow the scope of the exemption has been identified, as it can be concluded from the exemption application and questionnaire responses that the need for HeNe lasers has been justified only for semiconductor manufacturing.

The wording of the exemption was discussed with *(TMC 2024e, 2024f, 2024g, 2024h). The applicant does not agree with narrowing the scope to semiconductor manufacturing because metrology applications are not exclusive to semiconductor manufacturing. The proposed exemption statement would restrict the scope of the exemption including metrology applications to semiconductor manufacturing. Semiconductor manufacturing was presented as a well-understood example of heterodyne laser interferometry. The applicants point out that the criterion of "heterodyne interferometry" in the exemption wording would prevent misuse of the exemption.*

The consultants followed the applicants' above argumentation and proposed a wording based on the heterodyne interferometry technique but included the main application fields that were mentioned in the renewal request and for which heterodyne interferometry seems to be irreplaceable at the time being.

> *Lead in glass frit binders for assembly of HeNe gas lasers used in heterodyne interferometry calibration and heterodyne interferometry positioning applications.*

(TMC 2024i) do not agree with the recommended wording, as it limits the application of the finished equipment (the HeNe laser) to specific applications ("used in heterodyne interferometry calibration and heterodyne interferometry positioning applications."). They state that this could limit innovation on the future uses of HeNe Laser devices and request to renew the current wording.

The above statement confirms that the proposed wording covers all current uses of these lasers, the more since the applicant was requested to indicate any uses that would not be covered. As to the innovation, the applicant can request to exempt further uses of these lasers if there is evidence that substitution or elimination of lead are impracticable. Exemptions are not intended to cover future uses of restricted substances.

21.3.6. Environmental, health, safety and socioeconomic impacts

(EPPA 2023) foresee severe socioeconomic, health and safety consequences if exemption IV-4 is not renewed for cat. 9 IMCI. The consultants focused on technical practicability and reliability. If the exemption is withdrawn in the absence of viable lead-free alternatives, the consultants cannot exclude that at least some of these negative impacts actually arise.

21.3.7. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria[119] is fulfilled:

1. 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**;
2. the **reliability of substitutes** is not ensured;
3. 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**.

TMC request a 7 year renewal of exemption IV-4 with its current wording for cat. 9 industrial monitoring and control instruments (IMCI) until 21 July 2031. The applicant argues that no lead-free alternatives are available, and once they are available, approximately four years are required for the re-design of the test & measurement industrial type products.

Even though the applicant had requested the renewal of the exemption in its current wording, the review showed that only HeNe gas lasers are used or produced by TMC's members. TMC also point out that the exemption is relevant for the reuse in the EEA of equipment originally placed outside the EEA. Recommending an exemption to allow this, contradicts the goal of substituting or eliminating hazardous substances.

Regarding lead elimination, DPSS lasers are a lead-free alternative to gas lasers, but they face challenges with beam quality. Although DPSS lasers matching HeNe lasers in coherence length (greater than 100 m) exist, they lack the specific 632 nm wavelength crucial for certain semiconductor applications. It is not the frequency itself that is critical but the laser accuracy achieved with the heterodyne interferometry method used in HeNe lasers, which allows a high wavelength stability, long coherence length, and a long lifetime. DPSS lasers use homodyne interferometry which seems to have a lower accuracy than the heterodyne systems that achieve an accuracy of ~0.5 ppb. In conclusion, while DPSS lasers

[119] Deviating from Art. 5(1)(a), the sub-clauses are numbered to allow addressing them specifically in the text.

with similar features and applications exist, these lasers have less wavelength accuracy and spectral stability than gas lasers. Heterodyne interferometry is needed to ensure the accuracy of the laser for precision positioning and calibration in semiconductor manufacturing.

Regarding lead substitution, TMC explored alternatives to lead in glass frit such as barium oxide (BaO) and Bi-based frit, but deemed them unsuitable. Concerning exemptions that allow use of lead in glass frits applied to seal tubes, exemption III-32 is similar to IV-4. TMC confirm that the justifications for the use of lead for argon- and krypton lasers are relevant for exemption IV-4 as well, In the last review of exemption III-32, a producer of argon-lasers announced to have developed an alternative technology to eliminate the use of lead by 2025. The consultants therefore recommend aligning the expiry of exemption IV-4 with the expiry of exemption III-32 to clarify whether the identified lead-free solution for argon- and krypton-lasers is applicable to HeNe-lasers as well. At the COM's discretion, exemption IV-4 could in principle be integrated into exemption III-32, or exemption 7(c)(I) as a specifc use of lead in glass.

21.4. Recommendation

The consultants recommend renewing the exemption only for the glass frit binders for the assembly of HeNe-lasers where elimination or substitution of lead are scientifically and technically still impracticable. Granting an exemption for this use of lead would thus be justifiable by Art. 5(1)(a).

The below wording is recommended for the renewed exemption IV-4, which reflects the specific uses of these HeNe-lasers:

No.	Exemption	Scope and dates of applicability
IV-4(a)	*Lead in glass frit binders for assembly of HeNe gas lasers used in heterodyne interferometry calibration and heterodyne interferometry positioning applications.*	Applies to category 9 monitoring and control instruments from 22 July [2024 + 12 months] Expires on 21 July 2026 for category 9 monitoring and control instruments

A period of 12 months is recommended to allow a smooth administrative transition from the current exemption IV-4 to the new exemption IV-4(a). Concerning the expiry of exemption IV-4(a), the COM should allow sufficient time for preparation and timely submission of renewal requests between the official publication of their decision as to the renewal of the exemption and its expiry.

As to the duration of the exemption, the consultants recommend aligning the expiry date with exemption III-32 where lead-containing glass frits are used for gas lasers (argon and krypton) as well to seal a tube. A producer of such lasers announced during the review of this exemption by (Baron et al. 2022b) to have a reliable lead-free solution – a mechanical seal - available by 2025. (Baron et al. 2022b) recommend assessing the status of development of this alternative in the next review, which raises the question of whether this solution would also be applicable to HeNe lasers.

TMC stated that the use of lead under exemption III-32 is consistent with their justifications for the renewal of exemption IV-4 for HeNe-lasers. They said later that the only similarity of the lasers in scope of these two exemptions is that both are gas lasers, and that the lead-free solution would probably be proprietary and not commercially available to other producers.

The consultants consider a joint review of exemptions III-32 and IV-4 as useful to clarify the above questions. The adverse socioeconomic impacts assessed by EPPA will not arise until 2026 since the consultants do not recommend revoking the exemption but TMC will have to bear the cost of preparing and processing a renewal request prior to 2031, which they requested as expiry date in their current renewal request.

The COM may also consider merging above recommended exemption IV-4 with exemption III-32 given the principal technical similarity of the exemptions (sealing of vacuum tubes with a lead-containing glass). Exemption IV-4 could, for example, be added to exemption III-32 as exemption III-32(a), or both exemptions could be numbered as a) and b) respectively under exemption entry III-32.

For the next review of the exemption, the consultants would like to encourage the participation of DPSS laser manufacturers if they deem their DPSS laser technology appropriate to eliminate the use of restricted substances in the lasers in the scope of exemption IV-4. It is also recommended in a next step to define the exemption scope via precision thresholds if scientifically and technically practicable, instead of the current technology-based (heterodyne interferometry) scope definition.

Applicants' feedback on the recommendation

(TMC 2024i) do not agree to the recommended wording as it limits the application and thus innovation on the future uses of HeNe Laser devices. They also disagree with the expiry date aligned with exemption III-32 stating that the justification is technically inappropriate.

The consultants are confident that they considered all relevant arguments made available by applicants and stakeholders during the review, and that the arguments have been evaluated taking into account the requirements of Art. 5(1)(a).

21.5. References

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Baron et al. (2022b): RoHS Pack 24. Study to assess requests for renewal of seven (-7-) exemptions 18(b), 18(b)-I, 24, 29, 32 and 34 of Annex III and exemption 34 of Annex IV of Directive 2011/65/EU (Pack 24) – Final Report. In cooperation with Yifaat Baron, Carl-Otto Gensch, Andreas Köhler, Ran Liu, Clara Loew, Katja Moch, Öko-Institut. Retrieved from https://data.europa.eu/doi/10.2779/123658.

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Goodman (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report July 2006, amended 19 Sep 2006. ERA Report 2006-0383. In cooperation with Paul Goodman, ERA Technology Ltd. ERA Technology Ltd. Retrieved from https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf.

TMC (2023a): RoHS Annex V request for renewal of exemption IV-4. RoHS Pack 27. In cooperation with Meglena Mihova.

TMC (2023b): Answers to questionnaire 1 (clarification questionnaire) sent by Tobias Steinbrecher, EPPA, to Dr. Otmar Deubzer via e-mail. RoHS Pack 27. Retrieved from https://rohs.biois.eu/IV-4_TMC_Questionnaire-1_Clarification.pdf.

TMC (2024a): Answers to questionnaire 2 sent by Tobias Steinbrecher, EPPA, to Elena Fernández via e-mail. RoHS Pack 27.

TMC (2024b): Answers to questionnaire 3 sent by Tobias Steinbrecher, EPPA, to Elena Fernández via e-mail. RoHS Pack 27.

TMC (2024c): Answers to questionnaire 4 sent by Tobias Steinbrecher, EPPA, to Elena Fernández via e-mail. RoHS Pack 27.

TMC (2024d): Answers to questionnaire 5 sent by Tobias Steinbrecher, EPPA, to Elena Fernández via e-mail. RoHS Pack 27.

TMC (2024e): Answers to questionnaire 6 sent by Tobias Steinbrecher, EPPA, to Elena Fernández via e-mail. RoHS Pack 27.

TMC (2024f): Answers to questionnaire 7 sent by Tobias Steinbrecher, EPPA, to Elena Fernández via e-mail. RoHS Pack 27.

TMC (2024g): Answers to questionnaire 8 sent by Tobias Steinbrecher, EPPA, to Elena Fernández via e-mail. RoHS Pack 27.

TMC (2024h): Answers to questionnaire 9 sent via e-mail by Tobias Steinbrecher, EPPA, to Dr. Otmar Deubzer. RoHS Pack 27.

TMC (2024i): Applicants' feedback on the recommendation by Tobias Steinbrecher, EPPA, to Elena Fernández via e-mail. RoHS Pack 27.

22. Exemption 9 of Annex IV: Cd in helium-cadmium lasers

The below Table 22-1 shows the wording, scope and expiry dates of the exemption.

Table 22-1:Current wording of the exemption

No.	Current exemption wording	Current scope and dates of applicability
IV-9	Cadmium in helium-cadmium lasers	Applies to categories 8 and 9. Expires on - 21 July 2021 for category 8 other than in-vitro diagnostic medical devices and for category 9 other than industrial monitoring and control instruments. - 21 July 2023 for category 8 in-vitro diagnostic medical devices. - 21 July 2024 for category 9 industrial monitoring and control instruments.

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
Cd	Cadmium
COM	European Commission
DPSS	Diode pumped solid state, used in the context with lasers (DPSS lasers)
EEE	Electrical and electronic equipment
He	Helium
IMCIs	Industrial monitoring and control instruments

RoHS 1	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
SSM	Semiconductor stress measurement
UV	Ultraviolet, here referring to ultraviolet light (wavelength spectrum between 100 nm and 400 nm)

Definitions

22.1. Background and technical information

On 19 January 2022, (JBCE et al. 2023a) requested the 7 year renewal of this exemption as displayed in Table 22-2 for EEE of category (cat.) 9 industrial monitoring and control instruments (IMCIs).

Table 22-2: Wording and scope of the requested exemption

No.	*Requested exemption*	*Requested scope and dates of applicability*
IV-9	*Cadmium in helium-cadmium lasers*	*Applies to category 9 monitoring and control instruments.* *Expires on 21 July 2031 (2024 + 7 years)*

22.1.1. History of the exemption

(Goodman 2006) found that helium-cadmium (HeCd) are the only light source producing 325 nm ultraviolet (UV) wavelengths in the required quality in particular for semiconductor analyses. HeCd lasers were listed on Annex IV of (Directive 2011/65/EU 2011) (RoHS Directive) when it was published in 2011.

(JBCE et al. 2023a) requested the renewal of the exemption to avoid its expiry on 21 July 2024 for category (cat.) 9 industrial monitoring and control instruments (IMCI), so that the exemption is due for review the first time since its adoption to Annex IV.

22.1.2. Summary of the requested exemption

(JBCE et al. 2023a) describe Raman Spectroscopy as a non-destructive chemical analysis technique which provides detailed information about chemical structure, phase and polymorphy, crystallinity and molecular interactions. It is based on the interaction of light with the chemical bonds within a material. Helium cadmium lasers enable wavelengths of 325 nm to be used in Raman spectroscopy measurements.

Diode Pump Solid State (DPSS) lasers, as an alternative to helium cadmium lasers, can be used in many applications. However, although DPSS lasers can be used for Raman spectroscopy, at the moment 325 nm DPSS lasers for Raman spectroscopy are not

available commercially, due to a lack of stability and precision. Therefore, the extension of the exemption is required for helium cadmium lasers to continue to be used in Raman applications.

22.1.3. Roadmap towards substitution or elimination of the restricted substance

(JBCE et al. 2023a) say that, once the DPSS laser characteristics have been improved, equipment manufacturers will conduct a detailed performance and stability evaluation. At the same time, the system for procurement, manufacturing and service will be improved. (JBCE et al. 2023a) reference (Goodman 2006) stating: "The new product development time for many Category 8 and 9 products is over 4 years and can be 7 years or longer."

(JBCE et al. 2023a) therefore estimate that it will take 4-7 years to develop the equipment after the characteristics of the DPSS lasers are improved. They highlight that equipment manufacturers sometimes change electronic circuits and mechanical designs in order to adopt lasers that eliminate the use of cadmium, and it is therefore not appropriate to describe the equipment manufacturer's schedule in general.

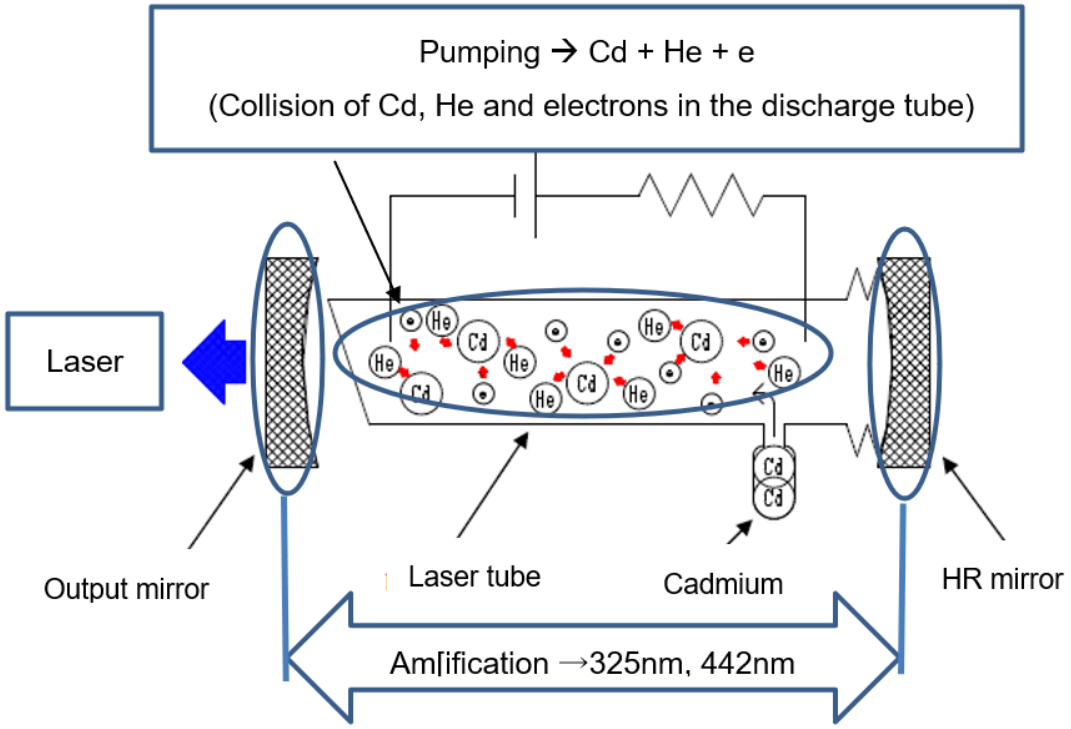
(JBCE et al. 2023b) detail the steps to be taken:

1) Re-design of the instruments and reliability test; if successful,
2) Evaluation of performance in service;
3) Durability testing

22.1.4. Technical description of the exemption and use of the restricted substance

According to (JBCE et al. 2023a), helium-cadmium lasers enable wavelengths of 325 nm to be used in Raman spectroscopy measurements. Cadmium (Cd) and helium (He) gas are enclosed in the laser tube. The cadmium is heated to convert it to its gas phase. Collisions with He atoms which have been excited by electrical discharge then excite the Cd atoms into the laser-emitting excited state. This generates lights of a specific wavelengths (325 nm and 442 nm) in the laser tube, which is amplified by mirrors at both ends.

Figure 22-1: Schematic diagram of the HeCd laser



Source: (JBCE et al. 2023a)

(JBCE et al. 2023a) describe Raman Spectroscopy as a non-destructive chemical analysis technique based on the interaction of light with the chemical bonds within a material. It probes the chemical structure of a material and provides information about:

- Chemical structure and identity
- Phase and polymorphism
- Intrinsic stress/strain
- Contamination and impurity

Laser wavelengths used in Raman spectroscopy range from ultra-violet through visible to near infra-red. Typical examples include (but are not limited to):

- Ultra-violet: 244 nm, 266 nm, 325 nm
- Visible: 405 nm, 458 nm, 473 nm, 488 nm, 515 nm, 532 nm, 633 nm, 638 nm, 660 nm
- Near infra-red: 785 nm, 830 nm, 980 nm, 1064 nm

The choice of laser wavelength depends on the application. The HeCd laser is used as a laser source. It can stably emit a wavelength of 325 nm and provides the below benefits according to (JBCE et al. 2023a):

- Increased sensitivity from UV excitation, since Raman scattering efficiency is proportional to λ^{-4}, where λ is the laser wavelength. Thus, Raman scattering at 325 nm is a factor of 14 times more efficient than for example at 633 nm.

- With certain samples, UV laser excitation can interact in ways not possible when using visible laser sources. For example, in semiconductor materials, the penetration depth of UV light is typically in the order of a few nanometres, and thus UV Raman can be used to selectively analyse a thin surface layer as it is commonly found in silicon on insulator (SOI) materials. In another example, UV excitation can give rise to specific resonance enhancement with biological moieties, in particular protein, DNA and RNA structures. Specific analysis of these materials within tissue can be difficult using visible laser wavelengths.
- Resonance Raman on carbon materials is well documented in scientific literature at 325 nm and is frequently used for material characterisation. A small shift in excitation even to 320 nm may invalidate the results.[120]
- Fluorescence suppression can often be assisted using UV lasers, by spectrally separating the Raman and fluorescence signatures. With visible lasers it frequently occurs that Raman and fluorescence are superimposed, and the incomparable strength of the fluorescence is what can perturb or completely mask the Raman spectrum. With UV excitation, the Raman spectrum lies close to the laser line, whereas the fluorescence is often slightly removed to higher wavelengths. Thus, they no longer overlap, and the fluorescence is no longer an issue.

(JBCE et al. 2023a) highlight that with certain samples, UV laser excitation can interact in ways not possible when using visible laser sources. For example, in semiconductor materials, the penetration depth of UV light is typically in the order of a few nanometres, and thus UV Raman can be used to selectively analyse a thin, surface layer (as is commonly found in silicon on insulator (SOI) materials). For example, the penetration depth is around 5 nm if a 320 nm laser is used. On the other hand, the penetration depth is around 450 nm if a 500 nm laser is used like in the below table for a silicon sample.

Table 22-3: Penetration depth of Si samples with light of different wavelengths

Wavelength of light [nm]	*250*	*320*	*500*	*800*	*1000*	*1200*
Penetration depth	*2.72 nm*	*3.91 nm*	*450 nm*	*5.88 µm*	*78.1 µm*	*227 mm*

Source: (JBCE et al. 2023a)

(JBCE et al. 2023a) report that helium-cadmium lasers are used for photoluminescence (PL) measurements, too. The application field is semiconductor materials for defect measurement and energy state analysis. In PL, light energy, or photons, stimulate the emission of a photon from any matter. It is a non-contact, non-destructive method of probing materials. In essence, light is directed onto a sample, where it is absorbed and where a process called photo-excitation can occur. The photo-excitation causes the material to jump to a higher electronic state, where it will then release energy (photons) as it relaxes and returns back to a lower energy level. The emission of light or luminescence through this process is photoluminescence.

[120] See for example Ferrari et.al (2004), Raman spectroscopy of amorphous, nanostructured, diamond–like carbon, and nanodiamond, Volume 362, Issue 1824, https://royalsocietypublishing.org/doi/10.1098/rsta.2004.1452; source as referenced by JBCE et al. 2023a.

22.1.5. Amount(s) of restricted substance(s) used under the exemption

According to (JBCE et al. 2023a), helium-cadmium lasers use elemental cadmium, not cadmium compounds. They report approximately 800 g of cadmium being placed on the market in "Europe" annually with helium-cadmium lasers.

