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

August 2022

Prepared by Fraunhofer-Institute for Reliability and Microintegration (IZM), the United Nations Institute for Training and Research (UNITAR), and BIO Innovation Services (Bio IS)

Dr. Otmar Deubzer, Fraunhofer IZM, UNITAR
Christian Clemm, UNITAR
Jana Rückschloss, Fraunhofer IZM
Saskia Huber, Fraunhofer IZM
Shailendra Mudgal, Bio IS

18 August 2022

United Nations Institute for Training and Research (UNITAR) Bonn Office

UN Campus, Platz der Vereinten Nationen 1, 53113 Bonn, Germany
Tel: +49-30-417 258 33
Web: https://unitar.org/about/offices-training-centres-around-world/bonn
E-mail: otmar.deubzer@unitar.org

Fraunhofer IZM

Gustav-Meyer-Allee 25
13355 Berlin, Germany
Tel.: +49 (0)30 / 46403-157
Fax: +49 (0)30 / 46403-131
Web: www.fraunhofer.de
E-mail: christian.clemm@izm.fraunhofer.de

BIO Innovation Service

7 rue Oberkampf
75011 Paris (France)
Tel: +33 662 767 565
Fax: +33 95 72 12 598
E-mail: contact@biois.eu

Acknowledgements

We would like to express our gratitude towards stakeholders who contributed information concerning the requests for exemptions handled in the course of this project.

EUROPEAN COMMISSION

Directorate-General for Environment
Directorate B — Circular Economy and Green Growth
Unit [B3 — Waste Management and Secondary Materials

Contact: Hendrik Engelkamp

E-mail: hendrik.engelkamp@ec.europa.eu

European Commission
B-1049 Brussels

LEGAL NOTICE

Print	ISBN [number]	ISSN [number]	doi: [number]	[Catalogue number]
PDF	ISBN [number]	ISSN [number]	doi: [number]	[Catalogue number]
EPUB	ISBN [number]	ISSN [number]	doi: [number]	[Catalogue number]
HTML	ISBN [number]	ISSN [number]	doi: [number]	[Catalogue number]

Printed by [XXX] in [Country]

PRINTED ON ELEMENTAL CHLORINE-FREE BLEACHED PAPER (ECF)

PRINTED ON TOTALLY CHLORINE-FREE BLEACHED PAPER (TCF)

PRINTED ON RECYCLED PAPER

PRINTED ON PROCESS CHLORINE-FREE RECYCLED PAPER (PCF)

Manuscript completed in March 2022

First Draft edition

The European Commission is not liable for any consequence stemming from the reuse of this publication.

Luxembourg: Publications Office of the European Union, 2022

Table of Contents

List of Figures

List of Tables

1. Executive 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 16 exemptions to Annex IV 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 Annex 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 request covered in this project and the applicant concerned, as well as the final recommendation and proposed expiry date are presented in Table 1-1 below. In cases where more than one option is recommended for the COM to choose, only one option is listed in the below table. An asterisk is added to indicate this situation. Like in the RoHS legal text, commas are used as a decimal separator for exemption wordings appearing in this table, in contrast to the decimal point used throughout the rest of the report as a separator.

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

Ex. no	Current exemption wording	Appli-cants	Recommendation	Expiry date and scope IVD: in-vitro diagnostic medical devices (I)MCI: (industrial) monitoring and control instruments
IV-1	*Pb, Cd and Hg in detectors for ionising radiation*	COCIR JBCE	**Renew with modified scope:** *1(I): Cadmium in cadmium telluride and cadmium zinc telluride detectors for ionising radiation* *1(II):* *Lead in coatings of ionisation chambers of X-ray detectors*	1(I): 21 July 2028 for cat 8 medical devices others than IVD, and for cat. 9 MCI including IMCI 1(II): Expiry on 21 July 2024 for cat 8 med. devices others than IVD
IV-1(a)	*Lead and cadmium in ion selective electrodes including glass of pH electrodes*	JBCE	**Renew* with modified scope:** *1(a): Lead and cadmium in ion selective electrodes including glass of pH electrodes* *1(a)-I: Cadmium in ion selective electrodes including glass of pH electrodes* *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.*	1(a): 21 July 2023 for cat. 8 IVD 1(a)-I: 21 July 2024 for cat. 9 IMCI 1(a)-II: 21 July 2025 for cat. 9 MCI incl. IMCI