22.2. Justification of the requested exemption

(JBCE et al. 2023a) state that without cadmium, it is not possible to achieve the specific wavelengths of 325 nm and 442 nm. Cd is the only substance that can achieve 325 nm wavelength light.

22.2.1. Substitution and Elimination of the restricted substance

The applicant discusses the possibility to eliminate the use of lead by alternative technologies.

Diode Pump Solid State (DPSS) lasers with an oscillation wavelength band of 320 nm are a potential technology that could eliminate the use of cadmium. (JBCE et al. 2023a) report that a HeCd laser manufacturer has also been developing a DPSS 320 nm band laser that complies with the RoHS Directive. It is a laser that excites a fluoride-doped fibre with a semiconductor laser and converts red fundamental laser light into UV light with a wavelength conversion element. The laser has an oscillation wavelength of 318 ± 1 nm and an output of 100 mW, which is similar to a HeCd laser. As such, it is considered an alternative laser for many of the applications that use HeCd lasers. Currently, they are verifying whether DPSS lasers can actually be used in many applications, including Raman spectroscopy. Today, the specifications of this laser types do not yet match what is required for Raman spectroscopy. Various evaluations are conducted to improve the quality of the laser, and they plan to place it on the market in the near future.

Raman spectroscopy requires a high stability of the wavelength value (better than 0.1 cm^{-1}, which is 0.001 nm for 325 nm excitation, for measuring stress in semiconductors, and a laser power of more than 20 mW). A Raman peak is typically 0.01 nm wide, and its position is expected at the same precision level.

Recently, semiconductor lasers operating with a 320 nm wavelength have been released by some laser manufactures. However, in these products the laser wavelength is generally unstable because the resonator length is impacted by the temperature of both the laser body and atmosphere. As a result, the wavelength value shifts by approximately 0.1 nm to 1 nm, which inevitably affects the Raman measurement, making it impossible for correct spectral peak analysis. Semiconductor lasers are not yet suitable as an alternative. Wavelength variations/instability also affect the Rayleigh filters, making it impossible to guarantee Raman spectra close to the laser line.

(JBCE et al. 2023a) also present the below table comparing the characteristics of a Raman spectrometer for which the HeCd-laser is used with other type of analysers that operate near UV wavelengths.

Table 22-4: Comparison of analytical methods for detecting ultraviolet spectrum

		Analytical methods for detecting ultraviolet spectrum		
		Raman Spectrometer	Fluorescence meter	Spectro-photometer
Wavelengths range	ɤ-ray	Unable	Unable	Unable
	X-ray	Unable	Unable	Unable
	UV	Able	Able	Able
	Visible	Able	Able	Able
	Infrared	Able	Able	Unable
	Micro	Unable	Unable	Unable
	Electric/wave	Unable	Unable	Unable
Sample type of analysis	Gas	Able	Able	Able
	Liquid	Able	Able	Able
	Solid	Able	Able	Unable
Applications of the scope	Metal material structure analysis	Unable	Unable	Unable
	Inorganic compounds material structure analysis	Able	Able	Unable
	Organic compounds material structure analysis	Able	Able	Able
	Crystal analysis	Able	Unable	Unable
	Stress analysis	Able	Unable	Unable

Source: (JBCE et al. 2023a)

A fluorescence meter measures the fluorescence or light emitted by different fluorescing objects. A fluorescence meter cannot be used for crystal analysis and stress analysis. A spectrophotometer absorbs the lights of solutions and gases, and it measures concentrations, characteristics and molecule structures. A spectrophotometer cannot be used to analyse solid materials.

Raman spectroscopy enables analysis of the physical properties of gases, liquids and solids, and has many different applications beyond metal material structure analysis in the ultraviolet, visible and infrared ranges.

22.2.2. Environmental, health, safety and socioeconomic impacts

(JBCE et al. 2023a) claim that waste lasers are returned to a laser supplier outside the EU, and are refurbished by the supplier. There are no cadmium emissions originating from HeCd lasers in the EU.

During operation, cadmium flows out of a cadmium reservoir into the discharge tube. It then moves from the anode side to the cathode side, adheres to the discharge tube wall and solidifies. When the cadmium in the cadmium pool has completely moved, the laser tube reaches the end of its useful life. Laser manufacturers provide the service of replacing waste laser tubes that have reached the end of their life. Manufacturers receive inquiries from users for replacing laser tubes. The waste laser is returned to the laser manufacturer's factory outside the EU, and in less than a month, the old laser tube is replaced with a new laser tube, adjusted, inspected and shipped back. Each laser tube is numbered and managed by recording the number, characteristics, etc. in the laser history document.

22.3. Critical review

22.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several restrictions of cadmium and its compounds are listed on Annex XVII (cf. section 4.1 on page 48). None of those, however, is applicable to the use of cadmium and cadmium compounds in the scope of exemption IV-9.

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

22.3.2. Substitution and elimination of the restricted substance

Elimination of cadmium by DPSS lasers and exemption scope

(JBCE et al. 2023a, 2024a, 2023b) concede that 320 nm DPSS lasers can eliminate the use of cadmium in many UV Raman spectroscopy tasks. They report about a DPSS laser that operates at 318 nm ± 1 nm with 100 mW output similar to HeCd lasers and which may be placed on the market "in the near future". The applicants claim that these lasers cannot yet replace HeCd lasers in Raman spectroscopy at 325 nm due to their lacking wave length stability at more than 20 mW output power which is required for semiconductor stress measurement (SSM).

An investigation on the internet showed that 320 nm DPSS lasers are offered for Raman spectroscopy.[121] The consultants contacted a manufacturer of such DPSS lasers. The (DPSS laser manufacturer 2024) stated *that their design for a DPSS Laser at 320 nm has proven capable of delivering stable single-frequency emission at 20 mW output power over more than 8,000 h, which is longer than the typical lifetime of a HeCd laser. The product has been commercially available for at least two years. As to photoluminescence, the producer stated that their 320 nm lasers which are used in Raman spectroscopy are also often used for photo luminescence applications as the performance requirements are quite similar. Therefore, although not specifically stated on their web page, they believe their 320 nm laser to meet all requirements for photoluminescence applications.* When asked whether these lasers can provide the wavelength stability for SSM - better than 0.1 cm^{-1} at laser

[121] As an example see https://hubner-photonics.com/applications/lasers-for-raman-spectroscopy/)

power of more than 20 mW – the DPSS laser producer did not answer the question despite a second effort to obtain a reaction.

In the absence of contrary information, the consultants conclude from the above information that elimination of cadmium by DPSS lasers is scientifically and technically not yet practicable for Raman spectrometers that are used in SSM.

(JBCE et al. 2023b, 2024b) indicate that, once appropriate lasers are available, seven years or more would be required to develop and qualify Raman spectrometers operated with such lasers. They state that this applies only to Raman spectrometers for SSM because they do not know about other applications.

Scope of the renewed exemption

The applicant focused the discussion as to the elimination of cadmium by DPSS lasers to SSM applications, and the applicants' above statement suggests that the members of the applying consortium require the exemption for use in SSM.

The consultants therefore proposed the below wording for the renewed exemption IV-9:

"Cadmium in helium-cadmium lasers for stress measurement in semiconductors with 325 nm wavelength and more than 20 mW laser output power"

(JBCE et al. 2024b) replied that they request "Cadmium in helium-cadmium lasers" for category 9 IMCI. Stability is important in this application but "more than 20mW" is an example and should not refer to the output in this proposed wording. Regarding the wavelength, He-Cd lasers generate 325 nm and 442 nm waves at the same time so that the exemption wording should not refer to the wavelength.

Since the 325 nm and 442 nm wavelengths are inherent to HeCd lasers, i.e. they do not generate different wavelengths, mentioning the wavelength in the exemption wording does not contribute to define the scope.

The consultants wondered, however, why the applicants designated the 20 mW threshold as a mere example while previously they consistently have pointed out the importance of the wavelength stability of 325 nm at more than 20 mW output power. The applicant was requested to detail the range of output power use for SSM.

(JBCE et al. 2024b) explain that the required laser power varies depending on the application and the device to which the laser is mounted. For example, the optics of a Raman spectrometer reduce its laser intensity. Importantly during measurements, these must be properly adjusted so that the sample is not altered by laser irradiation. According to (JBCE et al. 2024c), the output power of the lasers is adjusted to ensure that the sample is not damaged when the laser is irradiated onto it. Measurements are sometimes made at less than 20 mW. They confirm that the same HeCd laser can produce each output power required for SSM.

The above replies do not answer the question and they are not fully plausible. The applicants point out that the output power depends on the application and the device and do not give any clear indication as to the outpower power range used in SSM. The consultants assume that the 20 mW output power which the applicants repeatedly stress as a threshold would also depend on the application, device and optics. In this case, the applicants do not relativise this value. The information that had been provided so far specified more than 10 mW output power used for surface measurements of inorganic

samples. It is not clear whether this is related to SSM. Also mentioned is the output power of 100 mW in the context with HeCd-lasers. The applicant was requested again to clarify the situation for SSM with Raman spectroscopy.

(JBCE et al. 2024d) reply that sometimes measurements are made at 1 mW or less, sometimes at 100 mW, depending on the damage caused by the laser to the sample. (JBCE et al. 2024e) complement this information adding that the Raman intensity is generally proportional to the power of the irradiated laser. Therefore, if the sample is not damaged by the irradiation of the laser at high power, sufficient Raman signal can be obtained in a short time. If sufficient Raman signal can be obtained in a short time, a large number of locations can be measured. This is useful for identifying where stresses are present on a semiconductor wafer.

The consultants asked the applicant why the damage levels of semiconductors inspected in SSM with the lasers is so different. *(JBCE et al. 2024e) replied that the semiconductor samples include not only silicon but also compound semiconductors.*

While the above explanation would have benefitted from some more detail, e.g. differences in damage thresholds of different materials inspected in SSM, the consultants did not follow up further since the applicant had been asked for a sound explanation twice already, and the information provided already suggests that SSM with Raman spectrometers is conducted at a range of output powers that may exceed 20 mW.

The consultants thereupon proposed the below wording:

Cadmium in helium-cadmium lasers of Raman spectrometers for stress measurement in semiconductors.

(JBCE et al. 2024c) disagree proposing the current wording and that they had included photoluminescence into their renewal request.

While the latter is correct, the applicants focused the discussion as to the elimination of cadmium in HeCd lasers to SSM with Raman spectroscopy, and they concede that there expertise does not cover other applications of HeCd lasers. There is thus no evidence that elimination or substitution of lead is scientifically and technically impracticable so that the above wording reflects the technological status that was elaborated during the review.

Elimination of cadmium by lasers with different wavelengths

According to (JBCE et al. 2023a), the advantage of using 325 nm wavelength instead of longer ones is the shallow penetration depth, e.g. around 3.9 nm in silicon compared to around 450 nm and more for 500 nm and longer waves (cf. Table 22-3 on page 467). This enables measurement of thin layers on semiconductors and stress measurement close to the surface of semiconductors. Table 22-3 shows that a 500 nm laser would already penetrate a silicon material 450 nm deep. It is thus clear that short wavelength lasers like the HeCd lasers cannot be replaced by longer wavelength lasers. Lasers of various wavelengths are used to measure stress levels in different layers or depths of semiconductors.

The applicants were requested to provide an independent source that describes the SSM with Raman spectroscopy. They referenced the publications of (Liu 2003) and (Nazari et al. 2018) who explain the advantages of Raman spectroscopy with UV-light in the context of

silicon semiconductors confirming the advantages of short wavelengths for semiconductor inspections.

(Nazari et al. 2018) write that "Lasers operating in the near UV, and having sufficiently narrow emission lines, are primarily argon (363.8, 351.1 nm), krypton (406.7, 350.7 nm), and helium-cadmium (325.0 nm). […] In the wavelength range above 350 nm, standard-grade optical materials are transparent. […] Generally, below 350 nm, specialized UV-grade materials are needed for the optical components of micro-Raman instrumentation."

The applicant list in Table 22-3 on page 467 only wavelengths of 250 nm, 320 nm and 500 nm. The above information shows that argon (Ar) and krypton (Kr) lasers fill the wavelength gap between 320 nm and 500 nm in Table 22-3 provided by (JBCE et al. 2023a). (Nazari et al. 2018) illustrate the penetration depths of the various wavelengths in silicon in the below table.

Table 22-5: Optical penetration depth in silicon at characteristic micro-Raman wavelengths

	Air		Diamond		Silicon		
Wavelength (nm)	**Airy *d* (nm)**	**Depth of focus (nm)**	***n*[61]**	**Depth of focus (nm)**	***n*[62]**	**Depth of focus (nm)**	**d_{opt} (nm)[62]**
514.5	1260	2510	2.4	1050	4.2	600	334
363.8	890	1780	2.5	710	6.4	280	5.3
325.0	790	1590	2.5	630	5.1	310	4.0

Source: (Nazari et al. 2018)

The applicants were asked the penetration depth of Ar- and Kr-lasers in the material which is used as reference for the penetration depths listed for different wavelengths in Table 22-3 on page 467.

(JBCE et al. 2024d) reply that both argon and krypton lasers have several oscillation wavelengths. The penetration length for silicon depends on the wavelength of lights. The applicants reference Table 22-3 on page 467.

The applicants' reply does not answer the question. *Upon further request, (JBCE et al. 2024e) indicate about 10 nm penetration depth at the wavelength of 350 nm and 100 nm at 400 nm wavelength.* These values do not quite coincide with the ones in the above Table 22-5 even though both reference materials are silicon. The applicants, however, also indicate slightly different penetrations for 320 nm lasers (3.91 nm in Table 22-3, and around 5 nm in the text of their renewal request) so that there seems to be a certain range of penetration depths even if silicon is inspected in both cases.

In any case, some wavelengths emitted by HeCd and Ar-/Kr-lasers are close to the 325 nm waves of HeCd lasers, i.e. 363.8 nm (Ar-lasers) and 350.7 nm (Kr-lasers), and the penetration depths are similar. The applicant was therefore asked whether the small

differences in penetration depths are significant, and if not, whether the use of cadmium in the HeCd lasers could be eliminated by applying Ar-/Kr-lasers in SSM.

(JBCE et al. 2024d) point out that common wavelengths for argon lasers are 488 nm and 514 nm. Stable semiconductor lasers are available at these wavelengths, which has reduced the demand for argon lasers. For this reason, the market of argon lasers, including lasers with oscillation wavelengths around 325 nm, have recently been limited. As a result, the stable lasers in the UV region are He-Cd lasers.

The applicants did not answer the question. Ar-lasers have several emission wavelengths according to (JBCE et al. 2024e) but (Nazari et al. 2018) explicitly mention the shorter emission wavelengths of these lasers to be applied in near UV Raman inspection of semiconductors.

Following up on this with the applicant, (JBCE et al. 2024e) state that Ar lasers at these wavelengths are difficult to procure as the manufacturers have withdrawn them from the market. As for Kr lasers, they do not know of many cases there are where semiconductor stresses have been measured by Raman.

In the report of (Baron et al. 2022) applicants stated in the context of the review exemption III-32 (lead in glass-frits of Ar- and Kr-lasers) that *"[…] these lasers are an integral component in nearly all OEM semiconductor manufacturing processes for the inspection of silicon wafers." "the demand for argon and krypton lasers has remained steady since 2019 […]. "[…] argon creates higher power for UV lasers with optics optimized for 364.1 nm transmission."" (Baron et al. 2022) conclude that "A discontinuation date for the use of such lasers is currently not planned, indicating that this market shall probably remain stable or shall further decline gradually."* There are at least two manufacturers of such lasers.[122]

These statements contradict the applicants' claim concerning the availability of such lasers and that Ar-lasers commonly emit at 488 nm and more. The consultants understand from the above reply of (JBCE et al. 2024e) that Ar-lasers can in principle be used to eliminate cadmium in HeCd-lasers. The applicant's do not explicitly state this, but the consultants are of the opinion that the applicant had ample opportunity to explain in detail why and where Ar-lasers – and possibly Kr-lasers – are technically inappropriate to replace HeCd-lasers in SSM.

It should be noted in this context that Ar- and Kr-lasers use lead in seal frits of window assemblies in line with exemption III-32. This exemption was reviewed and recommended for renewal by (Baron et al. 2022) until 21 July 2026 since substitution and elimination of lead – e.g. via DPSS lasers - were found to be scientifically and technically impracticable. *(JBCE et al. 2024e) confirm that HeCd-lasers use such glass frits as well, however, under the current exemption III-7(c)(I).*

The use of Ar-lasers instead of HeCd-lasers would thus not increase the amount of lead used in glass frits for sealing of laser tubes but the use of cadmium would be eliminated.

[122] Cf. https://www.coherent.com, https://www.lumentum.com/en

22.3.3. Environmental, health, safety and socio-economic impacts

JBCE exclude cadmium-emissions into the environment from their laser tubes due to a well-organized manufacturer takeback of the spent tubes (cf. section 22.2.2 on page 469).

The consultants acknowledge the degree of protection which this systems offers. It needs, however, to be noted that a well-established end-of-life stage per se would not justify granting an exemption in line with Art. 5(1)(a).

22.3.4. Summary and conclusions

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

1. 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**;
2. the **reliability of substitutes** is not ensured;
3. 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**.

(JBCE et al. 2023a) request the 7 years renewal of exemption IV-9 claiming that the substitution or elimination of cadmium in the HeCd lasers emitting the near-UV (ultraviolet) wavelength of 325 nm is scientifically and technically still impracticable.

The discussion whether and how far DPSS-lasers can eliminate the use of cadmium showed that the applying consortium was focused on the use of these lasers for semiconductor stress measurement (SSM) with Raman spectroscopy. They claim that DPSS-lasers are technically inappropriate for this task due to the still lacking quality of the light beam. The consultants' exchange with a manufacturer of such DPSS-lasers did not yield information to refute this claim.

During the review, the discussion evolved around the elimination of cadmium via argon (Ar) and krypton (Kr) lasers that emit wavelengths close to 325 nm and do not use restricted substances to generate the emitted electromagnetic waves. Upon repeated requests to provide a clear answer, the applicants stated that the market for Ar-lasers has become limited, and that they do not know Kr-lasers to be used in Raman spectroscopy. The consultants take from this explanation that at least the Ar-lasers can be used for SSM with Raman spectroscopy after the applicants had not expressed technical objections.

The consultants found that Ar- and Kr-lasers are available and, according to information provided by manufacturers of such systems in the report of (Baron et al. 2022), their market has more or less been stable since 2019.

Overall, the consultants conclude that the applicants neither substantiated their claim as to the impracticability of cadmium substitution or elimination in HeCd-lasers in general, nor in the specific application of SSM.

22.4. Recommendation

The applicants claim that elimination of cadmium in HeCd lasers is scientifically and technically still impracticable. While this seems to be correct for the use of these lasers in semiconductor stress measurement with Raman spectrometers, the applicants could not substantiate this claim for the elimination of cadmium by argon lasers.

In the consultants' view, the renewal of the exemption would infringe Art. 5(1)(a) in the absence of evidence that any of the criteria are met. It is therefore recommended not to renew the exemption.

If the COM decides to renew the exemption, the consultants recommend the below wording:

No.	Exemption	Scope and dates of applicability
IV-9	Cadmium in helium-cadmium lasers	Applies to categories 8 and 9. Expires on - 21 July 2021 for category 8 other than in-vitro diagnostic medical devices and for category 9 other than industrial monitoring and control instruments. - 21 July 2023 for category 8 in-vitro diagnostic medical devices. - **21 July [2024 + 12 or 18 months] for category 9 industrial monitoring and control instruments.**
IV-9(a)	Cadmium in helium-cadmium lasers of Raman spectrometers for stress measurement in semiconductors	Applies to category 9 industrial monitoring and control instruments from [expiry date of exemption IV-9 + 1 day] on. Expires on XXX

In the case of a next review of this or other laser exemptions (exemptions III-32 and IV-4), the consultants would like to encourage the participation of DPSS laser manufacturers either in the stakeholder consultation, or with own revocation requests if they deem their DPSS laser technology appropriate to eliminate the use of restricted substances in the lasers in the scope of the afore-mentioned lasers.

Applicants' feedback on the recommendation

(JBCE et al. 2024e) do not agree to the above recommendation argueing with insufficient time allowed for the answers to the consultants' questions.

The consultants are confident that there was sufficient opportunity for applicants to provide and substantiate arguments for the renewal of justifiable applications in the scope of the current exemption. All relevant arguments made available by applicants and stakeholders during the review time available for this exemption were evaluated taking into account the requirements of Art. 5(1)(a).

22.5. References

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JBCE et al. (2024c): Answers to questionnaire 4 sent via e-mail by Miura Tetsusaburo, JBCE, to Dr. Otmar Deubzer. RoHS Pack 27 (RoHS 29).

JBCE et al. (2024d): Answers to questionnaire 5 sent via e-mail by Miura Tetsusaburo, JBCE, to Dr. Otmar Deubzer. RoHS Pack 27 (RoHS 29).

JBCE et al. (2024e): Answers to questionnaire 6 sent via e-mail by Miura Tetsusaburo, JBCE, to Dr. Otmar Deubzer. RoHS Pack 27.

JBCE et al. (2024f): Feedback on the recommendation for exemption IV-9, sent via e-mail by Miura Tetsusaburo, JBCE, to Dr. Otmar Deubzer. RoHS Pack 27.