Ex. no	Current exemption wording	Appli-cants	Recommendation	Expiry date and scope IVD: in-vitro diagnostic medical devices (I)MCI: (industrial) monitoring and control instruments
IV-1(b)	*Lead anodes in electrochemical oxygen sensors*	COCIR JBCE	**Renew with modified scope:** *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.* *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.* *(b) designed for the measurement of dissolved oxygen in concentrations below 30 ppb.*	1(b)-I: 21 July 2025 for cat. 8 med. devices others than IVD 1(b)-II: 21 July 2025 for cat. 9 MCI incl. IMCI
IV-1(c)	*Lead, cadmium, and mercury in infrared light detectors*	COCIR JBCE Laser Comp. Perkin Elmer PPTF	**Renew with modified scope:** *1(c)-I:* *Cadmium and mercury in mercury cadmium telluride (MCT) of infrared-detectors* *1(c)-II: Lead in lead sulphide (PbS) and lead selenide (PbSe) of infrared detectors* *1(c)-III: Lead in PZT ceramics of infrared light detectors*	1(c)-I: 21 July 2028 for cat. 8 med. devices incl. IVD, and for cat. 9 MCI incl. IMCI 1(c)-II: 21 July 2028 for cat. 8 med. devices incl. IVD, and for cat. 9 MCI incl. IMCI 1(c)-III: - 21 July 2023 for cat. 8 IVD - 21 July 2027 for cat. 9 MCI incl. IMCI
IV-2	*Lead bearings in X-ray tubes*	COCIR	**Renew with current wording:** *Lead bearings in X-ray tubes*	- 21 July 2024 for cat. 9 IMCI - 21 July 2028 for cat. 8 med. devices others than IVD
IV-3	*Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate*	COCIR	**Renew with modified scope:** *Lead in electromagnetic radiation amplification devices: capillary plate* *Note: Micro-channel plates were transferred to ex. IV-39*	- 21 July 2021 for cat. 8 med. devices others than IVDs and for cat. 9 MCI others than IMCI - 21 July 2023 for cat. 8 IVD - 21 July 2024 for cat. 9 IMCI

Ex. no	Current exemption wording	Appli-cants	Recommendation	Expiry date and scope IVD: in-vitro diagnostic medical devices (I)MCI: (industrial) monitoring and control instruments
IV-5	*Lead in shielding for ionising radiation*	COCIR JBCE TMC	**Renew with current wording:** *Lead in shielding for ionising radiation*	- 21 July 2026 for category 8 med. devices others than IVD - 21 July 2026 for category 9 MCI incl. IMCI
IV-11	*Lead in alloys as a superconductor and thermal conductor in MRI*	COCIR	**Renew* with modified scope:** *Lead in alloys as a superconductor in MRI and NMR*	21 July 2028 for cat. 8 med. devices other than IVD, and for cat. 9 IMCI
IV-13	*Lead in counterweights*	COCIR	**Renew with modified scope:** *Lead in counterweights of surgical C-arm X-ray and C-arm fluoroscopy devices designed to have a radiologist present with the patient*	21 July 2026 for cat. 8 med. devices others than IVD
IV-14	*Lead in single crystal piezoelectric materials for ultrasonic transducers*	*COCIR*	**Renew with current wording:** *Lead in single crystal piezoelectric materials for ultrasonic transducers*	- 21 July 2023 for cat. 8 IVD - 21 July 2024 for cat. 9 IMCI - 21 July 2025 for cat. 8 med. devices others than IVD
IV-15	*Lead in solders for bonding to ultrasonic transducers*	COCIR JBCE	**Renew with current wording:** *Lead in solders for bonding to ultrasonic transducers*	- [Date of the COM's decision + 12 months] for cat. 9 MCI others than IMCI - 21 July 2023 for cat. 8 IVD - 21 July 2024 for IMCI - 21 July 2028 for cat. 8 med. devices others than IVD [for which the Declaration of Conformity is issued for the first time before 1 January 2014]
IV-17	*Lead in solders of portable emergency defibrillators*	COCIR	**Renew* [with modified wording]:** *Lead in solders in portable emergency defibrillators [for which the Declaration of Conformity is issued for the first time before 1 January 2015]*	31 December 2025 for cat. 8 med. devices others than IVD
IV-26	*Lead in the following applications that are used durably at a temperature below –20 °C under normal operating and storage conditions:* *(a) solders on printed circuit boards;* *(b) termination coatings of electrical and electronic components and coatings of printed circuit boards;*	COCIR Lake Shore	**Renew with current wording and revised structure:** - *26(a):* *Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions:* *(I) solders on printed circuit boards;*	26(a): - 30 June 2026 for cat. 8 low helium content MRI (< 10 kg/device) - 30 June 2027 for other cat. 8 MRI scanners for which the Declaration of Conformity is issued for the first time before 30 June 2024