Liu (2003): Applications of UV-Raman Spectroscopy to Microelectronic Materials and Devices. In: *AIP Conf. Proc.* 683 (1), S. 738–743. DOI: 10.1063/1.1622552.

Nazari et al. (2018): Near-ultraviolet Raman and micro-Raman analysis of electronic materials. In: *Appl. Phys. Rev.* 5 (4), Artikel 041303. DOI: 10.1063/1.5054660.

23. Exemption10 of Annex IV: Pb and Cd in atomic absorption spectroscopy lamps

The below Table 23-1 shows the wording, scope and expiry dates of the exemption.

Table 23-1: Current wording of the exemption

No.	Exemption	Scope and dates of applicability
IV-10	Lead and cadmium in atomic absorption spectroscopy lamps	Applies to categories 8 and 9. Expires on - 21 July 2021 for category 8 other than in vitro diagnostic medical devices and for category 9 other than industrial monitoring and control instruments. - 21 July 2023 for category 8 in vitro diagnostic medical devices. - 21 July 2024 for category 9 industrial monitoring and control instruments

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

AAS	Atomic absorption spectroscopy
AFES	Atomic fluorescence emission spectroscopy
AJ	Analytik Jena
Cat.	Category, referring to the categories of EEE specified in Annex I of the current RoHS Directive 2011/65/EU
Cd	Cadmium
COM	European Commission
CS-AAS	Continuum light source AAS
CS-AAS	Continuous spectrum AAS
CVG-AAS	Chemical vapour generation AAS

CVG-AAS	Cold vapour generation AAS
EDL	Electrodeless discharge lamp
EEA	European Economic Area (EU 27 + Iceland, Liechtenstein and Norway)
EEE	Electrical and electronic equipment
EU	European Union
F-AAS	Flame AAS
GF-AAS	Graphite furnace AAS
HCL	Hollow cathode lamp
Hg	Mercury
HR-CS-AAS	High resolution continuum light source atomic absorption spectrometry
ICP-OES	Inductively coupled plasma optical emission spectroscopy
ICP-MS	Inductively coupled plasma mass spectroscopy
IMCI	Industrial monitoring and control instruments
LED	Light emitting diode
LS-AAS	Line source AAS, umbrella term for various types of AAS like CVG-AAS, F-AAS, etc. that differ in the way of the sample preparation
Pb	Lead
PE	Perkin Elmer
RF	Radio frequency
RoHS	Directive 2011/65/EU
RoHS 1	Directive 2002/95/EC
UV	Ultraviolet
X-free	Not containing restricted substance X in the applications in scope of the exemption to be reviewed, e.g. cadmium-free, or lead-free

23.1. Background and technical information

On 18 January 2023, Perkin Elmer, Agilent Technologies, JBCE, Analytik Jena, and Heraeus (PE et al. 2023a), requested the renewal of exemption IV-10 as displayed in Table

23-2 for EEE of category (cat.) 9 industrial monitoring and control instruments (IMCI). Underlined phrases indicate deviations from the current wording.

Table 23-2: Requested exemption renewal

No.	Requested exemption	Requested scope and dates of applicability
IV-10	*Lead, cadmium, and mercury in atomic absorption spectroscopy lamps*	*Applies to category 9 industrial monitoring and control instruments.* *Expires on 21 July 2031 (2024 +7 years).*

23.1.1. History of the exemption

(Goodman 2006) stated that the exemption appeared to be justified if cat. 9 was included into the scope of the RoHS Directive. The exemption would have had to include mercury as well, which had, however, already been exempted for use in "other lamps" by exemption III-4 of the Annex of (European Union 13.02.2003) (RoHS 1). When the recast directive 2011/65/EU (RoHS 2) was published with cat. 8 and 9 being included into the scope, the exemption was listed on Annex IV in its current wording and scope as exemption 10. Following the exemption request of (PE et al. 2023a), the exemption is due for review for the first time since its publication on Annex IV in 2011.

23.1.2. Summary of the requested exemption

(PE et al. 2023a) describe that Line Source Atomic Absorption Spectroscopy (LS-AAS) systems use lamps which contain lead, cadmium, or mercury. The substance is used as a reference material in the cathode of the Hollow Cathode Lamps (HCL) or in the bulb of the Electrodeless Discharge Lamp (EDL).

For detecting a substance, a reference material of the same substance is required, for example to detect cadmium, a reference cathode of cadmium is required in the HCL or a bulb containing cadmium in an EDL. The primary requirement of the lamp in a LS-AAS system is to generate a narrow emission line of the substance which is being measured. The narrow spectral line width optimises the conditions for absorbance by any atoms matching the reference substance, in the sample under test. The transmitted light detected enables the accurate calculation of absorbance and therefore the determination of the concentration of the substance in the sample.

There are no alternatives for using the substance under analysis as the reference material in HCL and EDL lamps. These are the only substances that produce the precise light spectra required in LS-AAS, for determining the concentration of the same substance in test samples. (PE et al. 2023a)

The exemption wording has been amended to cover mercury. To date AAS lamps containing mercury (HCL and EDL) have been covered under exemption III-4(a)(I) – Mercury in other low pressure non-phosphor coated discharge lamps, where the application requires the main range of the lamp-spectral output to be in the ultraviolet spectrum: up to

15 mg mercury may be used per lamp. Due to the wide application scope of the III-4(a)(I) exemption and the use of mercury in AAS for the same technical rationale as outlined in this application, it would be preferable to cover its use in AAS lamps under exemption IV-10. No technically viable alternatives to the use of these substances, in lamps in line source AAS systems, have been identified.

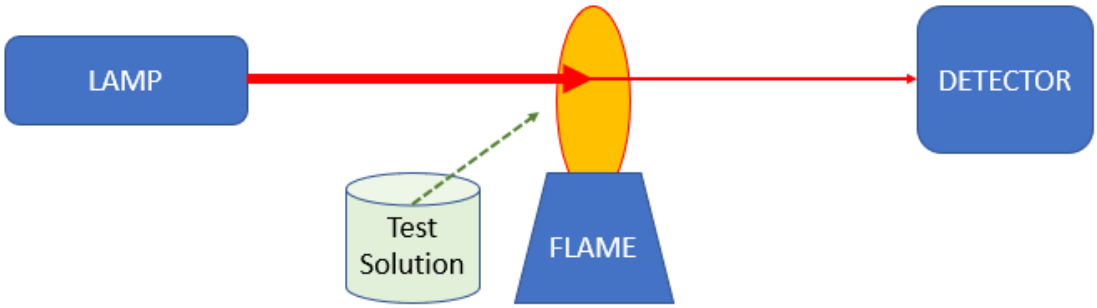
Analysis using LS-AAS has been an established methodology for over 50 years and is embedded in numerous European standards. The development of products to support alternative methodologies and to qualify them for the wide range of established line source AAS applications is anticipated to take more than seven years and have significant implications on end users. Based on data from the Analytical Life Science & Diagnostic Association (ALDA) an installed base of approximately 5,000 LS-AAS systems in Europe[123] is estimated."(PE et al. 2023a)

23.1.3. Technical description of the exemption and use of the restricted substance

(PE et al. 2023a) state that line source atomic absorption spectroscopy (AAS) has been established for over 50 years as an analysis technique used to determine the concentrations of metals. It is widely used to analyse alloys, ceramics, plastics, and other materials.

Figure 23-1 illustrates the principle of AAS. The test solution (sample) is vaporized in a flame (F-AAS) or graphite furnace (GF-AAS), light produced by a lamp passes through the vaporized sample which absorbs a portion of the emitted spectrum, and the part of the spectrum that passes through the sample is detected.

Figure 23-1: Outline of an AAS



Source: (PE et al. 2023a)

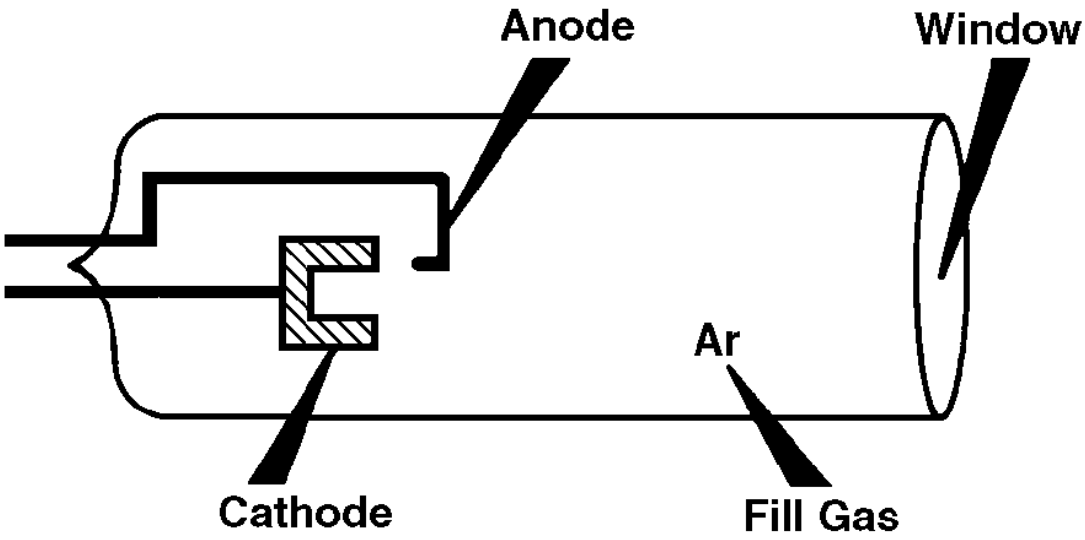
Comparing the intensity of the emitted spectrum with the intensity of the detected spectrum after passage through the sample allows concluding on the content of a specific substance, e.g. Cd, Hg or Pb, in the sample.

[123] ALDA data covers: Western Europe, the UK, Scandinavia, Eastern Europe (Belarus, Bulgaria, Czechia, Hungary, Moldova, Poland, Romania, Russia, Slovakia and Ukraine), the Balkans (Cyprus, Greece and Turkey and the Baltics)

Hollow Cathode and Electrodeless Discharge Lamps as light sources in AAS

(PE et al. 2023a) explain that Line source Atomic Absorption Spectroscopy (AAS) systems use lamps which contain lead, cadmium, or mercury, either hollow cathode lamps (HCLs) or electrodeless discharge lamps (EDLs). To detect lead, cadmium or mercury with HCLs, reference cathodes made of the same substances are used as reference materials in Hollow Cathode Lamps (HCL, see Figure 23-2 below) or in the bulb of the Electrodeless Discharge Lamp (EDL). For example cadmium is required to detect cadmium, a reference cathode of cadmium is required in the HCL, or a bulb containing cadmium in an EDL.

Figure 23-2: Outline of a HCL with cathode made of restricted substance



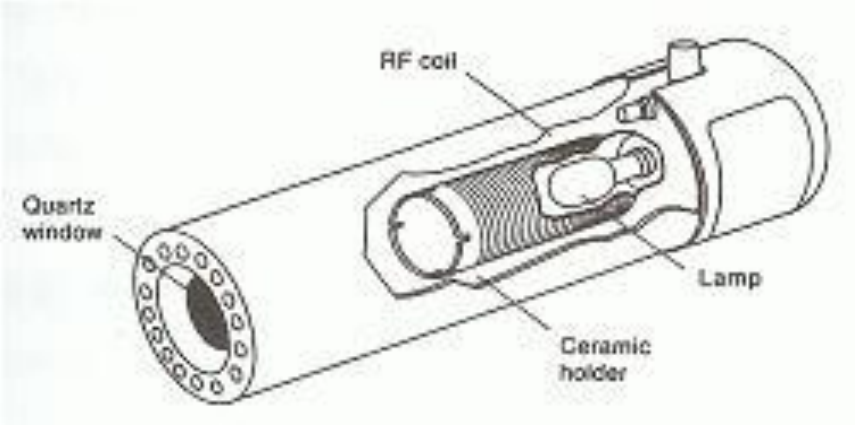
Source: (PE et al. 2023a)

(PE et al. 2023a) further elaborate:

When an electrical potential is applied between the anode and cathode, some of the fill gas atoms (typically argon or neon, filling the inside of the lamp) are ionized. The positively charged fill gas ions accelerate through the electrical field to collide with the negatively charged cathode and dislodge individual metal atoms in a process called "sputtering". Sputtered metal atoms are then excited to an emission state. The emitted light is at a wavelength characteristic of the sputtered metal. For example, if the cathode is made from lead the emitted spectra will be characteristic of lead. Light with a specific wavelength characteristic is required for the next step in the AAS process.

EDLs contain a small quantity of cadmium, lead or mercury in the bulb as illustrated in Figure 23-3.

Figure 23-3: Outline of an EDL with the restricted substance contained within the part labelled as "Lamp"



Source: (PE et al. 2023a)

Instead of electrical energy, an intense field of radio frequency (RF) radiation provides ionization and excitation of the metal to produce a spectrum to be used in Line Source AAS.

Line Source Atomic Absorption Spectroscopy:

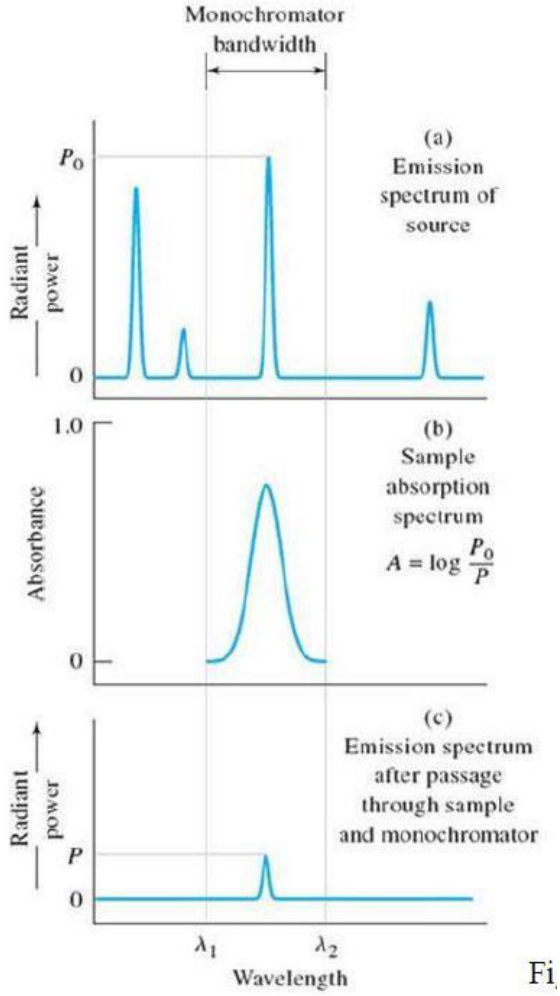
(PE et al. 2023a) explain that the HCLs and EDLs described above are used to produce the 'line source, i.e. a narrow emission line of the element, which is being measured in AAS, e.g. Cd, Hg or Pb. The primary wavelengths for the substances of concern are:

- *Lead 217.0 nm*
- *Cadmium 228.8 nm*
- *Mercury 253.7 nm*

As a result of the low pressure and temperature in the HCL, the linewidth of the substance specific emission is very narrow in the order of the linewidth of 10^{-3} to 10^{-4} nm. The wavelength and the spectral linewidth of the element specific emission matches exactly or is even narrower than the spectral absorption characteristic of the specific substance to be detected in a sample.

Therefore, the spectral sensitivity is high, and the signal-to-noise ratio is low, allowing the characterisation of samples when only containing very low levels of the substance (parts per quadrillion (ppq), for some applications). Figure 23-4 (top) shows the narrow bandwidth of the primary wavelength of light produced by the lamp. This is narrower that the absorption bandwidth (middle) of the sample under analysis and narrower than the bandwidth of the detector (monochromator).

Figure 23-4: Bandwidths of lamp emission spectrum and sample absorbance spectra



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Source: (PE et al. 2023a)

According to (PE et al. 2023a), only a small sample size is required (between µg and mg) depending on the sample introduction methodology. Pb-HCLs have their principal wavelength at 217.0 nm, Cd-HCLs at 228.8 nm and Hg-HCLs at 253.7 nm. Those wavelengths cannot be addressed by spectral lines of other elements in a discharge lamp as the emission wavelength is wholly dependent on the specific element. One strong line in the spectrum is chosen (one where any other metals present will not interfere) and this light passes through the flame where any vaporised atoms of the test metal will absorb light of the wavelength chosen. Figure 23-4 (bottom) shows the resulting spectrum after passage through the sample. There is a logarithmic relationship between absorbance and the ratio of incident intensity and transmitted intensity (transmittance) as given below.

Equation 23-1: Relationship between absorbance, and ratio of incident and transmitted intensity (transmittance)

$$A = \log_{10} \frac{I_0}{I}$$
$$A = -\log_{10} T$$

A Absorbance

I_0 *Incident intensity*

I *Transmitted intensity*

T *Transmittance*

Source: (PE et al. 2023a)

The light that has passed through the flame is measured using a monochromatic detector, an optical device that selects and transmits a specified wavelength set at the required wavelength. The detector produces an electrical signal that is proportional to the intensity of light. The intensity value is compared with the known intensity of that emitted from the lamp, from which the absorbance can be calculated. (PE et al. 2023a)

The Beer-Lambert Law (Beer's Law, c.f. Equation 23-2), defines the linear relationship between absorbance, concentration, the molar absorption coefficient, and the optical coefficient of a solution it is then possible to determine the concentration of the test substance (lead / cadmium / mercury) in the test solution:

Equation 23-2: Beer-Lambert Law

$$A = \varepsilon c l$$

A	Absorbance	
ε	Molar absorption coefficient	$M^{-1}cm^{-1}$
c	Molar concentration	M
l	optical path length	cm

Source: (PE et al. 2023a)

(PE et al. 2023a) mention a number of different types of line source AAS, including:

- F-AAS – Flame AAS, as described above.
- GF-AAS – Graphite Furnace AAS
- CVG-AAS – Chemical Vapour Generation AAS

They all use the line source lamps described above but different methods to introduce and atomise the sample.

End Use Applications

(PE et al. 2023a) highlight the importance of detection and monitoring of toxic elements such as lead, cadmium and mercury to prevent the exposure of humans and the environment to these toxic elements.

End use applications include:

- Environmental testing for contaminants or pollutants
- For example, the mining and metal processing industry can pollute the air in the form of dust, water in the form of 'washings' from ore processing, and the land in the form of waste heaps.

- Another example of a critical application would be the analysis of drinking water for harmful contaminants.[124]
- Pharmaceuticals (manufactured pharmaceuticals), for example in the quality control process to ensure a pharmaceutical product is free from heavy metals such as cadmium, mercury & lead.[125]
- Food (contaminants)
  Heavy metals like arsenic, cadmium, mercury, and lead can enter the food chain through water, air, and soil. Although usually present at trace levels, the toxicity of heavy metals, even at low levels, requires very sensitive analysis of metals in foods to ensure safe levels that meet regulatory requirements.[126]
- Industrial (raw materials, finished goods)
- Clinical testing, for research purposes rather than diagnostic purposes, for example for detecting lead levels in blood.[127]

Across the various application sectors, appropriate analytical methods are prescribed by standards. Numerous standards require the use of AAS, explicitly by means of Hollow Cathode Lamps (HCL). A non-exhaustive list of these standards is outlined in Table 23-3, all of which mandate the use of AAS.

[124] C.Radulescu.Determination of heavy metal levels in water and Therapeutic mud by atomic absorption spectrometry. Romanian Journal of Physics 59(9-10):1057–1066,October2014; source as referenced by the applicant

[125] Nessa F, Khan SA, Abu Shawish KY. Lead, Cadmium and Nickel Contents of Some Medicinal Agents. Indian J Pharm Sci. 2016 Jan-Feb;78(1):111-9. doi: 10.4103/0250-474X.180260. PMID: 27168689; PMCID: PMC4852560; and Nancy S. Lewen, Martha M. Schenkenberger,Atomic Spectroscopy, Pharmaceutical Applications, Pages 107-114, Encyclopedia of Spectroscopy and Spectrometry (Third Edition),ISBN 9780128032244; source as referenced by the applicant

[126] Flame Atomic Absorption Spectrophotometry Analysis of Heavy Metals in Some Food Additives Available in Baghdad Markets, Iraq. Indian Journal of Forensic Medicine and Toxicology, October 2020. Abdulwahid, Dawood, Mohammed, Jamur; source as referenced by the applicant

[127] Determination of lead in blood by graphite furnace atomic absorption spectrometry with Zeeman background correction: Improving a well-established method to support a lower blood lead reference value for children – ScienceDirect; source as referenced by the applicant

Table 23-3: Standards adopting AAS for detection of lead, cadmium and/or mercury

Standard		Title
DIN EN	237	Liquid petroleum products - Petrol - Determination of low **lead** concentrations by atomic absorption spectrometry
DIN EN ISO	5961	Water Quality; Determination of **cadmium** by atomic absorption spectrometry; (ISO 5961:1994)
EN	10181	Steels - Determination of **lead** content - Flame atomic absorption spectrometric method (FAAS)
DIN ISO	11047	Soil Quality - Determination of **cadmium**, chromium, cobalt, copper, **lead**, manganese, nickel, and zinc in aqua regia extracts of soil - Flame and electrothermal atomic absorption spectrometric methods (ISO 11047:1998)
EN ISO	12193	Animal and vegetable fats and oils - Determination of **lead** by direct graphite furnace atomic absorption spectroscopy
CEN EN	14082	Foodstuffs - Determination of **lead, cadmium,** zinc, copper, iron, and chromium by atomic absorption spectrometry (AAS) after dry ashing
CEN EN	14083	Foodstuffs - Determination of trace elements - Determination of **lead, cadmium**, chromium, and molybdenum by graphite furnace atomic absorption spectrometry (GFAAS) after pressure digestion
CEN EN	14084	Foodstuffs - Determination of trace elements - Determination of **lead, cadmium**, zinc, copper, and iron by atomic absorption spectrometry (AAS) after microwave digestion
CEN EN	15550	Animal feeding stuffs: Methods of sampling and analysis - Determination of **cadmium and lead** by graphite furnace atomic absorption spectrometry (GF-AAS) after pressure digestion
CEN EN	16277	Animal feeding stuffs - Determination of **mercury** by cold-vapour atomic absorption spectrometry (CVAAS) after microwave pressure digestion
CEN EN ISO	11212-2	Starch and Derived Products - Heavy Metals Content - Part 2: Determination of **Mercury** Content by Atomic Absorption Spectrometry
CEN EN ISO	11212-3	Starch and derived products - Heavy metals content - Part 3: Determination of **lead** content by atomic absorption spectrometry with electrothermal atomization
CEN EN ISO	11212-4	Starch and Derived Products - Heavy Metals Content - Part 4: Determination of **Cadmium** Content by Atomic Absorption Spectrometry with Electrothermal Atomization - Incorporating Corrigendum September 1997
CEN EN ISO	12846	Water quality - Determination of **mercury** - Method using atomic absorption spectrometry (AAS) with and without enrichment (ISO 12846:2012)

Standard		Title
CEN EN	13094-2	**Lead** and **cadmium** in metallic items in contact with the body - Part 2: Flame atom absorption spectrometry (F-AAS) after acidic extraction
CEN EN	13806	Foodstuffs - Determination of trace elements - Determination of **mercury** by cold-vapour atomic absorption spectrometry. (CVAAS) after pressure digestion
CEN EN ISO	14902	Ambient air quality – Standard method for the measurement of **Pb, Cd**, As and Ni in the PM10 fraction of suspended particulate matter
CEN EN	15411	Solid recovered fuels – Methods for the determination of the content of trace elements (As, Ba, Be, **Cd**, Co, Cr, Cu, Hg, Mo, Mn, Ni, **Pb**, Sb, Se, Tl, V and Zn)
CEN EN ISO	15774	Animal and vegetable fats and oils - Determination of **cadmium** content by direct graphite furnace atomic absorption spectrometry
DIN EN	15841	Ambient air quality – Standard method for determination of arsenic, **cadmium, lead** and nickel in atmospheric deposition
CEN EN	16175-1	Sludge, treated biowaste and soil - Determination of **mercury** - Part 1: Cold-vapour atomic absorption spectrometry (CV-AAS)
DIN	38406-6	German standard methods for the examination of water, waste water and sludge - Cations (group E) - Determination of **lead** by atomic absorption spectrometry (AAS) (E6)
DIN	54605	Testing of pulp, paper and board; atomic absorption spectrometric determination of the **cadmium** content
CENELEC EN	62321-4	Determination of certain substances in electrotechnical products - Part 4: **Mercury** in polymers, metals, and electronics by CV-AAS, CV-AFS, ICP-OES and ICP-MS - Incorporates Amendment A1: 2017
CENELEC EN	62321-5	Determination of certain substances in electrotechnical products - Part 5: **Cadmium, lead** and chromium in polymers and electronics and cadmium and lead in metals by AAS, AFS, ICP-OES and ICP-MS

Source: (PE et al. 2023a)

As a further area of regulation, (PE et al. 2023a) point out the European Pharmacopoeia (Ph.Eur. 10.0). The European Pharmacopoeia (Ph. Eur.) is a single reference work for the quality control of medicines. The official standards it contains provide a scientific basis for quality control during the entire life cycle of a product.

These standards are legally binding – as laid down in the Council of Europe Convention on the Elaboration of a European Pharmacopoeia and in EU and national pharmaceutical legislation. Ph. Eur. quality standards become mandatory on the same date in all States Parties to the convention.[7]

- *In chapter Ph. Eur. 2.2.23 AAS and hollow cathode lamps are listed as a permitted measurement technique. For the determination of lead in sugar the Pharmacopoeia is regulated using AAS (Ph. Eur. chapter 2.4). Another example for the application of AAS in pharmaceutical industries is the determination of extractable cadmium in materials used for the manufacture of containers (Pharm.Eur. chapter 3.1).*

23.1.4. Amount(s) of restricted substance(s) used under the exemption

(PE et al. 2023a) provide the below information as to the use of the restricted substances that would be used under the exemption if it was granted:

- *Lead: 99.140 kg*
- *Mercury: 0.010 kg*
- *Cadmium: 44.646 kg*

According to (PE et al. 2023b), the above quantities are an estimate of the total expected volumes of the restricted substances being placed on the market under the renewed exemption by all producers. The estimate is based on extrapolating sales and market share data made available by applicants.

23.2. Justification of the requested exemption

23.2.1. Substitution and Elimination of the restricted substance

(PE et al. 2023a) claim that there are no alternatives for using the substances under analysis as the reference material in HCLs and EDLs. These are the only substances that produce the precise light spectra (c.f. Figure 23-4 on page 484) required in line source AAS for determining the concentration of the same substance in test samples. (PE et al. 2023a) note that EDL utilises less of the restricted substance in comparison with HCL.

EDLs are an alternative light source for HCL. (PE et al. 2023a) note that EDLs utilise less of the restricted substance in comparison with HCL. In the case of lead, the EDL contains less than 1 mg of lead while an HCL contains 8-12 g of lead. So, although it would not eliminate the use of lead, cadmium, or mercury in line source AAS lamps, a change to solely EDL lamps would result in a reduction in the use of the restricted substances. In order for EDL lamps to be used in place of HCL lamps in line source AAS systems, modifications to the systems would be required, including but not limited to the addition of an EDL driver (High Frequency power source), mechanical, electrical, firmware & software interfaces.

According to (PE et al. 2023a), currently only one of the applicants has explored this option and has a commercial solution. The development time for the other applicants would be similar to the development of a new platform, i.e. around 10 years. This option would not eliminate the use of the substances but would result in a 99 % reduction of the quantities of restricted substances involved.

While there seems to be no substitute for cadmium, lead and mercury in line source AAS, (PE et al. 2023a) discuss alternative light sources, and inductively coupled plasma systems as potential alternatives that might facilitate the elimination of these restricted substances.

Alternative light sources - LEDs

(PE et al. 2023a) explain that solid state light sources, like ultraviolet (UV)-LEDs do not utilise any of the restricted substances and offer flexibility with peak wavelengths by adjusting the design and composition of the active region of the semiconductor. However, UV-LED devices with peak wavelengths of < 250 nm are currently not commercially

available so that they cannot replace lead and cadmium which emit at 217.0 nm and 228.8 nm respectively. Even though mercury at a wavelength of 253.7 nm is detectable, a UV-LED equipped system`s overall poor sensitivity does not render it a viable alternative to HCL or EDL equipped systems.

UV-LEDs are adjustable in wavelength but have a typical spectral linewidth of around 10 nm. As a result, > 99.9 % of the light falls outside the absorption line of Cd, Pb or Hg in the sample but still arrives at the detector. This increases the background signal by a factor > 1000 and reduces the signal to noise-ratio correspondingly. Even if the peak wavelength of UV-LEDs was the same, this is not a viable approach for detection of low levels of specific trace elements in AAS. The perfect match of emission and absorption characteristic of the spectral line can only be achieved by using the substance to be detected in the sample as the light emitting reference substance in the lamp.

Alternative light sources - Continuum light source

(PE et al. 2023a) discuss continuum light sources (CSs), e.g. Xenon lamps, as an alternative to HCLs and EDLs. A continuum light source emits radiation over a broad range of wavelengths. A continuum light source cannot be used in the existing platform for an HCL/EDL based AAS. This is because the monochromators in these systems would provide too large a spectral bandwidth resulting in poor sensitivity and specificity, non-linear calibration curves and greater susceptibility to spectral interferences. In addition, the intensity of most CSs decreases dramatically below 280 nm to levels that are not detectable by a line source monochromator. Consequently, the use of a CS for AAS requires re-design of the whole instrument.[128]

(PE et al. 2023a) mention, however, one known example of a commercially available AAS system using a continuum source (HR-CS AAS) launched in 2011 and manufactured by Analytik Jena (AJ). This system provides simultaneous multi-element analysis. Whilst it can perform the analysis carried out by traditional HCL- and EDL-based AAS systems, it is considered overly complex in terms of hardware and software for applications where single element analysis is required or where sequential multi-element analysis is not required.

(PE et al. 2023a) consider this to be reflected by the fact that Analytik Jena continue to market their traditional AAS systems. Having been launched in 2011 it is still relatively new to market compared with line source AAS systems which have been around for over 50 years. Consequently, the adoption of this technology and qualification of testing on different sample types/applications is still relatively low. There are no known standards prescribing the use of this technology. In some applications, line source AAS is still considered to be the optimal test method rather than CS-AAS. Steps that manufacturer's other than Analytik Jena would need to take in developing a new system platform based on a continuum source would result in a total time to market of around 10 years, and additional time would be required for the conversion/qualification of established test methods to the new platform.

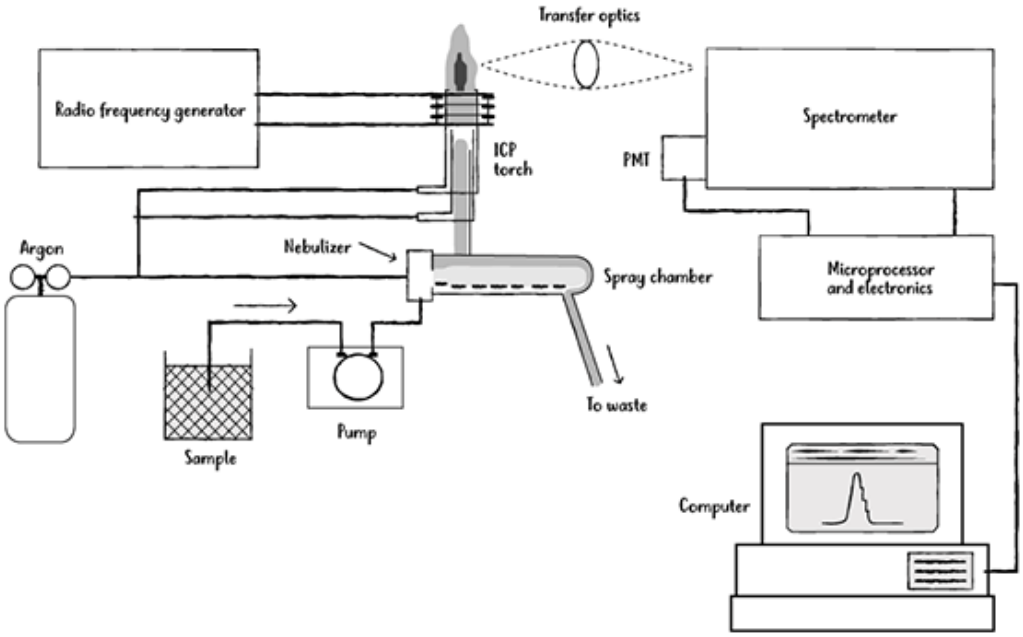
[128] Welz et al. 2003 Source referenced by TMC

Inductively Coupled Plasma (ICP) Systems

(PE et al. 2023a) comment Inductively Coupled Plasma–Optical Emission Spectroscopy (ICP-OES)[129] and Inductively Coupled Plasma Mass Spectrometry (ICP-MS) as alternatives to line source AAS.

(PE et al. 2023a) describe ICP-OES as being an optical emission spectrometry method, as opposed to absorption like in AAS. Figure 23-5 shows an outline of an ICP-OES.

Figure 23-5: Outline of an ICP-OES



Source: *(PE et al. 2023a)*

One of the methods of sample introduction into an ICP-OES system and the analysis method is that the sample to be analysed is dissolved in acid and water. Nitric acid is the most common acid used as most elements form water soluble nitrates. The water solution is then pumped into the instrument nebulizer, which turns the sample into a spray that is subsequently fed into the plasma. This plasma is most commonly composed of argon, although nitrogen gas and mixed gas compositions may also be used. The plasma is generated through the use of a high-power radio frequency signal or through microwave irradiation, which causes the gas to ionize to form electrons and other charged species within the plasma matrix. The plasma ionises the elements of interest in the sample. The ionised elements recombine with free electrons available in the plasma source, emitting specific spectral lines that are picked up by a detector. The detector converts the light signal emitted from the elements into an electrical signal producing a response that is proportional to the concentration of the element in the solution.

According to(PE et al. 2023a), the inductively coupled plasma mass spectrometry (ICP-MS), like ICP-OES, operates with a fine aerosol of a sample that is introduced into a hot (6,000 – 10,000 K) argon plasma of sufficient energy to dry the aerosol and form analyte

[129] *Also referred to as Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP-AES) or Microwave Plasma Atomic Emission Spectroscopy (MP-AES);* information as provided by TMC.

atoms, which are simultaneously ionized. The ions are then sorted and quantified based on their mass-to-charge (m/z) ratio in the mass spectrometer.

(PE et al. 2023a) point out some disadvantages of ICP-OES and ICP-MS compared to AAS.

Complexity of use

AAS is much simpler to operate than ICP-OES or ICP-MS enabling its use by a lower skilled operator. This is reflected in the training courses offered, the ICP-OES course being twice the duration of that for AAS. Method development using ICP techniques can be a time-consuming process, as it necessarily involves multiple steps:

4) Crude analysis to obtain a basic idea of the elements present in the sample;
5) Wavelength selection based on that initial knowledge;
6) Optimisation of separation so that signals from the various wavelengths have limited overlap;
7) Comparison with an internal standard to validate the method and system performance;
8) Analysis for spectral interferences and ways to eliminate those from the read-out without eliminating target signals.

Due to the above the upfront time investment is greater for ICP-OES/MS than AAS, in situations where a fast turnaround for results is required, this is a limiting factor for ICP-OES/MS. One example is the fast and immediate determination of oil in tankers before they are unloaded. Pb and Cd are elements determined with ET-AAS before the ship is unloaded. With ET-AAS, the procedure can be run night or day without the need for an analytical chemist.

Sensitivity and sample dilution

The ICP-OES technique is in most cases not sensitive enough (% to ppb) to reach the detection limits of GF-AAS (ppm to ppt), especially for lead. So, this quantification technique is no alternative to GF-AAS and ICP-MS (ppm to ppt) for many applications.

In applications where high salt concentrations are present GF-AAS is often technically favoured as it requires minimal, or no dilution of the sample compared with ICP-MS which requires dilution factors between 1:100 to 1:1000.

Isobaric Interferences

Isobaric interferences refer to different elements whose isotopes share a common mass, which causes an issue in analysis techniques reliant on mass spectrometry such as ICP-MS. Isobaric interferences occur in the quantification of cadmium by ICP-MS for molybdenum oxides, which leads to incorrect results if the molybdenum concentration is dominant. Tin is another element forming isobaric interferences regarding cadmium. As a result, low cadmium concentrations in molybdenum or tin content in components or chemicals, can yield poor results when using ICP-MS. Isobaric interferences do not arise with AAS techniques.

Complexity of instrument architecture

(PE et al. 2023a) point out that more infrastructure and consumables are required for an ICP-OES/MS system than for an AAS system. An AAS system typically requires the following consumable items and utilities: Compressed air source, ethylene, lamps, reagents, standards and power. An ICP system requires argon gas (typically 25-20 L/min),

quartz torches, reagents and standards, pump tubing, power and cooling water. ET-AAS & CVG-AAS, require argon, but at a consumption rate of 20 times less than ICP. This means, flame AAS can operate at remote sites (specifically for mining or chemical hygiene) where it would be nearly impossible to run an ICP-OES/MS. ICP-OES/MS requires costly instrumentation for plasma generation, sample aerosolising, and signal analysis. The complexity of the instrument architecture results in a larger equipment footprint (as indicated in the below table) and initial capital cost. (PE et al. 2023a) indicate that ICP-OES is typically twice the cost of AAS and ICP-MS in the region of five times the cost of AAS. The ICP systems also usually require an ultra-clean, thermostatically controlled environment.

There may be instances where this larger footprint prohibits the use of the larger systems in some laboratory spaces. It is also possible that a laboratory would want to retain the AAS for the detection of substances other than lead, mercury and cadmium.

Figure 23-6: Comparison of footprints of AAS and potential alternatives

System Type		Width /m	Depth /m	Footprint/m^2	Height /m	Weight /Kg
Line source AA	Single flame	0.67	0.63	0.42	0.64	57
	Flame & GF combined	0.95	0.68	0.65	0.73	133
Continuum source AA	Single flame	0.787	0.751	0.59	0.64	90
	Flame & GF combined	0.78	0.775	0.61	0.625	170
ICP	Middle end	0.65	0.76	0.49	0.81	99
	High end	0.76	0.84	0.64	0.87	163
ICP-MS	Middle end	0.81	0.69	0.56	0.75	150
	High end	1.15	0.85	0.98	0.75	205

Source: (PE et al. 2023a)

Adaptation of established methods

(PE et al. 2023a) reference Table 23-3 on page 487 which demonstrates that the use of AAS is embedded in a number of prescribed procedures. Many applications have methods which have been developed and validated for years. Although these methods could be adapted and converted into a method to enable the analysis using one of the other atomic spectroscopy techniques such as ICP-OES or ICP-MS, this is not an easy or quick undertaking. They illustrate this with an example from one of the applicants ("Applicant X").

This Applicant X has recently worked with ASTM and an international collaboration task group consisting of 12 independent laboratories around the world, to develop and validate two new test methods for determination of elements in biodiesel and biodiesel blends by Microwave Plasma Atomic Emission Spectrometry (MP-AES) and determination of metals and other elements in residual fuel and crude oil by Microwave Plasma Atomic Emission Spectrometry (MP-AES). The goal was to streamline this elemental analysis by allowing the use of a single technique. Measuring the same elements previously required using multiple ASTM methods and multiple techniques: Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES), Flame Atomic Absorption Spectrometry (Flame AAS), and X-ray spectrometry.

Initially, this required Applicant X to develop a method for determination of the target elements in biofuels, residual fuel and crude oil using a MP-AES method. This was completed and a draft standard test method was prepared in December 2014. It was then necessary to "recruit" 12 laboratories who were either routinely completing this analysis

already – or had the expertise to participate. Applicant X equipped these laboratories with the MP-AES instrumentation, the analytical standards and other consumables required to complete the analysis and provided on-site training for each of the laboratories. The goal was to generate data demonstrating the achieved performance, especially interlaboratory reproducibility, for the ASTM committee. As part of this collaboration, the laboratories involved in the study also compared the results for metals content in the biodiesel, residual fuel and crude oil samples using the techniques of Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES), Inductively Coupled Plasma Mass Spectrometry (ICP-MS), and Microwave Plasma Atomic Emission Spectroscopy (MP-AES).

The ASTM D8322-20 method for determination of metals and other elements in residual fuel and crude oil using the Microwave Plasma Atomic Emission Spectrometry (MP-AES) technique (ASTM D8322-20 Standard Test Method for Determination of Elements in Residual Fuels and Crude Oils (V, Ni, Ca, Na, Al, Si, Zn, P, and S for residual fuel oil and Fe, V, Ni, Ca, Na, K, and S for crude oils) by Microwave Plasma Atomic Emission Spectroscopy (MP-AES) was finally released in July 2020.

The ASTM D8351-22 method for determination of trace elements (calcium (Ca), magnesium (Mg), phosphorus (P), potassium (K), and sodium (Na) in Biodiesel and Biodiesel Blends using the Microwave Plasma Atomic Emission Spectrometry (MP-AES) technique (ASTM D8351-22 - Standard Test Method for Determination of Trace Elements in Biodiesel and Biodiesel Blends by Microwave Plasma Atomic Emission Spectrometry (MP-AES) was finally released in May 2022.

The scope of this method development is similar to what would be expected for any of the European (EU) methods using atomic absorption to either an ICP-OES or an ICP-MS method. As noted in the above example where new ASTM methods were developed, the elapsed time was 6 – 8 years for EACH method.

23.2.2. Environmental, health, safety and socioeconomic impacts

(PE et al. 2023a) inform that complete AAS system including lamps are collected and sent to treatment where the AAS lamps and reference cathode materials are recycled. They assume that the lamps recycled will approximately equate to lamps purchased so that the annual volumes of restricted substances in the waste arising from the AAS devices is the same as the masses of these materials that are used under the exemption on an annual basis, c.f. section 23.1.3 on page 481.

23.2.3. Roadmap towards substitution or elimination of the restricted substance

Reduction of restricted substances

Conversion of existing HCL source systems to EDL sources

(PE et al. 2023a) inform that changing from HCL to all EDL in line source AAS is an option. The EDL utilises less material than HCL, for example for lead the EDL contains less than 1mg of lead compared with HCL, which contains 8-12 g lead. So, although it would not

eliminate the use of lead, cadmium, or mercury in AAS lamps, a change to solely EDL lamps would result in a reduction in the use of these substances.