Ex. no	Current exemption wording	Appli-cants	Recommendation	Expiry date and scope IVD: in-vitro diagnostic medical devices (I)MCI: (industrial) monitoring and control instruments
	(c) solders for connecting wires and cables; *(d) solders connecting transducers and sensors.* *Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C.*		*(II) termination coatings of electrical and electronic components and coatings of printed circuit boards;* *(III) solders for connecting wires and cables;* *(IV) solders connecting transducers and sensors.* - *26(b): Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °**C***	26(b): 30 June 2028 for cat. 8 med. devices incl. IVD and cat. 9 MCI incl. IMCI
IV, 29	*Lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments.*	COCIR	**Renew with modified scope:** *29(a):* *Lead in alloys as a thermal conductor in cryo-cooled cold probes in medical devices*	30 June 2024 for cat. 8 med. devices others than IVD
IV-31(a)	*Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.*	COCIR	**Renew with modified scope:** *Lead, cadmium, hexavalent chromium, and deca-brominated diphenyl ethers (deca-BDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that* - *the reuse takes place in auditable closed-loop business-to-business return systems;* - *that each reuse of parts is notified to the customer; and* - *that the reuse does not weaken the environmental and health protection afforded by regulation (EC) No 1907/2006.*	21 July 2028 for ca.8 med. devices incl. IVD

Ex. no	Current exemption wording	Appli-cants	Recommendation	Expiry date and scope IVD: in-vitro diagnostic medical devices (I)MCI: (industrial) monitoring and control instruments
IV-39	*Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is present:* *(a) a compact size of the detector for electrons or ions, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable;* *(b) a two-dimensional spatial resolution for detecting electrons or ions, where at least one of the following applies:* *(I) a response time shorter than 25 ns;* *(II) a sample detection area larger than 149 mm^2;* *(III) a multiplication factor larger than $1,3 \times 10^3$.* *(c) a response time shorter than 5 ns for detecting electrons or ions;* *(d) a sample detection area larger than 314 mm^2 for detecting electrons or ions;* *(e) a multiplication factor larger than $4,0 \times 10^7$.*	JBCE	**Renew* with modified scope to include MCPs from ex. IV-3:** *Lead in micro-channel plates (MCPs) used in equipment for the amplification or detection of ionising radiation, electrons or ions, where at least one of the following properties is present:* *(a) a compact size of the detector, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable;* *(b) a two-dimensional spatial resolution, where at least one of the following applies:* *(I) a response time shorter than 25 ns;* *(II) a sample detection area larger than 149 mm^2;* *(III) a multiplication factor larger than $1,3 \times 10^3$.* *(c) a response time shorter than 5 ns;* *(d) a sample detection area larger than 314 mm^2;* *(e) a multiplication factor larger than $4,0 \times 10^7$.*	31 December 2026 for cat. 8 medical devices including in-vitro diagnostic medical devices and cat. 9 monitoringa and control instruments including industrial monitoring and control instruments

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 16 exemptions à l'annexe IV 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. Dans les cas où il est recommandé à la COM de choisir plus d'une option, seule une option est mentionnée dans le tableau ci-dessous. Un astérisque est ajouté pour indiquer cette situation. Comme dans le texte juridique de la Directive ROHS, des virgules sont utilisées comme séparateur décimal pour les libellés d'exemption apparaissant dans ce tableau, contrairement au point décimal utilisé comme séparateur dans le reste du rapport.