They further state that changing to ED lamps would require modifications to the existing AAS platforms for some of the applicants, which is platform design / manufacturer specific and is anticipated to be similar to new product development timescales in the region of 10 years. This excludes the program required to replace or retrofit installed units. This solution does not result in the elimination of the substances. They further estimate that the majority (> 95%) of the atomic absorption spectrometers that have already been installed and are in operation incorporate HCLs.

Substitution or elimination of restricted substances

Change to Continuum Source AAS

Eliminating the use of restricted substances by means of continuum light source (CS) based systems is currently possible for only one manufacturer with a commercial product available on the market. For the others to take this approach would require just under a 10-year new product development cycle for the technology.

The applicants provide as an example the steps and timeframes involved for the product development cycles for EDL- or CS-based AAS systems (PE et al. 2023a)*.*

Pre-concept stage: requirements specification and technical feasibility ~12 months.

Concept stage: develop concept ideas and some proof of concepts to verify if they are achievable ~18 months.

Planning Stage: generate the baseline of schedule, cost, and quality, and define SRS (system requirements specs) ~12 months.

Development phase: generate detailed designs & drawings, build prototypes, and run prototype verification (typically two prototype runs are required) ~48 months.

Validation & commercialisation stage: prepare materials and build pilot run instruments in the manufacturing plant, run instrument validation tests, to make sure instruments accord with URS12. This stage is also used to verify the design is ready for mass production and train service engineer ~24 months.

In total this is 114 months or around 10 years.

Change to ICP based System

All the applicants that manufacture line source AAS systems, also market ICP solutions. Whilst this technology could perform the function of line source AAS, a blanket change to this technology would require an extensive feasibility study involving end users and standardisation bodies. Developing and qualifying new methodology for standardisation would take up to a total duration of 10 years. This excludes the manufacture (typically 4-8 weeks), transit to (variable) and installation (typically 1-2 days) of ICP systems at end user facilities.

23.2.4. Stakeholder contributions

The consultants reached out to different stakeholders[130] producing similar analytical instruments to inquire their perspective on the technological feasibilities of reducing or substituting/replacing components or entire instrument systems including restricted substances. Despite cooperatively providing information they could not provide substantial evidence against restricting exemption IV-10 for cadmium, mercury and lead to EDL lamps.

23.3. Critical review

23.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several restrictions of cadmium and its compounds are listed on Annex XVII (cf. section 4.1 on page 48). None of those, however, is applicable to the use of cadmium and cadmium compounds in the scope of exemption IV-10.

Further on, uses of lead and lead compounds are listed on Annex XIV. Additionally, Annex XVII contains several restrictions for lead and its compounds. None of those entries are, however, relevant for the use of lead in the scope of exemption IV-10 (cf. section 4.2 on page 51 for details).

Finally, Annex XVII contains several restrictions for the use of mercury and its compounds. None of those entries are relevant for the use of mercury and mercury compounds in the scope of exemption IV-1(c) (cf. section 4.3 on page 54 for details).

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

23.3.2. Substitution and elimination of the restricted substance

The applicants' information indicates two principal options to avoid or at least to considerably reduce the use of restricted substances. The CS-AAS manufactured by one member of the applicants' consortium may replace LS-AAS at least in some of its uses thus eliminating the use of cadmium, lead and mercury in AAS. EDL as an alternative light source

[130] Thermo Fisher Scientific GmbH and Lumex Analytics GmbH

for HCLs require around 1 % of the volumes of the restricted substances used in HCLs. The review will therefore focus on the potentials to eliminate or at least reduce the use of the restricted substances in AAS.

Alternative light sources for elimination of Cd, Hg and Pb

Solid state light sources

(PE et al. 2023a) state that UV-LEDs are no alternative light source for LS-AAS with lead, cadmium and mercury because they are not available for peak wavelengths below 250 nm.

The primary wave length of mercury is above 250 nm and thus within the spectral range of UV-LEDs. *However, (PE et al. 2023c) add that "Although UV-LEDs are available at wavelengths above 250 nm, their spectral line width of several 10 nm makes them not suitable for line source AAS, as the sensitivity is far too low, even for very high Hg concentrations." In comparison LS-AAS have a linewidth of 10^{-3} to 10^{-4} nm (PE et al. 2023a).*

With the evidence provided above and in section 23.2.1, the consultants conclude that due to the lack of sensitivity for mercury and due to the lack of peak wavelengths below 250 nm, UV-LEDs are no alternative to HCL/EDL for the elimination of mercury, lead and cadmium in AAS.

Continuum light sources

Continuum light sources (CS), such as Xenon lamps, emit radiation over a broad range of wavelengths and reach wavelengths below 200 nm without the need of restricted substances. However, these light sources are not considered an alternative to existing lamps [as a direct replacement] *because they cannot be retro fit on LS-AAS instruments currently on the market due to drastically more complex monochromators (PE et al. 2023a).*

(PE et al. 2024a) further explain that the spectral resolution required for continuum source AAS is about 100 times higher than for a line source AAS. This is an extremely high optical resolution which can only be achieved by gratings[131] with an extremely high number of grooves per mm combined with a large focal length of about 1 m, or with a resolution in two dimensions using 2 gratings or a grating/ prism combination. Both designs are more complex, significantly more expensive and require much stricter control of the environmental conditions of the instruments compared with the monochromator of line source AAS. In addition, the intensity of most CSs decreases dramatically below 280 nm to levels that are not detectable by a line source monochromator.

A lamp substitution of LS-AAS systems with CS lamps would thus require a complete re-design of the system. While, overall, the above explanations also seem to exclude CS as a RoHS-compliant alternative for HCL.

[131] Diffraction gratings are optical components critical for a wide variety of applications including spectrometers, other analytical instruments, telecommunications, and laser systems. Gratings contain a microscopic and periodic groove structure - which splits incident light into multiple beam paths through diffraction, causing light of different wavelengths to propagate in different directions. https://www.edmundoptics.com/knowledge-center/application-notes/optics/all-about-diffraction-gratings/

(PE et al. 2023a) mention that one such re-designed system has been brought to market by a member of the consortium Jena Analytik in the form of a high-resolution continuum source AAS (HR-CS AAS) in 2011. According to (Welz et al. 2003) other HR-CS AAS had been brought to market by the same company years earlier and when questioned (PE et al. 2024a) elaborated on the timeline of instruments brought to market by Jena Analytik:

- *2005: "contrAA 300", the first commercially available HR-CS AAS, flame-only*
- *2007: "contrAA 600", the first HR-CS AAS for graphite furnaces*
- *2011: "contrAA 700", the first HR-CS AAS that supports F-AAS and GF-AAS*

These systems offered by Jena Analytik can perform analyses carried out by traditional HCL- and EDL-based AAS systems.

This raises the question how the limitations of CSs described above could be overcome to enable their use in a system that can replace conventional AAS at least partially.

Jena Analytik have addressed the intensity loss below 280 nm by using a special design xenon arc lamp that has been optimized to run in the so called "hot-spot" mode, characterized by an extremely small plasma spot close to the cathode surface. This is achieved using selected materials for the anode and cathode rods, maintaining a short electrode distance, using a higher xenon pressure inside the lamp and a specific temperature regime. In addition to the lamp power supply of 300 W nominal (typically 20 V and 15 A), an additional circuit is used to apply a short high-voltage pulse of about 30 kV to enable ignition (PE et al. 2024a).

Finally, the requirements of HR-CS-AAS on the spectrometer are extremely sophisticated. The resolving power required is at least two orders of magnitude higher than in conventional LS-AAS spectrometers, to ensure comparable sensitivity for each element and freedom from spectral interferences due to wavelength overlaps. This requires a more expensive, specially designed echelle spectrometer with either internal or external order separation (PE et al. 2023c).

Increasing successful academic method development for specific use cases demonstrates the applicability and competitiveness of these CS-based AAS systems in many use cases compared to traditional HCL/EDL-based AAS systems under controlled laboratory experimental conditions (Welz 2005) (Ferreira et al. 2018) (Resano et al. 2013). From these controlled laboratory-based efforts it is apparent that methodological development and standardisation is still an ongoing process with currently no successful transfer or adoption into industry-relevant HR-CS-AAS technical standards or norms, which can be regarded as a presently low industrial market adoption of the system.

HR-CS-AAS can, depending in use case, produce competitive results in single element analysis compared to LS-AAS, however, it was developed as a multi element, simultaneous or sequential analysis system. These inherent instrumental features result in drastically more complex technological implementations as described above but also require higher operational skill levels and control over the environmental conditions.

When questioned about the operational complexity (PE et al. 2024a) responded that *the presence of bands* [results of matrix interference stemming from sample preparation] *requires careful application of background correction. The continuous background can be corrected by the computer-aided signal processing of the instrument itself, which records successive reference intensity spectra without any analyte absorption using a mechanical shutter to block the radiation from the xenon lamp. The correction of the fine-structured*

background from the molecular absorption bands requires a reference spectra to be created for the interfering species (without the analyte absorption). A least squares fitting algorithm can then be applied through the instrument software to correct for this contribution. This requires a higher level of training and experience to operate the system.

They further elaborate on the environmental conditions that *the higher the optical resolution of the monochromator, the more delicate is the system with respect to stable temperature and atmospheric conditions. In the case of HR-CS AAS, for example the photon intensity of the continuum lamp on the first collecting mirror is extremely high and much higher than in LS-AAS. Fogging of this mirror by dust will result in a fast degradation of signal to noise, specifically in the short wavelength range below 250 nm. This refers to a more controlled environment than that required for LS-AAS (PE et al. 2024a). LS-AAS is able to operate in a wider range of environments, including production areas, non-air-conditioned environments and non-clean room conditions (BBT 2023a).*

(PE et al. 2023c) exemplify critical non-clean room industrial work environments by referring to *the principle of LS-AAS also being used in specialized measuring devices for various gas measurements, e.g. flue gas analysis for cement plants, combustion power-plants, waste incineration plants, etc. These devices are not known as AAS because they specialize in testing only one or a few selected elements (especially mercury) and are sometimes only subsystems of more complex measuring systems that measure many other parameters. They will, however, employ the same HCL/EDL lamp technology.*

Based on the above the consultants conclude that despite being competitive in many aspects, LS-AAS and HR-CS-AAS are not a direct instrumental replacement for one another. End users must critically assess their use cases in terms of target analyte, sample matrices, operational environment and choose a system most adequate to their individual analytical circumstance. It is impossible to address every individual use case in the scope of this critical review. Furthermore, when the capability to work in non-air-conditioned environments is part of the definition of the technical requirements of the system/technology, then HR-CS-AAS does not offer a technological solution for a substitution of HCL/EDL based AAS.

Inductive coupled plasma systems

ICP-OES and ICP-MS are elemental analysis methods based on emission and mass spectrometry, in contrast to AAS as which is based on absorption spectroscopy. (PE et al. 2023a) *regard ICP systems as alternatives to LS-AAS and elaborate in great detail on the sample introduction, analysis methods and operating principles, summarized in section 23.2.1above.*

Depending on the use case ICP methods can replace HCL/EDL-based AAS. Indeed *ICP-OES is gaining popularity and more and more users are switching over, particularly coming from F-AAS (SPECTRO 2017).* Some advantages of ICP methods are higher throughput of samples and multi-element analysis, with reduced sensitivity to matrix interference (ICP-OES) and very low limits of detection (ICP-MS), to name but a few examples (Agilent 2024).

When asked for a direct comparison of the analytical capabilities of AAS and ICP systems (PE et al. 2023c) responded that *Flame AAS (F-AAS) has detection limits for Cd, Pb, and Hg in the µg/L (Pb, Cd) to mg/L (Hg) range and is comparable or worse in terms of detection limits than conventional ICP-OES. GF-AAS has a better detection limit for Cd and Pb compared to the ICP-OES technique. For lead, the difference between GF-AAS and ICP-OES in standard operation is around a factor of 10 or more, for cadmium around 2 or more.*

The detection strength for GF-AAS can be further increased by using multiple injections of the sample. This option is not available for F-AAS and ICP techniques. Hg has detection limits in the medium µg/L range in the GF technique and shows therefore a lower performance regarding the limit of detection than the ICP-OES technique. CV-AAS/AFES (CVG or cold vapor) offers detection limits for Hg in the ng/L to sub ng/L range. CV-AFS (cold vapor atomic fluorescence spectrometry) is one of the most powerful detection techniques for Hg (CV-AES offers better detection limits than ICP-MS).

The ICP-MS technique offers detection limits in the low ng/L range for the elements Cd, Pb as well as Hg and is more powerful than GF-AAS. This ICP technique, like the ICP-OES instruments, has a high resource consumption [and sample volume!] compared to the AAS technique. The high quantities of argon required, which is obtained through the energy-intensive air liquefaction process, as well as high power consumption required for plasma generation and cooling (ICP techniques in the several kilowatt range, AAS technique in the approx. 1000 watt range).

In section 23.2.1 (PE et al. 2023a) detail some *disadvantages of ICP systems and refer to the complexity of use with the need to specially trained analytical chemists, high upfront economical costs (up to five times the cost of AAS) and time investment in method development. The complexity of the instrument architecture demands ultra-clean thermostatically controlled environments, rendering these methods impracticable for situations where a clean work environment cannot be guaranteed, e.g. cement industry or mining sites*.

The consultants take from the above explications that the choice of the optimum instrumental setup in elemental analysis by end users highly depends on the specific task. Similar to the discussion about continuum light sources above, there are particular use cases where AAS systems are considered irreplaceable. In cases when a clean work environment cannot be guaranteed, when analytes are contained in complex matrices with high total dissolved solids and when a low sample volume (microlitre range) where further dilution would result in analyte falling below the limit of detection GF-AAS is currently indispensable (TMC; PE et al. 2023; Agilent 2024). The consultants therefore do not see the potential to replace LS-AAS systems as a whole with the aforementioned ICP technology.

Reduction of the amounts of restricted substances by EDL light sources

Technological considerations

(PE et al. 2023a) estimate that EDL-based AAS systems would not eliminate the use of restricted substances but would result in a 99 % reduction of the quantities compared to HCL-based AAS systems, with lead content of Pb-HCL of 8 – 12 g and Pb-EDL of less than 1 mg. They further mention EDL to have about half the lifetime compared to HCL. *When asked about the average lifetimes of HCL (PE et al. 2023c) responded the following:*

- *HCL-Lead can be operated at 8mA for about 3.000 - 10.000 mAh*, which equates to around 375 – 1.250 h of operation.
- *HCL-Cadmium can be operated at 6mA for around 3.000 - 10.000 mAh*, which equates to around 500 - 1.666 h of operation.
- *HCL-Mercury can be operated at 5mA for around 3.000 - 10.000 mAh*, which equates to around 600 - 2.000 h of operation.

When considering half the lifetime of EDL compared to HCL lamps, and the estimated masses of Pb-HCL and Pb-EDL provided, the reduction of lead would amount to up to 99.98 % of that of HCL lamps. Upon further inquiry they could, however, not provide further non-confidential information about the exact contents of mercury and cadmium in EDLs (PE et al. 2023c).

The applicants bring forward several technological disadvantages and challenges of EDL-based AAS. (PE et al. 2023a) state that *with EDL-based AAS systems there will be high heat generation during operation.* Due to the atomization chambers in flame chambers or graphite furnaces, significant heat generation is an intrinsic characteristic of AAS. So, the consultants consider high heat generated by EDLs to be an insignificant additional inconvenience to the end user. The instrument's capability to handle these temperatures has already been proven by manufacturers with machines already on the market.

Figure 23-7: AAS for operation with HCL and EDL lamps

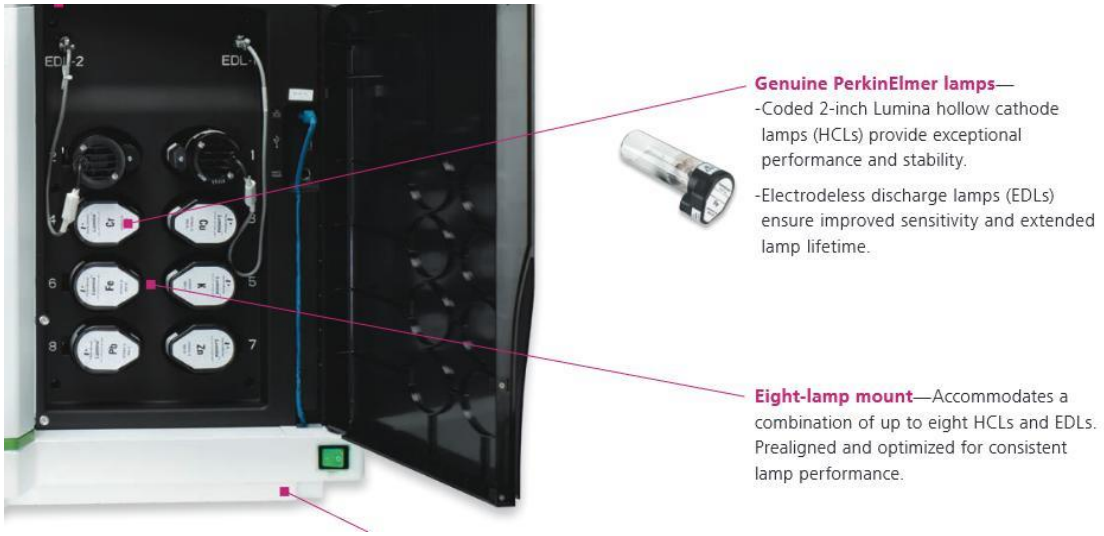


Figure 23-7 is showing a commercially available spectrometer by PerkinElmer,Inc. showing that both HCL and EDL can be accommodated within the same instrument.

(PE et al. 2023a) bring forward that *95% of AAS on market are HCL-based* and explain that *in order for EDL lamps to be used in place of HCL lamps in line source AAS systems, modification to the systems would be required, including but not limited to the addition of an EDL driver (High Frequency power source), mechanical, electrical, firmware & software interfaces.* (PE et al. 2023b) point out the *necessity for existing HCL-AAS owners to otherwise upgrade or modify their instruments and the difficulty to maintain CE compliance when retrofitting instruments with EDL power supplies.* The consultants do not regard the above arguments as evidence to substantiate the necessity to include HCL in exemption IV-10. The estimated 95 % market share of HCL in LS-AAS systems refers to all HCL out of which the majority does not include restricted substances and which would remain unaffected should the extension request for exemption IV-10 not be granted. In the consultants' understanding, Art. 4(4) would ensure that HCLs including restricted substances could still be supplied to the market as spare parts for AAS systems that were placed on the market before the expiry of the current exemption, and therefore no upgrade or modification to systems currently on the market would be required.

Should the COM decide not to extend, or to restrict the exemption to EDL-based AAS, AAS systems including HCLs not containing restricted substances could still be provided to the market after the expiry. Since HCL are spare parts of LS-AAS systems, exchanging these lamps is relatively simple and HCL not including restricted substances can easily be swapped out for HCL including restricted substances. In order to avoid circumvention of a restriction, HCL provided as spare parts would need to be made available to AAS systems placed on the market prior to expiry of the exemption only, which may require additional administrative control mechanisms (e.g. documentation with date of purchase of the LS-AAS system).

(PE et al. 2024a) further add that EDL lamps are available on the market for fewer elements compared to HCL lamps because *EDL have not been developed for elements where an improvement in lifetime or analytical quality could not be realized. S*ince EDL for Cd, Pd, and Hg are available and AAS systems that can make use of both lamp types are also available, the consultants conclude that where EDLs are not available for certain elements users can keep using HCLs without restricted substances.

Development of EDL-based AAS systems

(PE et al. 2023a) state *that currently only one of the applicants has explored this option* [EDL-based AAS systems, *Figure 23-7*] *and has a commercial solution. The development time for the other applicants would be similar to the development of a new platform as detailed in section 1.2.3 (around 10 years).*

When questioned about the first commercial availability of EDL (PE et al. 2023b) stated that *the first use or description of EDLs specially designed for AAS is from 1973*. The consultants further inquired why only one manufacturer made efforts to reduce amounts of restricted substances (by means of EDL systems) since cat. 9 IMCI have been integrated into the scope of the RoHS Directive since 2011. According to *(PE et al. 2023c) the manufacturer in question held the patent for this technology. This patent has now expired so it is possible for other manufacturers to exploit the technology.* The consultants inquired the exact expiration date and (PE et al. 2024a) responded that the patent had expired in *2002*. Since the patent had expired prior to 2011 the consultants do not consider the above argument as evidence to substantiate an inability of the exploitation of EDL technologies since 2011. In fact, at least one other company which is not part of the applicant consortium has made these development efforts and is offering an AAS system that can be equipped with EDL and HCL within the same instrument (Lumex Instruments Ltd.). Even though this company does currently not offer EDL for Cd, Pb and Hg, this underlines the feasibility of HCL/EDL-AAS hybrid systems beyond targeting solely restricted elements.

Nonetheless, (PE et al. 2023c) further add their main concern that, since EDL lamps still use RoHS restricted substances, dedicating the resources and costs for the qualification of such equipment would be misplaced and could be considered a regrettable substitution as it would detract from the investigation into solutions which are free from RoHS restricted substances.

Depending on the use case LS-AAS certainly has its analytical advantages, however, it is apparent to the consultants that multi-element analysis is increasingly gaining market share in the field of elemental analysis. (PE et al. 2023a) stated that *all applicants that manufacture AAS systems also market ICP solutions*. Furthermore (PE et al. 2023b) provided a list of 12 manufacturers of AAS systems out of which 8 also offer ICP systems. This is further supported by *(SPECTRO 2017) who state that ICP-OES is gaining popularity and more and more users are switching over, particularly coming from F-AAS. Measuring*

heavy metals simultaneously provides a drastic reduction in analysis time, therefore instruments able to perform simultaneous multielement analysis, namely ICP-OES and ICP-MS, are becoming more and more popular. New development in this field, such as ICP-OES/MS with reduced argon consumption, contributes to decreasing instrument running costs (Pasinszki et al. 2023). Additionally, new technologies such as HR-CS-AAS are also taking up market share.

Considering the above information, the consultants agree that EDL technologies could become very much a niche application in the future and that further development of these technologies might be considered a regrettable substitution since more and more market share is drawn from LS-AAS systems. However, i*t is worth to note that if the number of target analytes is limited, AAS is expected to continue wide scale application in this field as it is highly sensitive and instrumental costs are lower than those of ICP-OES and ICP-MS (Pasinszki et al. 2023).*

EDL-based AAS system availability and standardization

The availability of commercial EDL-based solutions shows that the reduction of the restricted substances in LS-AAS lamps is not only scientifically and technically practicable but that it could have been achieved in the available time until the expiry of exemption IV-10. The consultants asked why exemption IV-10 should still be extended beyond 2024 without a restriction to the use of Cd, Hg and Pb in EDL lamps only.

(PE et al. 2023b) refer to the market share of the commercially available EDL-AAS instrument provider and that *currently, there is only one applicant that offers instrumentation that can support or be used with the EDL lamps. While this is a major supplier, they do not have a dominant share in the market.* The consultants understand that the restriction of HCL may include the risk of potential instrument supply shortages during a market transition from HCL to EDL when the market abruptly has to be shouldered by a single provider. However, it should be emphasized that the replacement of HCL with EDL would only be necessary for lamps including Hg, Cd and Pb in AAS systems new to the market. AAS systems including HCL with other not restricted elements will remain unaffected. Additionally, next to the instrument provider in the consortium, there is at least one more manufacturer (Lumex Instruments) of such HCL/EDL-AAS hybrid system on the market, which would only have to further develop EDL including restricted substances.

Given the 10 year development time of EDL-AAS put forward by (PE et al. 2023a),(section 23.2.3), the consultants believe that there was enough time since 2011, when 9 IMCI were integrated into scope of the RoHS Directive, for all manufacturers in the AAS market sector to develop new technologies reducing the use of restricted substances via the use of LS-AAS systems using EDLs. This is further underlined by the fact that PerkinElmer, Inc., a member of the consortium and Lumex Instruments, Ltd., already have such HCL/EDL-AAS hybrid systems on the market,

demonstrate that the use of AAS is embedded in a number of standards, many of which have been developed and validated for years. They illustrate the complexity of such standard method developments with an example highlighting the total duration of 6-8 years. The consultants inquired about the lamp types used for the referenced AAS methods and (PE et al. 2024a) specified with selected examples in Figure 23-8 below.

Figure 23-8: Selected standards using AAS and the respective light source

Standard	Light source	Note
DIN EN ISO 5961	Standard specify the light source as "Light source for cadmium determination"	See chapter 2.4.1
EN 10181	PB HCL	Lead is determined by spectrometric measurement of the atomic absorption of the light emitted by a lead hollow cathode lamp at a wavelength of 283.3 nm.
DIN ISO 11047	HCL or EDL	See chapter 3.4.2
DIN EN ISO 12193	HCL or EDL	See chapter 4.5
ISO 11047	HCL or EDL	See chapter 3.4.2
EN ISO 11212-3	HCL or EDL	See chapter 5.2.5
EN ISO 11212-4	HCL or EDL	See chapter 5.2.5
EN ISO 12193	HCL or EDL	See chapter 4.5
EN ISO 14902	HCL or EDL	See chapter 7.2.6
DIN EN 15841	HCL or EDL	See chapter 5.3.4
EN 11084	HCL or EDL	See chapter 5.5

Source: (PE et al. 2024a)

The provided information about the standards using AAS and their respective lamp types shows that the vast majority of presented standards already include the use of AAS with EDL technology. In only one instance a standard specifically refers to the use of HCL and another one generically refers to "light source for cadmium determination", which would include EDL. Therefore, the consultants conclude that if the scope of the exemption IV-10 were to be restricted to EDL, the vast majority of methodological standards would remain unaffected. Where HCL are specifically addressed a re-issuance of the standard including EDL should not be compared to the lengthy development of a completely new method, and therefore the expected time frames to standard adaptation should be much shorter.

23.3.3. Environmental, health, safety and socioeconomic impacts

(PE et al. 2023a) *estimate that the amount of restricted substances entering the market is about the same as is being recycled under the current exemption.* Restricting the exemption IV-10 to EDL lamps would not result in significant reductions of restricted substances at first due to the availability of HCL as spare parts for HCL-based AAS systems brought to market prior to the renewal of the exemption. Significant reduction of restricted substances are expected once the market has adapted to AAS with incorporated EDL technology for restricted substances.

It is to be noted that the recycling of restricted substances per se cannot justify granting an exemption in line with the stipulations of Art. 5(1)(a). The third clause of Art 5(1)(a) (cf. section 23.3.4 on page 505) is not applicable either. EDL can be expected to be recycled like HCL. Since EDLs contain less than 1 % of the restricted substances compared to HCL, the *total negative environmental, health and consumer safety impacts caused by substitution can be assumed not to be likely to outweigh the total environmental, health and consumer safety benefits thereof.*

(PE et al. 2023a) *foresee the premature disposal of a large number of systems already on the market as they could no longer source AAS lamps for these* [restricted] *substances. In the absence of lead, cadmium and mercury line source lamps, line source AAS systems will become obsolete in the EU for the analysis of these substances. The typical life of a line source AAS is in excess of 10 years, so where the system is being used solely for the*

detection of one or more of these substances (lead, mercury, or cadmium) the whole system would become obsolete before end of life.

The consultants disagree. In the consultants' understanding, to Art. 4(4) would ensure that HCL lamps could still be supplied to the market as spare parts for AAS systems that were placed on the market before the expiry of the current exemption in case the COM decides to restrict the exemption to ED lamps only. Such AAS systems operating with HCL could be used until the end of their life. *(PE et al. 2023c) confirm that they consider HCL as spare parts.*

23.3.4. Summary and 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.*

(PE et al. 2023a) request a 7 year renewal of exemption IV-10 for cat. 9 industrial monitoring and control instruments (IMCI) until 21 July 2031. They further request the uptake of mercury in the exemption with an updated wording to compensate the potential revocation of exemption III-4(a)(l) which so far has been covering the use of mercury in the applications in the scope of exemption IV-10. The applicants argue that there are no alternatives to the use of lead, cadmium and mercury in hollow cathode lamps (HCL) and electrodeless discharge lamps (EDL) for the production of distinct spectral lines in line source atomic absorption spectroscopy (LS-AAS) and that LS-AAS systems cannot be replaced by other systems in every use case.

Alternative lamp technologies for LS-AAS (i.e. solid state and continuum light source lamps) and entire analytical systems as a replacement of AAS as a whole (e.g. ICP-OES, ICP-MS) are available to the market and could substitute or eliminate the use of restricted substances in many use cases. However, depending on the combination of type and concentration of the elements to be detected, sample matrix and the environmental conditions of operation, the use of these alternatives can be scientifically or technically impracticable. Given the large number of sample conditions, environments in which the analytical tools are used, amount of total dissolved solids and total sample volume, and the interdependency of these, it was not feasible to define conditions where alternative analytical tools can eliminate the use of the restricted substances.

HCL and EDL contain, within their cathodes or bulbs, the element of interest to be detected in a sample. Hence, HCL and EDL made to detect restricted substances contain restricted substances. In comparison to HCL, the use of EDL does not eliminate but significantly reduce the use of restricted substances. The vast majority of AAS systems solely rely on HCL as their light source, whereas, as to the knowledge of the consultants, there are no

AAS systems that solely rely on EDL which are not highly niche applications utilizing a single EDL to detect a single element. However, there are currently two manufacturers on the market providing a commercial system utilizing a combination of HCL and EDL lamps. These systems have proven to be reliable and scientifically and technically practicable, even though only one manufacturer currently provides EDLs for the detection of Cd, Pb, and Hg. The applicants estimate a total development time of about 10 years for other manufacturers to develop and bring to the market such HCL/EDL-AAS hybrid systems. .

ICP-based multi-element analysis is increasingly gaining market share in the field of elemental analysis and instruments are continuously improved on for cheaper cost of operation and new methodological adaptation to new use cases. New fields of application and method development for continuum light source AAS (HR-CS-AAS) is progressing and these instruments also take up market share in the field of elemental analysis. These developments put the economic feasibility for the development of EDL-based AAS systems by other manufacturers in questions as it might be a regrettable substitution.

Based on the information provided the consultants conclude that there are still many applications and specific use cases where there are no scientifically and technically practicable alternatives to eliminate the use of LS-AAS in the coming years.

They further do not see a potential for the substitution of Cd, Hg and Pb in LS-AAS. The consultants see a potential to significantly reduce the use of restricted substances by restricting the exemption to the use of EDL in AAS even though there may be repercussions on the market and its supply and demand dynamics due the fact that there is currently only one manufacturer of such a system.

Since HCL are spare parts of LS-AAS systems, exchanging these lamps is relatively simple and HCL not including restricted substances can easily be swapped out for HCL including restricted substances in LS-AAS systems that operate with HCL. This may pose challenges to the market surveillance, but the problem should be diminished over the years since it is increasingly implausible to supply HCL with cadmium, lead and mercury.

23.4. Recommendation

Given the provided information by the applicants, the consultants do not see a potential for the substitution of Pb, Hg and Cd in HCLs for LS-AAS.

Various alternative technologies that do not contain the restricted substances are available and can replace or even outperform LS-AAS in several analytical tasks. It was, however, not possible to derive clear criteria to restrict the use of LS-AAS with HCLs to analytical tasks where for the time being and for the coming years their use is indispensable. Thus, while elimination of the restricted substances is scientifically and technically practicable in some cases, these cases cannot be transferred into a clear exemption wording. The alternative technologies are, however, steadily gaining popularity with novel method and technological improvements so that the elimination of the restricted substances may become feasible in an increasing number of analytical tasks and a future scope restriction may become viable.

EDL are an alternative lamp technology for HCL in LS-AAS. They contain the restricted substances as well but in much smaller quantities so that using EDL in LS-AAS systems would largely reduce but not completely eliminate their use. The applicants point out that

such a shift from HCL to EDL implies the risk of a "regrettable substitution" due to further development of the above-mentioned alternative technologies.

One producer, however, has been offering LS-AAS with EDLs for more than 10 years already so that the effort related to the development and qualification of such an LS-AAS system has already been performed. The consultants therefore recommend restricting the exemption scope to EDL lamps after a transition period of around 3 years to allow time for the adaptation of standards that stipulate the use of LS-AAS with HCLs.

No.	Exemption	Scope and dates of applicability
IV-10	Lead and cadmium in atomic absorption spectroscopy lamps	Applies to categories 8 and 9. Expires on - 21 July 2021 for category 8 other than in vitro diagnostic medical devices and for category 9 other than industrial monitoring and control instruments. - 21 July 2023 for category 8 in vitro diagnostic medical devices. - **24 February 2027* for category 9 industrial monitoring and control instruments**
IV-10(a)	Lead, cadmium, and mercury in electrodeless discharge lamps for atomic absorption spectroscopy	**Applies to category 9 industrial monitoring and control instruments from 25 February 2027 on.** **Expires on 21 July 2031**

*****Aligned with expiry of exemption III-4(a)(I) to ensure the use of mercury in AAS remains covered by an exemption during the transition time to exemption 10(a).

Applicant's feedback on the recommendation

Most members of the consortium of (PE et al. 2024b) expressed strong concerns that the recommended renewed exemption does not allow sufficient time for system manufacturers without an EDL system to develop one. This could result in losses of jobs and in a monopoly position of one manufacturer in the EEA market. It is believed the risk to the EU testing sector (including environmental testing) would outweigh the environmental benefit of a premature termination of this exemption. The majority of the consortim members would like a 7 years renewal of the exemption for HCL lamps.

The consultants are confident that they considered all relevant arguments made available by applicants and stakeholders during the review, and that the arguments have been evaluated taking into account the requirements of Art. 5(1)(a).

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24. Exemption 46 of Annex IV: DEHP in MRI detector coils

The below Table 24-1 shows the wording, scope and expiry dates of the exemption.

Table 24-1:Current wording of the exemption

No.	Current exemption wording	Current scope and dates of applicability
IV-46	Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils	Applies to categories 8 medical devices other than in vitro diagnostic medical devices. Expires on 1 January 2024 for category 8

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

COM	European Commission
DEHP	Bis(2-ethylhexyl) phthalate
DPSS	Diode pumped solid state, used in the context with lasers (DPSS lasers)
EEE	Electrical and electronic equipment
IVD	In vitro diagnostic medical devices
RoHS 1	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	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; RoHS Directive, RoHS

Definitions

24.1. Background and technical information

In May 2022, (COCIR 2022) requested the renewal of this exemption as displayed in Table 24-2 for EEE of category (cat.) 8 medical devices other than in vitro diagnostic (IVD) medical devices with the below wording and expiry date.

Table 24-2: Wording and scope of the requested exemption

No.	*Requested exemption*	*Requested scope and dates of applicability*
IV-46	Bis(2-ethylhexyl) phthalate (DEHP) in plastic cable strain reliefs in MRI detector coils	Applies to category 8 medical devices other than in vitro diagnostic medical devices. Expires on 31 December 2026

24.1.1. History of the exemption

(Baron et al. 2020) reviewed the exemption request submitted by COCIR and recommended granting the exemption until 1 January 2024. The Commission (COM) followed the consultants recommendation resulting in the current exemption IV-46. (COCIR 2022) requested the renewal of the exemption so that it became due for review.

24.1.2. Summary of the requested exemption

(COCIR 2022) request to extend the time period to replace the existing materials of MRI coil cable strain reliefs for tests to qualify adequate performance and redesign them, if necessary, after tests with the new identified materials. In 2019 COCIR submitted the request for exemption 46 that was then published in 2021 with the validity period expiring on 1 January 2024.

Since then COCIR Companies have made progress according to the indicated timeline. Alternatives for all plastic parts have been identified and by 2024 all models of non-integrated coils will be placed on the market with cable covers, fixing belts and mattresses DEHP free. Alternatives have been identified also for cable strain reliefs and already today all new models are placed on the European market DEHP free.

Due to unexpected external events, the redesign of old models has been delayed and we expect a number of coils design will not be available DEHP free by that date (1 Jan 2024). While limited in number, such coils are still needed by hospitals in EU and due to their older design cannot be substituted with the newer designs due to compatibility issues. While the negative health and socio-economic impacts without this exemption are explained in their request, the overall amount of DEHP placed into EU market is going to be minimal.

(COCIR 2022) also note that if exemption 46 was worded using the "DoC approach" successfully included in exemption 27 and proposed for others, it would not have been required to submit this renewal as companies would have had enough time to phase out older designs, while ensuring DEHP free new designs.

24.1.3. Technical description of the exemption and use of the restricted substance

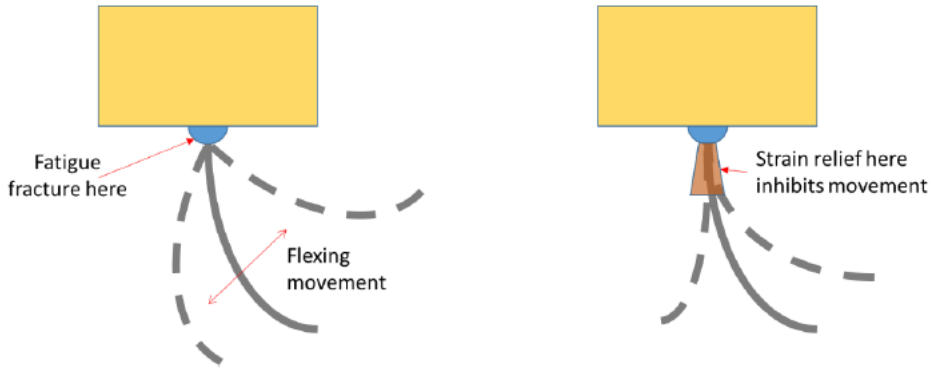
(COCIR 2022) present the below figure showing an MRI coil for imaging shoulders. The cable connect to the MRI system which contain the strain reliefs are circled in red.

Figure 24-1: MRI shoulder coil with cable connects containing DEHP

Source: (COCIR 2022)

(COCIR 2022) describe MRI and the associated coils as long-lifetime products that must be very reliable because if a part were to fail so that it is not possible to use the MRI or a coil, the patient who may be very ill, could not be treated. Where flexible cables are attached to rigid electrical components such as shown in the above in Figure, they will flex repeatedly in use. Repeated flexing will cause both the electrical insulation and the internal copper wires to fracture as a result of mechanical fatigue. This will cause the coil to fail and not be usable. If the cable jacket breaks due to inadequate strain relief and the conductors are exposed before hard failure, it results in a safety risk to patient. This failure mode is commonly prevented in many types of electrical equipment including MRI coils using flexible plastic components that limit flexing movement. These are often referred to as strain relief boots or cord guards. There are many designs on the market, but the important property is that the wire can flex for sufficient times without fracture during the expected lifetime of the equipment. By reducing the angle of movement of the wire where it connects to the rigid connector (see below), this greatly extends the lifetime of the cable and electrical safety of connection.

Figure 24-2: Effect of cable strain relief on movement of cable at connection to equipment



Source: (COCIR 2022)

(COCIR 2022) describe the following requirements for the strain relief.

- The polymer plus all additives including the plasticiser must be acceptable for use in medical devices. New materials must comply with biocompatibility requirements according to ISO 10993 “Biological evaluation of medical devices”, before they can be used.
- Lifetime of at least 8 years of frequent use and without failures. This is on average equivalent to 30,000 repetitive bend cycles.
- Must not affect MRI image quality, so must be non-magnetic and have a proton signal emission material / air ratio as low as possible, ideally <1.2, but must be <4.0 when within the imaging zone (i.e., strain reliefs that are attached to coils).
- Coil assemblies must not be damaged when a patient has to be rapidly removed from an MRI scanner in an emergency, for example, if they suffer a heart attack. This is important if coil assemblies have to be redesigned.
- The strain relief must pass IEC 60601 safety testing for Cord Guard bend/ Cord anchorage requirements.
- The strain reliefs are external parts and are often close to the patients. The material selected shall meet Cleaning & Disinfection Spaulding classification requirements for Intermediate Level Disinfection. Hence the new material shall meet compatibility with cleaning agents used in hospital environments and efficacy per ISO ISO17664-2 -2021.

More details as to the technical background of this exemption are available in the report of (Baron et al. 2020).

24.1.4. Amount(s) of restricted substance(s) used under the exemption

(COCIR 2022) indicate 18 kg of DEHP to be placed on the EU market annually due to the exemption. The underlying calculation of the above volume includes confidential information and is thus not published.

(Baron et al. 2020) indicate the volumes of DEHP with 158 kg per year based on data from two MRI producers with 144 kg and 14 kg of DEHP respectively.

The current 18 kg can thus be assumed to reflect the ongoing substitution or elimination of DEHP in the strain reliefs.

24.2. Justification of the requested exemption

24.2.1. Substitution and Elimination of the restricted substance

(COCIR 2022) state that alternatives have been identified and are actually used for new models. The same alternatives are not drop-in replacement and cannot be used on older designs. Partial redesign and then full testing and validation as a new model is required. All coil assembly designs in companies' portfolios must be extensively tested with new material for reliability and performance as each design is different. The extent of movement and the stresses and strain of each strain relief depends on the design of each cable assembly and the coils vary in size and shape considerably to accommodate different parts of the human body. Testing includes repetitive bending, proton image intensity measurement, biocompatibility, IEC safety testing etc. and also tested with patients before re-approval under the Medical Devices Regulation can be obtained from an EU Notified Body as well as approval in other countries outside of the EU.

COCIR Members have been affected by the COVID crisis. Some of them ramped up the production of COVID critical devices up to 400 % diverting significant resources from other less critical projects, for instance redesigning older MRI coils.

Another impact of the COVID crisis has been the reduction of physical permanence in the work place that has undermined the availability of technicians for the physical testing of coils. The semiconductor scarcity is hitting the sector very badly as even the press reported, prompting the European Commission to consider taking action to ensure supply for the production of medical devices. At company level this has caused additional resources and expertise to be rerouted internally. A company even reported that the launch of their new line of innovative MRI coils also played a role in the delay of the substitution plan; but considering the benefit such new technology brings to patients, and the already mentioned constraints, it was not possible to avoid delays.

Due to such external events that were not considered in 2019 (the exemption request was developed between 2017 and 2019) the roadmap to full substitution has been delayed. Considering the volatility of the situation, COCIR estimated 1 January 2026 as a reasonable deadline. Depending on the situation, full substitution could be even achieved earlier but it is very hard to say.