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

Ex. no	Formualtion actuelle de l'exemption	Candi-dats	Recommendation	Date d'expiration et champ d'application DIV: Dispositifs médicaux de diagnostique In-Vitro IMC(I): Instruments de mesure et de contrôle (Industriels)
IV-1	*Le plomb, le cadmium et le mercure dans des détecteurs de rayonnements ionisants*	COCIR JBCE	**Renouveler avec un champ d'application modifié :** *1(I): Le cadmium dans le tellurure de cadmium et dans le tellurure de cadmium-zinc utilisé dans les détecteurs de rayonnement ionisants* *1(II):* *Le plomb dans les revêtements des chambres d'ionisation des détecteurs de rayons-X.*	1(I): 21 juillet 2028 pour la cat 8 dispositifs méd. autres que DIV, et pour la cat. 9 IMC y compris les IMCI, y pour la cat 8 dispositifs méd. autres que les DIV 1(II): Expire le 21 juillet 2024 pour la cat 8 dispositifs méd. autres que les DIV
IV-1(a)	*Le plomb et le cadmium dans les électrodes sélectives d'ions, y compris le verre des électrodes de mesure du pH*	JBCE	**Renouveler* avec un champ d'application modifié :** *1(a) : Le plomb et le cadmium dans les électrodes sélectives d'ions, y compris le verre des électrodes de mesure du pH* *1(a)-I: Le cadmium dans les électrodes sélectives d'ions, y compris le verre des électrodes de mesure du pH* *1(a)-II: Le plomb dans le verre de tige des électrodes de mesure du pH en verre et des électrodes sélectives d'ions est équipé d'une électrode de mesure du pH en verre de forme complexe comme suit :* - *Electrode de mesure du pH en verre de type micro* *Electrode composite comportant une membrane de verre sensible au pH, sphérique ou tubulaire, d'un diamètre inférieur ou égal à 4,0 mm, et une électrode de référence avec une jonction liquide à une position verticale située à moins de 6,5 mm de la pointe ;* - *Electrode de mesure du pH en verre de type plat*	1(a): 21 juillet 2023 pour la cat. 8 DIV 1(a)-I: 21 juillet 2024 pour la cat. 9 IMCI 1(a)-II: 21 juillet 2025 pour la cat. 9 IMC y compris les IMCI

Ex. no	Formualtion actuelle de l'exemption	Candi-dats	Recommendation	Date d'expiration et champ d'application DIV: Dispositifs médicaux de diagnostique In-Vitro IMC(I): Instruments de mesure et de contrôle (Industriels)
			Electrode de mesure du pH en verre avec une membrane plate sensible au pH à l'extrémité d'un tube de verre d'un diamètre de 6,0 mm ou plus ; - *Électrode de mesure du pH en verre de type aiguille* *Électrode composite dont la membrane sensible au pH est conique, dont l'angle de pointe est inférieur ou égal à 40° et dont le diamètre est supérieur ou égal à 10 mm.*	
IV-1(b)	*Les anodes en plomb dans les capteurs électrochimiques d'oxygène*	COCIR JBCE	**Renouveler avec un champ d'application modifié :** *1(b)-I : 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.* *1(b)-II : Le plomb dans les capteurs d'oxygène galvaniques dans les instruments* *(a) conçus pour la mesure de l'oxygène dans les gaz avec un temps de réponse < 3 s (t95) et qui ne sont pas des dispositifs portatifs* *(b) conçus pour la mesure de l'oxygène dissous dans des concentrations inférieures à 30 ppb.*	1(b)-I: 21 juillet 2025 pour la cat. 8 dispositifs méd. autres que les DIV 1(b)-II: 21 juillet 2025 pour la cat. 9 IMC y compris les IMCI
IV-1(c)	*Le plomb, le cadmium et le mercure dans les détecteurs à infrarouges*	COCIR JBCE Laser Comp. Perkin Elmer PPTF	**Renouveler avec un champ d'application modifié :** *1(c)(I) :* *Le cadmium et le mercure dans le tellurure de mercure-cadmium (HgCdTe) dans les détecteurs à infrarouges* *1(c)(II) : Le plomb dans le sulfure de plomb (PbS) et le séléniure de plomb (PbSe) dans les détecteurs à infrarouge* *1(c)(III): Le plomb dans les céramiques en PZT dans les détecteurs à infrarouge*	1(c)(I): 21 juillet 2028 pour la cat. 8 dispositifs méd. y compris les DIV, et pour la cat. 9 IMC y compris les IMCI 1(c)(II): 21 juillet 2028 pour la cat. 8 dispositifs méd. y compris les DIV, et pour la cat. 9 IMC y compris les IMCI 1(c)(III): - 21 juillet 2023 pour la cat. 8 DIV