24.2.2. Environmental, health, safety and socioeconomic impacts

(COCIR 2022) confirm their estimate in their exemption request reviewed by (Baron et al. 2020) that an impact on healthcare providers in the EU can be expected, even if smaller than in the original application for exemption 46, if many types of MRI coils cannot be purchased by EU hospitals. It is also important to note that a too short deadline would force

manufacturers to drop the project of redesigning some older coils that would become permanently unavailable for hospitals.

Per 2018 estimate, there are more than 1900 MRI scanners installed in European hospitals (which may correspond to a slightly lower number of EU hospitals) that may be directly affected by scarcity of MRI coils. While the risk is now lower than previously estimated in 2019, all of these hospitals and their patients are at risk being affected negatively in their ability to provide MRI scan examination to patients if this exemption is not accepted. If hospitals are unable to buy the current wide range of MRI coils for their MRI scanners that they already own, the waiting time for receiving an examination are bound to increase and many patient's conditions would be more difficult to diagnose and treat as other less suitable methods would have to be used, if this is possible. For example, a whole-body coil can be used to examine all parts of a patient's body, but the detail obtained for a small area such as a foot is less than that which can be obtained by a dedicated foot coil. Also, the time required to obtain a scan of a whole patient is much longer than a foot scan and this can cause delays, as MRI demand often exceeds their availability. Other techniques may not be suitable, for example, CT (Computed Tomography) is used to obtain 3-dimensional images of patients, but the information it provides is different from MRI images, not to consider the unnecessary exposure to radiation.

From online sources[132], one MRI scanner typically treats around 4,500 patients per year (this is old and conservative data from 2004, the number is higher today). The impact described above on healthcare for patients can therefore affect more than 9,000,000 patients in Europe per year who could not be treated using the most suitable diagnostic equipment.

24.2.3. Roadmap towards substitution or elimination of the restricted substance

In their exemption request reviewed by (Baron et al. 2020), COCIR submitted the below table to show the different steps of substitution or elimination of DEHP.

Table 24-3: Stages for establishment of possible substitute and respective timeframe needed for completion of such stages

Phase	Elapsed time for one coil design	
	COCIR for plastic components	**GE Healthcare for strain reliefs**
Identify materials	Currently underway	Not known at present
Biocompatibility and other tests	Approx. 6 months per material being altered to DEHP free	Approx. 6 months
Reliability testing	6 months to a year	1-2 years
Verification and global approvals if needed	Up to 2 years	Up to 2 years

Source: COCIR in (Baron et al. 2020)

[132] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2645123/; source as referenced by COCIR 2022.

(COCIR 2022) report that all the stages for identification of a substitute have been completed. They expect that by 1 January 2026 all remaining steps will have been absolved and only DEHP-free coils will be placed on the market.

24.3. Critical review

24.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

DEHP is listed on Annex XIV so that its use requires authorisation. *(COCIR 2024c) confirm that, like at the time of the last review of the exemption by (Baron et al. 2020), the material is supplied from outside the EU so that Annex XIV is not applicable.*

Additionally, Annex XVII contains several restrictions for DEHP. None of those entries are, however, relevant for the use of lead in the scope of exemption IV-46 (cf. section 4.4 on page 55 for details).

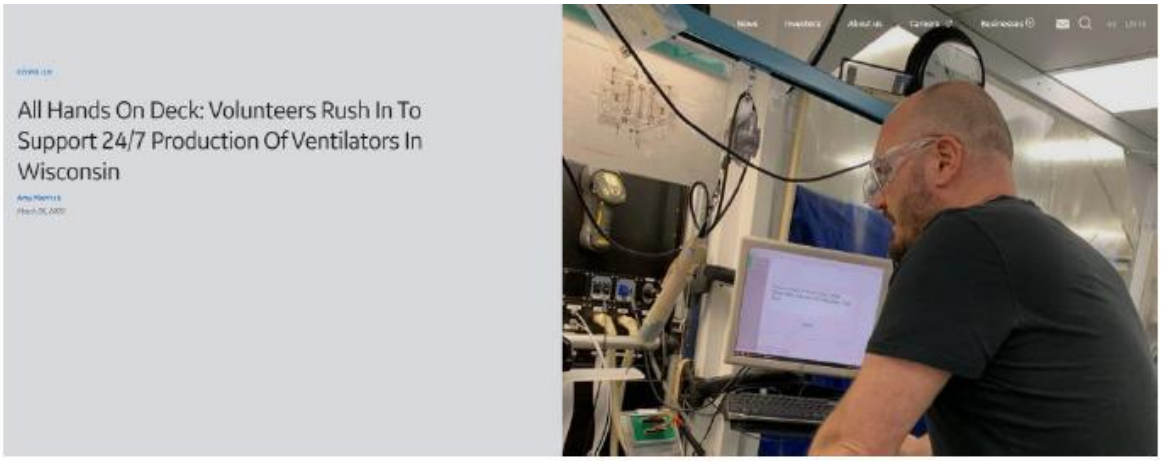
Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

24.3.2. Substitution and elimination of the restricted substance

(COCIR 2022) confirm that the first stage of their roadmap is achieved, i.e. the identification of materials that do not require the use of DEHP. The remaining steps in their roadmap (cf. section 24.2.3 on page 515) are specified as reliability testing of these identified DEHP-free alternatives for the various models of MRI, and their verification and global approvals (if needed). This implies that the reliability of the substitutes has to be ensured for which two years more are required until 1 January 2026 instead of 1 January 2024 like estimated in COCIR's exemption request reviewed by (Baron et al. 2020). (COCIR 2022) justify the delay with their members having considerably increased their production specifically for the treatment of COVID.

COCIR stated in the context of earlier exemption requests that redesign of coils requires highly qualified and specifically trained engineers. The consultants thus wondered how such highly specialized design and development engineers could be used to increase the production of other medical equipment whose demand had increased in the SARS-CoV2 pandemic, e.g. lung respirators.

(COCIR 2024a) confirm that the design of MRI coil is performed by very specialized engineers and in fact the work continued but that they claim a little delay in the roadmap to complete substitution. Nonetheless some of those engineers have been pulled to the production of medical devices needed for COVID. Resources and priorities were also drastically rerouted. Companies went through a storm during the COVID period with demand for certain devices going out of scale - up to 400 % for ventilators - and companies struggled to increase production to satisfy the demand. This effort involved re-purposing production lines of other devices to manufacture and assemble ventilators. Workers, engineers, technicians, resources were diverted from other business to work on multiple shifts and to assemble and test ventilators. CT demand increased drastically. The same happened also for companies with activities in the COVID testing field. (COCIR 2024a) reference a report on the internet about volunteers volunteering to work in assembly lines.[133]



The consultants understand that in this situation, all resources were re-allocated to overcome the emergency of missing life-saving equipment, which may imply involving engineers that are highly qualified for specific tasks into less demanding manufacturing and other activities. It is also plausible that as a further consequence of the SARS-CoV2 pandemic, the reduced physical permanence of technicians in the work place hampered the testing of coils.

Based on the applicant's above explanation, the consultants conclude that extending the expiry of exemption 46 for two years beyond the current expiry date could be justified by Art. 5(1)(a) to ensure the reliability of the substitutes for the various models of MRIs. It is understood that the exemption is no longer required after this extended validity period and the exemption can expire at beginning of 2026.

24.3.3. Environmental, health, safety and socio-economic impacts

COCIR state that coils may not be available to hospitals with adverse impacts on human health if the exemption is not extended for two years beyond 1 January 2024, even though this risk is lower than at the time when (Baron et al. 2020) reviewed COCIR's exemption request.

[133] The link provided in the 2022 renewal request (https://www.ge.com/news/reports/all-hands-on-deck-volunteers-rush-in-to-support-24-7-production-of-ventilators-in-wisconsin) is not functional anymore.

The consultants cannot exclude that such risks may arise at least to a certain degree if the validity of the renewed exemption is not extended for two years beyond 1 January 2024 as requested by the applicant.

24.3.4. Summary and conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria[134] is fulfilled:

4. 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**;
5. the **reliability of substitutes** is not ensured;
6. 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 current exemption IV-46 would have expired on 1 January 2024. COCIR requested its renewal until 1 January 2026 because of delays in the redesign of coils due to the consequences of the SARS-CoV2 pandemic.

The consultants can follow the applicant's reasoning. The redesign of coils needs to be finalized to ensure the reliability of the substitute, and to have the DEHP-free MRI coils certified where needed. The exemption is no longer required after this extended validity period so that it can expire at the beginning of 2026.

24.4. Recommendation

The consultants recommend granting the exemption to enable sufficient time to ensure the reliability of the DEHP-free substitutes in all models of coils. The applicant's reasoning is plausible that the consequences of the SARS-CoV2-pandemic delayed the finalisation of this task for two years beyond the current expiry date on 1 January 2024.

The consultants recommend the below wording for renewed exemption:

No.	Recommended exemption	Recommended scope and dates of applicability
IV-46	Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils	Applies to categories 8 medical devices other than in vitro diagnostic medical devices. Expires on 31 December 2026.

[134] Deviating from Art. 5(1)(a), the sub-clauses are numbered to allow addressing them specifically in the text.

Applicants' feedback on the recommendation

(COCIR 2024b) agreed to the above recommendation.

24.5. References

Baron et al. (2020): Study to assess one (1) request for a new exemption to Annex IV of Directive 2011/65/EU for bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils(Pack 20) – Draft final Report. Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation. RoHS 25. In cooperation with Yifaat Baron, Katja Moch, Öko-Institut und Dr. Otmar Deubzer, Fraunhofer IZM. Publications Office of the EU. Retrieved from https://data.europa.eu/doi/10.2779/065213.

COCIR (2022): Request for renewal of exemption 46 of Annex IV.

COCIR (2024a): Answers to questionnaire 1 sent via e-Mai by Riccardo Corridori, COCIR, to Dr. Otmar Deubzer.

COCIR (2024b): Feedback on recommendation for renewal of exemption 46 of Annex IV.

COCIR (2024c): Answers to questionnaire 2 sent via e-Mai by Riccardo Corridori, COCIR, to Dr. Otmar Deubzer.

25. Requested new Exemption 2022-2 of Annex IV: Cd in Hersch cell oxygen sensors

Declaration

In the sections preceding the “Critical review”, the phrasings and wordings of applicants’ and stakeholders’ explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. In all sections, this information as well as information from other sources is described in italics. Formulations were altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

Cat.	Category, referring to the categories of EEE specified in Annex II of the current RoHS Directive
COM	European Commission
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instruments
IVD	In-vitro diagnostic medical devices
MOCON	AMETEK MOCON
NIST	National Institute of Standards and Technology
RoHS 1	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	Directive 2011/65/EU, current RoHS Directive

25.1. Background and technical information

Annex IV exemption 43 used to cover cadmium in Hersch cells for which the applicant submitted a renewal request, which was, however, rejected, as it was within 18 months of the expiration of exemption 43. Therefore, this request is considered a request of a new exemption. The previously valid wording and scope of exemption 43 of RoHS Annex IV is displayed in Table 25-1.

Table 25-1: Previously valid wording and scope of the exemption

No.	Exemption	Scope and dates of applicability
IV-43	Cadmium anodes in Hersch cells for oxygen sensors used in industrial monitoring and control instruments, where sensitivity below 10 ppm is required.	Applies to category 9 industrial monitoring and control instruments. Expires on 15 July 2023 for category 9 industrial monitoring and control instruments.

(MOCON 2022) requested an exemption request for EEE of RoHS Annex I category 9 industrial monitoring and control instrument (IMCI) as displayed in Table 25-2.

Table 25-2: Wording and scope of the requested exemption

No.	Requested Exemption	Requested scope and dates of applicability
IV-X	*Cadmium in Hersch cells for oxygen sensors used in industrial monitoring and control instruments, where sensitivity below 100 ppm is required*	*Applies to category 9 industrial monitoring and control instruments. Expires on [7 years after official publication of the COM's decision]*

To ensure the availability of Hersch cells on the market, MOCON have, in parallel to this exemption request, requested the renewal of exemption IV-1(b) to enable them to use lead as anode material in Hersch cells. In that renewal request, MOCON revise some of the information provided in this current exemption request form regarding the performance of lead anodes in Hersch cells. This is further discussed in the review of the renewal request for exemption IV-1(b).

25.1.1. History of the exemption

Exemption 43 of Annex IV was not part of RoHS Directive 2002/95/EC (2003) (RoHS 1). It was first evaluated by (Gensch et al. 2015) and subsequently listed on Annex IV of RoHS Directive 2011/65/EU (2011) (RoHS 2) in an amendment dated 19 April 2016 [135]. At the time, the consultants concluded that while alternative, lead-free oxygen sensors exist, it can be followed that alternative technologies do not provide the same sensitivity and accuracy compared to Hersch cell sensors.

Exemption 43 was set to expire on 15 July 2023. As stated above, the applicants did not submit a renewal request 18 months before, but within the 18 months window before the expiry date. Therefore, this request is formally to be considered for a new exemption.

[135] Commission Delegated Directive (EU) 2016/1029 of 19 April 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium anodes in Hersch cells for certain oxygen sensors used in industrial monitoring and control instruments. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32016L1029

25.1.2. Summary of the requested exemption

(MOCON 2022) provided a summary of the exemption as follows:

An exemption is requested for cadmium in Hersch cells for high-sensitivity oxygen sensors capable of measuring oxygen concentration below 100 ppm. Using a Hersch Cell, the range of oxygen detection is from 80 ppt to 70 ppm.

With reference to Article 5.1.(a), this exemption is made for the following reason: 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.

An exemption request for the former Annex IV n. 43 for cadmium in anodes of oxygen sensors was rejected because the request to extend it was within the 18 month window before expiration. While lead is less toxic than cadmium, lead anodes are unable to provide the levels of sensitivity (measurements of tens or hundreds of parts per trillion) and stability required by certain industries. Therefore, the request is made for cadmium in equipment designed for sensitivity ranges where lead is unsuitable.

Of the industries requiring high-sensitivity oxygen measurement, the following industries provide examples where human health or the environment would be placed at risk if the technology were to become unavailable:

- *Manufacture of certain pharmaceutical products which are sensitive to extremely low levels of oxygen*
- *Integrity of food packaging design*
- *Lifespan of solar panels, which require a high oxygen barrier to ensure component integrity*

The above examples were chosen to identify socioeconomic costs. There are other industries requiring highly sensitive oxygen measurements but, there is no other use known for the Hersch cell outside of analytical equipment. The net environmental benefit to refusing this exemption request would be minimal, amounting to the removal of at most, 3.101 kg of cadmium from the European waste stream per year.

25.1.3. Technical description of the exemption and use of the restricted substance

Types of EEE for which the exemption renewal request is relevant

According to (MOCON 2022), cadmium is present in the anodes of Hersch cells, which are used in specialized, high sensitivity oxygen sensors where parts per trillion (ppt) measurements are required.

Function of the RoHS-regulated substance used

According to (MOCON 2022), cadmium anodes are used in oxygen sensors for specific applications when a high degree of sensitivity and long-term instrument stability is required. Given the absolute nature of the sensor, it is the only possible instrument where no calibration is necessary.

There are several properties that are important in the Hersch cell:

- *Must follow Faraday's Law*
- *Flat discharge curve (accuracy)*
- *Sensor life (charge)*
- *Inherent method of maintaining electrolyte heath over years*
- *Absolute method of measurement (Coulometric)*
- *Temperature independent*
- *Oxygen efficiency measurement > 95%*
- *Sensor response (fast)*
- *Size and format similar to current sensor*
- *Specific to Oxygen (Limited cross sensitivity)*

(MOCON 2022) explain that a Hersch cell operates by introducing a sample gas to an electrolytic solution; in this case it is potassium hydroxide (KOH).

The Coulox oxygen sensor is a fuel cell that performs in accordance with Faraday's Law. When exposed to oxygen, the Coulox generates an electrical current that is proportional to the amount of oxygen entering the sensor.

The Coulox sensor has a carbon cathode and a cadmium anode. The cathodic and anodic reactions respectively:

$$\tfrac{1}{2}O_2 + H_2O + 2e \rightarrow 2OH$$

$$Cd + 2OH^- - 2e \rightarrow Cd(OH)_2$$

The electrons create an electrical current, which can be used to calculate the amount of oxygen entering the Coulox sensor.

As noted, each oxygen molecule entering the Coulox results in four free electrons creating an electrical current. One mole of oxygen (22.4 litres at 0 ºC and 760 mmHg) would produce four Faradays of current. With one Faraday = 96,500 Ampere-seconds, each mole of oxygen will produce 4 x 96,500 = 3.86 x 105 Ampere-seconds.

In more practical terms: One cc of oxygen in 24 hours = 0.000199 Amperes of current. This means that the sensor has a sensitivity as little as 100 picoamps and a repeatability of 500 picoamps. To illustrate that; if you were to take the entire population of the world and multiply it by 40, so 312 billion people, and asked the sensor to find any one specific person it would pick them out.

This creates a current which is used to coulometrically determine the absolute amount of oxygen in solution with the electrolyte.

Lead is commonly used as an anode in this application. However, cadmium has specific properties which are necessary for high-sensitivity applications. Therefore, an application to extend the exemption for cadmium in anodes of Hersch cells for high-sensitivity oxygen sensors is requested.

Characteristics and functions of the RoHS-regulated substance

(MOCON 2022) elaborate that the two major reasons why certain industries are unable to substitute cadmium Hersch cell oxygen sensors:

- *The Hersch cadmium Cell is "Coulometric" and follows Faraday's Law at ppt levels. This removes the need to calibrate at these extreme low levels. This is critical because the lowest level of NIST calibration gas is 1 Mole% oxygen (10,000 ppm). The best "Certified" gas is about 10 ppm (± 20 %) which is still 10,000 times away from where the application requires accurate measurements. Competing technologies (exempt lead in particular) require calibration at the testing range of interest, for which there are no standards below 10 ppm.*
- *The solubility of cadmium in KOH (electrolyte) is very low, therefore does not migrate (like other metals) to the sensing electrode, precipitate or block the sensing electrode sights. This gives the Hersch cadmium cell extraordinary long stable sensitivity life, on the order of years. Other metals do not have the life, sensitivity, or stability.*

25.1.4. Amount(s) of restricted substance(s) used under the exemption

(MOCON 2022) indicate that 3.101 kg of cadmium will enter the EU annually.

MOCON add that while the average mass of cadmium sent to the EU over the last three years was 3.101 kg per year, since 1991 they have had a recycling program where they instruct their customers to send back the sensors when they are replaced or the instruments are thrown out. On average MOCON see about 67 % of our sensors which contain the cadmium come back to the US for proper recycling. So, the net result of added cadmium to the EU averaged 2.07 kg per year. It is important to note this is the maximum amount of cadmium added per year. This is because many of these instruments may still be in use or in inventory and not in use. The customer may have also properly recycled the sensor somewhere else. Therefore, this is worst case scenario.

25.2. Justification of the requested exemption

25.2.1. Substitution and Elimination of the restricted substance

The applicant currently manufactures several oxygen sensors, not all of which rely on cadmium. However, the sensors using other anode materials (lead) are suitable only for other applications that do not require the high sensitivity of the cadmium Hersch cell application.

(MOCON 2022) state that alternative substances exist and are commonly used in oxygen sensors. However, for specialized applications where stable sensitivity on the order of parts per trillion is required, there are no available substitutes. The basic type of oxygen sensor used is a Hersch Cell. By using cadmium, the instrument is able to measure oxygen transmission down to 0.0005 cc/m^2 x day which equals 170 ppt (parts per trillion) and a sensitivity of 0.0001 cc/m^2 x day (equal to 34 ppt). Another advantage is the long-term stability of the sensor sensitivity (years); over which the > 95 % efficiency to oxygen detection does not change. It should be noted that 70 ppm is the highest level of oxygen

measurable and still be linear. It is believed that the technology has another 100 to 1000 times more sensitivity for future development. This level of sensitivity has been requested by some users of the technology.

It should be noted that the sensor measurement is a direct absolute (Coulometric) measurement of oxygen and follows Faraday's Law. Second, the cadmium is very specific to oxygen and has very few interfering gases. Third is the sensitivity the cadmium has to oxygen without degrading over long periods of time (years).