Ex. no	Formualtion actuelle de l'exemption	Candi-dats	Recommendation	Date d'expiration et champ d'application DIV: Dispositifs médicaux de diagnostique In-Vitro IMC(I): Instruments de mesure et de contrôle (Industriels)
				- 21 juillet 2027 pour la cat. 9 IMC y compris les IMCI
IV-2	*Les paliers en plomb dans les tubes à rayons X*	COCIR	**Renouveler avec la formulation actuelle :** *Les paliers en plomb dans les tubes à rayons X*	- 21 juillet 2024 pour la cat. 9 IMC - 21 juillet 2028 pour la cat. 8 dispositifs méd. autres que les DIV
IV-3	*Le plomb dans les dispositifs d'amplification des rayonnements électromagnétiques : galette de microcanaux et plaque capillaire*	COCIR	**Renouveler avec un champ d'application modifié :** *Le plomb dans les dispositifs d'amplification des rayonnements électromagnétiques : plaque capillaire* *Note : Les galettes de microcanaux ont été transférées dans l'ex.IV-39*	- 21 juillet 2021 pour la cat. 8 dispositifs méd. autres que DIVs et pour la cat. 9 IMC autres que IMCI - 21 juillet 2023 pour la cat. 8 DIV - 21 juillet 2024 pour la cat. 9 IMCI
IV-5	*Le plomb dans les protections contre les rayonnements ionisants*	COCIR JBCE TMC	**Renouveler avec la formulation actuelle :** *Le plomb dans les protections contre les rayonnements ionisants*	- 21 juillet 2026 pour la category 8 dispositifs méd. autres que DIV - 21 juillet 2026 pour la category 9 IMC y compris IMCI
IV-11	*Le plomb dans les alliages en tant que supraconducteur et conducteur de chaleur pour l'IRM*	COCIR	**Renouveler* avec un champ d'application modifié :** *Le plomb dans les alliages en tant que supraconducteur pour l'IRM et la RMN*	21 juillet 2028 pour la cat. 8 dispositifs méd. autres que DIV, et pour la cat. 9 IMCI
IV-13	*Le plomb dans les contrepoids*	COCIR	**Renouveler avec un champ d'application modifié :** *Le plomb dans les contrepoids des appareils chirurgicaux de radiographie et de fluoroscopie à bras en C conçus pour qu'un radiologue soit présent avec le patient*	21 juillet 2026 pour la cat. 8 dispositifs méd. autres que DIV
IV-14	*Le plomb dans les monocristaux piézo-électriques pour les transducteurs ultrasoniques*	*COCIR*	**Renouveler avec la formulation actuelle :** *Le plomb dans les monocristaux piézo-électriques pour les transducteurs ultrasoniques*	- 21 juillet 2023 pour la cat. 8 DIV - 21 juillet 2024 pour la cat. 9 IMCI - 21 juillet 2025 pour la cat. 8 dispositifs méd. autres que DIV
IV-15	*Le plomb dans les soudures des transducteurs ultrasoniques*	COCIR JBCE	**Renouveler avec la formulation actuelle :** *Le plomb dans les soudures des transducteurs ultrasoniques*	- [Date de la decision de la COM + 12 à 18 mois] pour la cat. 9 IMC autres que IMCI - 21 juillet 2023 pour la cat. 8 DIV - 21 Juillet 2024 for IMCI - 21 juillet 2028 pour la cat. 8 dispositifs méd. autres que DIV [pour lesquels la Déclaration de Conformité a été publiée pour la première fois avant le 1er janvier 2014]

Ex. no	Formualtion actuelle de l'exemption	Candi-dats	Recommendation	Date d'expiration et champ d'application DIV: Dispositifs médicaux de diagnostique In-Vitro IMC(I): Instruments de mesure et de contrôle (Industriels)
IV-17	*Le plomb dans les soudures pour les défibrillateurs portables d'urgence*	COCIR	**Renouveler* avec un champ d'application modifié :** *Le plomb dans les soudures pour les défibrillateurs portables d'urgence [pour lesquels la Déclaration de Conformité a été publiée pour la première fois avant le 1 janvier 2015]*	31 décembre 2025 pour la cat. 8 dispositifs méd. autres que les DIV
IV-26	*Le plomb dans les applications suivantes, utilisées durablement à une température inférieure à – 20 °C dans des conditions normales de fonctionnement et de stockage :* *a) les soudures sur les cartes de circuits imprimés ;* *b) les revêtements des extrémités des composants électriques et électroniques et les revêtements des cartes de circuits imprimés ;* *c) les soudures de raccordement des fils et des câbles ;* *d) les soudures de raccordement des transducteurs et des capteurs.* *Le plomb dans les soudures de raccordement électrique des capteurs de température incorporés dans les dispositifs destinés à être utilisés périodiquement à des températures inférieures à – 150 °C.*	COCIR Lake Shore	**Renouveler avec la formulation actuelle et la structure révisée :** - *26(a) Le plomb dans les applications suivantes, utilisées durablement à une température inférieure à – 20 °C dans des conditions normales de fonctionnement et de stockage :* *(I) les soudures sur les cartes de circuits imprimés ;* *(II) les revêtements des extrémités des composants électriques et électroniques et les revêtements des cartes de Circuits imprimés ;* *(III) les soudures de raccordement des fils et des câbles ;* *(IV) les soudures de raccordement des transducteurs et des capteurs.* - *26(b): Le plomb dans les soudures de raccordement électrique des capteurs de température incorporés dans les dispositifs destinés à être utilisés périodiquement à des températures inférieures à – 150 °C.*	26(a): - 30 juin 2026 pour la cat. 8 IRM à faible teneur en hélium (< 10 kg/appareil) - 30 juin 2027 les autres cat. 8 de scanners IRM pour lequesls la Déclaration de Conformité est publiée pour la première fois avant le 30 juin 2024 26(b): 30 juin 2028 pour la cat. 8 dispositifs méd. y compris DIV et cat. 9 IMC y compris IMCI