According to (MOCON 2022), there are several major reasons why certain industries are unable to substitute Hersch cell oxygen sensors:

- *The Hersch cadmium cell is "Coulometric" and follows Faraday's Law even at ppt levels. This means calibration is not required at these extreme low levels.*
- *This is critical because the lowest level of NIST calibration gas is 1 Mole% oxygen (10,000 ppm). The best "Certified" gas is about 10 ppm (± 20%) which is still 10,000 times away from where the user needs to measure accurately. All competing technologies require calibration at the testing range of interest, which there are no standards below 10 ppm.*
- *The solubility of cadmium in KOH (electrolyte) is very low, therefore does not migrate (like other metals) to the sensing electrode, precipitate or block the sensing electrode sights. This gives the Hersch cadmium cell extraordinary long stable sensitivity life (years). Other metals do not have the life, sensitivity or stability.*
- *It is recognised by ASTM (D-3985, F-1307, F-1927), ISO (15105-2), JIS (K 7126-2), DIN (53380-3), GB/T (GB/T 19789, GB/T 31354), and other standards worldwide.*

(MOCON 2022) emphasize that available technologies for oxygen sensors are described by Dr. Paul Goodman in section 10.1.3 of "Reliability and Failure Analysis: Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report"[136]. In the context of lead as an anode material in electrochemical oxygen sensors, Dr. Goodman investigates several possible materials. He evaluates several possible Pb substitutes and concludes that:

- *Zn is unsuitable due to its high corrosion rate. This provides an unpredictable reference current and therefore precludes its use in anything but rudimentary measurements.*
- *Sn, Al, and In self-passivate, which prevents reaction from continuing after a short period.*
- *Ni, Cu, Fe are unsuitable due to the necessity of adding an external power supply.*
- *Au, Pt, Ag are unsuitable due to electrode potential issues.*

According to (MOCON 2022), sensor technologies discussed in ERA Report 2006-0383 "Alternative types of sensors"[137] are comparator type sensors which do not have the sensitivity, accuracy or the Coulometric characteristics the Hersch Cell has. To accurately

[136] Retrieved from http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf 2013-01-30

[137] Dr. Paul Goodman: Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report. Available: https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf

measure oxygen (gas) permeation through packaging barrier material below 0.001 cc/m2 ·day (0.36 ppb v/v) with an upper range of 200 cc/m2 ·day (72 ppm v/v). The Food, Pharmaceutical, Solar and OLED industries also need the permeation measurements to be NIST traceable. This method needs to be robust, economical and good response (minutes to T99).

All other sensor technologies require that a membrane be present to keep the electrolyte from leaving the sensor. When the membrane is present the sensors no longer directly measure all of the oxygen. This requires that the sensor be calibrated. MOCON explain in detail that to accurately calibrate the sensors a NIST [National Institute of Standards and Technology, the consultants] *traceable gas must be used. However, As of October 8, 2014, the lowest NIST Standard Reference Material which is available for purchase from NIST is 2 Mole % (20,000ppm). (MOCON 2022) conclude that clearly, if there is no calibration gas (or film) near 1 ppb, some other accurate (absolute) low level (ppb) oxygen measurement is required.*

Further discussing the coulometric concept, (MOCON 2022) state that several electrochemical oxygen technologies are fundamentally Coulometric, but when reduced to practice (sensor) they all have oxygen barriers or restrictions to the electrodes, therefore only measuring a fraction (< 0.001%) of the total oxygen present. Inherently, this means they are far less sensitive to oxygen, and they are not measuring all the analyte (O2), which is a critical Coulometric requirement. If a sensor does not collect and measure all the analyte, then it needs to be calibrated because the sensor is only measuring some unknown fraction of the total oxygen. Life of the sensor is the primary reason why electrochemical sensors have oxygen barriers or restrictions to the electrodes.

Discussing a number of elements as anode materials, (MOCON 2022) state:

- ***Cadmium** is the current anode used in today's oxygen Coulox sensor. It has a long history of accepted performance and ruggedness. Multiple sources in the required plaque format improve availability. The voltage discharge level is the flattest of the electrochemical sensors which gives the Coulox its accuracy and consistent measurements throughout its life. Cadmium doesn't meet the RoHS directives.*
- ***Lead** could substitute for cadmium as an anode, and it is available in plaque form. Its voltage discharge level is almost as flat as cadmium but has a significant and sooner drop at end of discharge. Substituting cadmium with lead does not make sense regarding the goals of the RoHS Directive.*
- ***Zinc** anodes would give a similar output as Cadmium; however, has a non-linear voltage discharge curve. In effect, this gives the appearances that the accuracy is significantly changing throughout the sensor's life. Zinc can be found in many formats, but plaque is more difficult to find. Some testing with Zinc/air batteries in a starved condition (as a sensor) says the concept may work. However, at low oxygen levels the sensors generate hydrogen and in a sealed condition this causes the sensor to burst.*
- ***Lithium** anodes would give similar output as Cadmium; however, it has a non-linear voltage discharge curve, about half as much as Zinc. In effect, this gives the appearances that the accuracy is significantly changing throughout the sensor's life. Like Zinc, Lithium can be found in many formats, but plaque is more difficult to find. Most important, Lithium and water is explosive, therefore aqueous electrolytes are*

not allowed. This leaves organic electrolytes and the evaporation of their solvents. As of now we don't know how to replenish these solvents.

- ***Exotic Materials**: MOCON has contacts with other sensor manufactures and has discussed other anode material. One of the bigger problems is finding a metal/alloy that uses gases oxygen as a fuel and meets RoHS directives.*

(MOCON 2022) explain that there are other technologies which have been researched but they too have their own limitations. In fact, MOCON uses several of these other technologies in other less sensitive instruments. They include Pb, ZrO2 and Optical Fluorescence. These technologies all measure oxygen as low as single ppm levels and all require frequent calibration with certified gases. Other technologies have been researched but have been met with their own limitations. These include Tunable Laser Diodes, Pb, ZrO2, other electrochemical sensors and Optical Fluorescence. They all have to be calibrated because there is no direct measurement of oxygen taking place.

25.2.2. Environmental, health, safety and socioeconomic impacts

According to (MOCON 2022), there are several users of high-sensitivity oxygen sensors requiring ppt measurements. Applications affecting human health and the environment include:

- *The pharmaceutical industry uses Hersch cell sensors to ensure certain medications are protected from oxygen. This is required to maintain strength, and therefore public safety. The high instrument sensitivity is required to manufacture some medicines which are very sensitive to even trace amounts oxygen.*
- *Freshness and Safety in food packaging design, which requires ppt sensitivity, is the largest application of Hersch cell sensor technology. This affects consumer safety and potentially human health.*
- *The solar panel industry relies on ppt oxygen sensors instruments to measure their high oxygen barriers. Oxygen barriers are required to prolong the lifetime of the panels. Long-lasting Solar Panels are necessary to generate "green" energy, which results in benefits for the environment.*
- *Similarly, the OLED industry requires oxygen barriers to create OLED screens. Only very sensitive instruments using Hersch cells are capable of measuring at the levels they require.*

(MOCON 2022) claim that the substitution of Hersch cells with lead-based instruments would result in (among other impacted industries):

- *Specific medicines being unable to be reliably manufactured*
- *Loss of integrity in food packaging design*
- *Decreased lifespan of solar panels*

This is compared to the net gain of eliminating 3.101 kg of cadmium annually from the European market.

25.2.3. Roadmap towards substitution or elimination of the restricted substance

Actions that have been taken to develop further possible alternatives

According to (MOCON 2022), since the original exemption they have tested 2 different galvanic cell combinations, and 2 different fuel cell designs. Both fell short of efficiency and sensitivity. The applicant is investigating 6-12 other materials. So far, none have been found to be an equivalent replacement for the cadmium. This has been a considerable effort of time and resources due to the degree of difficulty of these designs.

The length of a sensor development project can be 1 year or 10 years or never. The last electrochemical sensor development took 6-7 years. The last improvement (not the same as development) made in the cadmium (Cd) Coulox sensor took 3 years (only one component changed). The length of development depends on how many components or materials or geometries have to be changed to accommodate the new anode.

(MOCON 2022) state that it is very possible that they will never be able to find a successful substitution option.

Stages necessary for establishment of possible substitutes and timeframes needed

According to (MOCON 2022), at this time, it cannot be confidently stated that an alternative material exists. None is currently known. An analysis performed for the European Commission in which the consultant explores various metals which can potentially be used as anodes in oxygen sensors[137]. The conclusion is that lead and cadmium comprise the only two viable metals for scientific reasons.

As is shown elsewhere in this request, lead is unsuitable for ppt measurements.

25.3. Critical review

25.3.1. 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 consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Several restrictions of cadmium and its compounds are listed on Annex XVII (cf. section 4.1 on page 48). None of those, however, is applicable to the use of cadmium and cadmium compounds in the scope of the requested exemption.

Based on the current status of Annexes XIV and XVII, granting the requested exemption would not weaken the environmental and health protection afforded by the REACH

Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

25.3.2. Substitution and elimination of the restricted substances

MOCON explained that to ensure the availability of Hersch cells on the market, while the exemption for cadmium anodes in Hersch cells (IV-43) expired on 15 July 2023, they are developing a Hersch cell oxygen sensor with a lead anode, for which MOCON also requested a renewal of exemption IV-1(b).

When asked how the substitution of cadmium with lead was achieved, (MOCON 2024a) elaborated that the properties of lead are the most similar to the original design of cadmium, however, lead has distinct different technical parameters compared to cadmium. Importantly however, it still offers the necessary technical performance, especially when compared to alternatives that are free of RoHS restricted substances. Work to develop a fully RoHS restricted substance free alternative is still on-going but requires more time. The process to move from cadmium to lead is expected to take 24 to 36 months in total, with the development of the lead sensor still ongoing. It is important to note that due to the larger fundamental differences in properties between RoHS restricted substances and alternative, RoHS-compliant substances, the timeframe to qualify the latter is expected to be longer, and it is still not clear if they will be able to offer all of the necessary technical performance characteristics.

When first investigating a cadmium replacement, as well as RoHS compliant alternatives, an important item that must be considered is thermodynamic nobility. Thermodynamic nobility of any metal is assessed in contrast to the standard hydrogen electrode (0 V). Metals with a higher equilibrium reaction potential are considered more noble thus being less likely to corrode and poor anode candidates. Lead's thermodynamic nobility is quite similar to that of Cadmium, with standard reduction potentials of (-0.58 V) and (-0.81 V), respectively.

Specific capacity (mAh/g) or the amount of charge that can be held per gram of material is another characteristic that must be considered for replacement sensors. The specific capacity of lead is lower than cadmium meaning more material is required to achieve the same level of performance. As the amount of material is changed, considerations must be made for the anode area available within the sensor, as well as the amount of electrolyte used per sensor. Too much electrolyte per unit area of anode material reduces response time, while insufficient electrolyte reduces sensor efficiency.

(MOCON 2024a) further note that the quantity of electrolyte is one of many items that impact sensor response and efficiency. For example, the solubility of reaction products can also impede the reaction kinetics as well as contaminate the electrolyte both slowing down the sensor and making it less efficient.

Lastly, according to (MOCON 2024a), all of these parameters and others discussed in the renewal application require testing, and hence why the transition from cadmium to lead took some time to complete.

The consultants noted that MOCON relied on the report by (Goodman 2006) when discussing the potential to substitute cadmium with alternative substances, which was published in 2006, i.e. approximately 18 years ago. When asked whether tests had been carried out using other potential substitutes for lead since then, (MOCON 2024a) confirmed this, stating: *MOCON continues to research potential anode substitutes for both cadmium*

and lead based Hersch sensors. However, due to the demanding technical requirements of a Hersch cell, any change can have a detrimental impact on performance. For example, changing a single component in the cadmium version of the Hersch cell took 3 years to undertake and fully qualify. As a result, the development of a RoHS compliant Hersch cell requires meticulous and time-consuming attention to detail. To date, many development activities have taken place many of which were highlighted in our lead extension application. Since then, additional theoretical and experimental work has been conducted to narrow down potential candidates. Based on theoretical cell potentials, only seven metals exhibit characteristics that could work inside a Hersch Coulometric Cell (Alkaline Electrolyte). Three of these have been the focus of ongoing experimental investigations as they have the most similarities to lead and cadmium. However, experiment results have still not led to a suitable substitute. Shifting to an acidic electrolyte could open new options, which will be studied if no encouraging progress is made with the current alkaline one. The move to an acidic electrolyte would trigger the need for more extensive testing and potentially design changes of the sensor. Overall, this would have the impact of creating an even longer timeline to qualify a RoHS-substance free alternative, and why this has not been trailed at this point.

(MOCON 2024a) conclude that it is still uncertain whether a RoHS compliant alternative anode material will be able to offer the necessary technical performance we require of the Hersch Cell. Even with the most recent developments in technology, there are no other technologies which can detect oxygen to the very low concentrations which Hersch cells are able to detect.

Given that MOCON had both requested this exemption for the use of cadmium in Hersch cells and requested a renewal of exemption IV-1(b) to use lead in Hersch cells, the consultants inquired whether both variants would be needed on the market.

(MOCON 2024a) explained that the application for lead was submitted to ensure that Hersch cell devices, as MOCON is the only manufacturer worldwide of such devices, were able to be placed on the market. This is due to the consideration that the timeframe to renew the use for cadmium had passed and we were informed that this would be treated as a new application not benefiting from continued validity while the application was reviewed. The transition to lead ensures that the critical functions that Hersch cells provide are still able to be provided, although there are manufacturability concerns as outlined in our answer above.

(MOCON 2024b) added that as long as there is an exemption permitting the use of Hersch cells on a continuing basis, only one or the other exemption would need to be granted to cover the necessary uses. However, it is essential that the lead-based exemption is not rejected until the cadmium based exemption is fully implemented, such that devices are able to be continually sold in the EU.

MOCON had stated that cadmium is more toxic than lead. When asked whether this should mean that the phasing out of cadmium in favour of lead-based Hersch cells would be preferable, (MOCON 2024b) stated that it would be their preference that the exemption for cadmium be granted over lead due to the reduction in manufacturability of the lead sensors (~20 % reduction in sensors which meet performance criteria). Due to these manufacturing issues, there is an increase in scrap of such sensors from this, and therefore an increase in the use of lead overall to meet the customer demand for sensors of this type. It is also worthwhile noting that there is a difference between the amount of lead required for a cadmium sensor and a lead sensor, so this should be considered when reviewing the

potential environmental impact. The cadmium Hersch sensor uses at least 24 % less by weight than the lead Hersch sensor.

In light of the applicant‘s above explanations, the consultants conclude that the substitution of cadmium by lead may not involve any environmental or health benefits. RoHS Art. 4(2) sets a threshold value of 0.01 % for cadmium in homogeneous materials compared to 0.1 % for lead. This may be interpreted that cadmium is more toxic than lead. The lower amounts of cadmium in Hersch cells with cadmium anodes compared to the amount of lead in Hersch cells with lead anodes, and the reduced manufacturability of the latter, may, at least in part, compensate the lower toxicity of lead. This raises, however, the question whether an additional exemption for lead in Hersch cell as requested by the applicant is actually required. [138]

The consultants noticed that MOCON requested an exemption wording which does not match the wording of exemption IV-43, which previously covered cadmium-based Hersch cells. The wording of exemption IV-43 set a sensitivity threshold of “below 10 ppm”, while (MOCON 2022) requested the wording with a threshold of 100 ppm. *When asked for the rationale for this requested change, (MOCON 2024b) stated that Hersch sensors are able to measure to 100 ppm, with the useable range of sensor between 200 ppt to 70 ppm. As such, although both values are technically correct, it is most accurate to say that the sensor is able to measure to 100 ppm and below.*

Given that the useable range of Hersch sensors is between 200 ppt and 70 ppm, the consultants understand that confusion may arise regarding whether the sensors are covered by the exemption or not when the criterion for coverage is defined by “where sensitivity below 10 ppm is required”. In the consultants’ view, the function of the sensitivity threshold in the exemption wording is not entirely clear. Due to the fact that Hersch cells are explicitly mentioned in the wording, and MOCON are the only manufacturer of Hersch cells, it does not seem necessary to exclude other sensor technologies via a sensitivity threshold. However, it is also not detrimental to the definition of the exemption and its scope to maintain a sensitivity threshold as part of the wording. In the consultants’ view, whether the threshold is set at 10 ppm or 100 ppm is not expected to make a difference regarding the range of equipment covered by the exemption. Therefore, the argument that setting the sensitivity threshold at 100 ppm to ensure the entire useable range of Hersch sensors is covered, thereby avoiding uncertainty that arises from a threshold that covers only a part of the range, can be followed in the consultant’s opinion.

MOCON applied for this exemption using the wording “*Cadmium in Hersch cells for oxygen sensors used in industrial monitoring and control instruments, where sensitivity below 100 ppm is required”.* In parallel, MOCON applied for a renewal of exemption IV-1(b) with the wording *“Lead anodes in electrochemical Hersch cells for oxygen sensors for measurement of permeation”.* When asked whether, in their view, differing wording is required under exemption IV-1(b) and the current exemption request, with the obvious difference in the material, *(MOCON 2024b) responded that the differences in the requested exemption wording is a reflection of their thinking at the time in which the exemptions were submitted and not a reflection of technical differences. As such, either wording would cover their applications.*

[138] This question was addressed in the review of MOCON’s renewal request for lead anodes in Hersch cells under exemption IV-1(b)

In the consultants' view, the information provided by the applicants plausibly shows that only Hersch cells are capable of measuring the extremely low oxygen concentration ranges, and that, thus far, only lead- and cadmium-based anodes are capable of achieving this. Therefore, it seems reasonable to the consultants that the substitution and elimination of cadmium are technically and scientifically not yet practicable. Further, to ensure that Hersch cells continue to be available on the market, it appears reasonable to renew exemption 1(b) to cover lead-based Hersch cells until a new exemption for cadmium-based Hersch cells can be granted.

25.3.3. Environmental, health, safety, and socio-economic impacts

Given that Hersch cells have unique characteristics, particularly the measurement of extremely low oxygen concentration ranges, which cannot be matched by other oxygen sensor technologies, it cannot be excluded that the impacts described by the applicants may occur in case the exemption was not granted.

25.3.4. Summary and conclusions

Cadmium anodes in Hersch cell oxygen sensors were in the past covered by exemption 43, which expired on 15 July 2023. The sole manufacturer of Hersch cells, MOCON, requested the renewal of exemption 43 within 18 months before the expiry date. Therefore, their request cannot be considered a renewal request but is instead treated as a request for a new exemption. In practice, MOCON is therefore not able to place cadmium-based Hersch cells on the market at this time.

Hersch cells have unique properties. They allow for absolute measurements of oxygen that requires no calibration, and they are capable of measuring extremely low oxygen concentration ranges down to 200 ppt that cannot be matched by any other oxygen sensor technology.

To ensure the availability of Hersch cells on the market, as they are needed for permeation measurements in industries such as food and pharmaceutical packaging, MOCON is developing Hersch cells using lead anodes instead of cadmium anodes. In parallel to this exemption request, they have therefore also requested a renewal of exemption 1(b) that covers lead anodes in electrochemical oxygen sensors. Exemption 1(b) therefore covers lead anodes in Hersch cells while it is being reviewed in parallel with this new exemption request for cadmium anodes in Hersch cells.

MOCON have provided plausible arguments that cadmium (and lead) are the only materials that are currently capable of achieving the unique technical specifications of Hersch cells. Therefore, in the consultants' view, substitution or elimination of cadmium with substances not restricted under RoHS are scientifically and technically still impracticable, and a renewal of the exemption for Hersch cells appears to be justified in line with Art. 5(1)(a).

MOCON requested an exemption (IV-2022-2) to cover cadmium-based Hersch cells for the maximum validity period of 7 years. Given the lack of substitution and elimination possibilities at the current time, the consultants consider the timeframe proposed for the use of cadmium in Hersch cells justified.

As stated, MOCON also requested a renewal of exemption IV-1(b) until January 2028 to cover lead-based Hersch cells while cadmium-based Hersch cells are not covered by any

exemption. The consultants consider it may be appropriate to cover both exemptions for Hersch cells within the same exemption series, such as under exemption IV-1(b), which is specific to electrochemical oxygen sensors, albeit thus far only covering lead.

The previous exemption covering cadmium anodes in Hersch cell sensors set a sensitivity threshold of 10 ppm. However, this covers only a part of the useable range of Hersch cell sensors, being 200 ppt up to 70 ppm, which may lead to confusion regarding the coverage of Hersch cells. The consultants do not consider a risk of broadening the scope when the threshold would be changed to 100 ppm as requested by MOCON, given that Hersch cells are explicitly mentioned in the exemption wording, i.e. other sensor technologies will not benefit from the exemption either way.

Regarding the exemption wording, the consultants considered proposing a technologically open phrasing that restricts the scope of the exemption to oxygen sensor technologies that are capable of absolute measurements of oxygen at extremely low concentrations, without explicitly mentioning Hersch cells, which are a proprietary technology of one individual manufacturer. However, this would allow other manufacturers to develop and market sensor technologies to use cadmium, and lead under exemption 1(b), which may not be a desirable outcome when considering the goals of the RoHS Directive. Therefore, to keep the scope of the exemption as narrow as possible, the consultants consider maintaining a wording that explicitly mentions Hersch cells may be most suitable.

In case future reviews of this exemption are conducted, the consultants consider a renewed discussion of the progress of efforts to qualify alternative materials not restricted by the RoHS Directive as anode materials is needed.

25.4. Recommendation

The consultants recommend granting the exemption. However, instead of granting a new exemption with a new numbering, it may be more appropriate to grant an exemption for cadmium in Hersch cells as a new exemption under exemption IV-1(b). Exemption IV-1(b) is recommended by the consultants to be split into a number of exemption 1(b) series on lead in different oxygen sensor technologies, including lead in Hersch cells.

Therefore, if the COM decides to follow the consultants' recommendations, it is recommended using the wording and scope as shown in the below table, to align with the wording of related exemptions under exemption 1(b):

No.	Exemption	Scope and dates of applicability
IV-1(b)(V)	Cadmium anodes in Hersch cells for oxygen sensors where sensitivity below 100 ppm is required.	Applies to cat. 9 including industrial monitoring and control instruments and expires on - [7 years after official publication of the COM's decision]

Applicants' feedback on the recommendation

(MOCON 2024c) stated to agree with the above recommendation.

25.5. References

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