Ex. no	Formualtion actuelle de l'exemption	Candi-dats	Recommendation	Date d'expiration et champ d'application DIV: Dispositifs médicaux de diagnostique In-Vitro IMC(I): Instruments de mesure et de contrôle (Industriels)
IV, 29	*Le plomb en tant que supraconducteur ou thermoconducteur dans les alliages utilisés dans les têtes froides des cryoréfrigérateurs et/ou dans les sondes froides cryoréfrigérées et/ou dans les systèmes de liaison équipotentielle cryoréfrigérés, dans les dispositifs médicaux (catégorie 8) et/ou dans les instruments de surveillance et de contrôle industriels. Expire le 30 juin 2021.*	COCIR	**Renouveler avec un champ d'application modifié :** *29(a):* *Le plomb en tant que thermoconducteur dans les alliages utilisés dans les sondes froides cryoréfrigérées dans les dispositifs médicaux.*	30 juin 2024 pour la cat. 8 dispositifs méd. autres que DIV
IV-31(a)	*Le plomb, le cadmium, le chrome hexavalent et les polybromodiphényléthers (PBDE) dans les pièces détachées récupérées sur des dispositifs médicaux, y compris les dispositifs médicaux de diagnostic in vitro, ou sur des microscopes électroniques et leurs accessoires et utilisées pour la réparation ou la remise à neuf de ces dispositifs médicaux ou appareils, à condition que ce réemploi s'effectue dans le cadre de systèmes de récupération interentreprises en circuit fermé et contrôlables et que chaque réemploi de pièces soit notifié aux consommateurs.*	COCIR	**Renouveler avec un champ d'application modifié :** *Le plomb, le cadmium, le chrome hexavalent et les polybromodiphényléthers (PBDE) dans les pièces détachées récupérées sur des dispositifs médicaux, y compris les dispositifs médicaux de diagnostic in vitro, ou sur des microscopes électroniques et leurs accessoires et utilisées pour la réparation ou la remise à neuf de ces dispositifs médicaux ou appareils, à condition que :* - *ce réemploi s'effectue dans le cadre de systèmes de récupération interentreprises en circuit fermé et contrôlables ;* - *que chaque réemploi de pièces soit notifié aux consommateurs; et* - *que le réemploi n'affaiblisse pas la protection de l'environnement et de la santé assurée par le Règlement (CE) n° 1907/2006* *y compris les dispositifs médicaux de diagnostic in vitro, ou sur des microscopes électroniques et leurs accessoires et utilisées pour la réparation ou la remise à neuf de ces dispositifs médicaux ou appareils, à condition que ce réemploi s'effectue dans le cadre de systèmes de récupération interentreprises en circuit fermé et contrôlables et que chaque réemploi de pièces soit notifié*	21 juillet 2028 pour la cat.8 dispositifs méd., y compris l'utilisation dans des dispositifs médicaux, y compris les DIV

Ex. no	Formualtion actuelle de l'exemption	Candi-dats	Recommendation	Date d'expiration et champ d'application DIV: Dispositifs médicaux de diagnostique In-Vitro IMC(I): Instruments de mesure et de contrôle (Industriels)
			aux consommateurs.	
IV-39	*Le plomb dans les galettes de microcanaux (GMC) utilisées dans des équipements présentant au moins une des propriétés suivantes :* *a) un détecteur d'électrons ou d'ions de taille compacte, lorsque l'espace pour le détecteur est limité à un maximum de 3 mm/GMC (épaisseur du détecteur + espace pour l'installation de la GMC) et à un maximum de 6 mm au total, et qu'il est scientifiquement et techniquement impossible de prévoir une autre disposition offrant plus de place pour le détecteur ;* *b) une résolution spatiale bidimensionnelle pour la détection des électrons ou des ions, avec au moins une des caractéristiques suivantes :* *i) un temps de réponse inférieur à 25 ns ;* *ii) une surface de détection de l'échantillon supérieure à 149 mm^2 ;* *iii) un facteur de multiplication supérieur à 1,3 × 10^3 ;* *c) un temps de réponse inférieur à 5 ns pour la détection des électrons ou des ions ;* *d) une surface de détection de l'échantillon supérieure à 314 mm^2 pour la détection des électrons ou des ions ;* *e) un facteur de multiplication supérieur à 4,0 × 10^7.*	JBCE	**Renouveler* avec un champ d'application modifié to include MCPs from ex. IV-3:** *Le plomb dans les galettes de microcanaux (GMC) utilisées dans des équipements pour l'amplification ou la détection de rayonnements ionisants, d'électrons ou de radiations, où au moins une des propriétés suivantes est présente :* *(a) un détecteur de taille compacte, lorsque l'espace pour le détecteur est limité à un maximum de 3 mm/GMC (épaisseur du détecteur + espace pour l'installation de la GMC) et à un maximum de 6 mm au total, et qu'il est scientifiquement et techniquement impossible de prévoir une autre disposition offrant plus de place pour le détecteur ;* *(b) une résolution spatiale bidimensionnelle, avec au moins une des caractéristiques suivantes :* *(I) un temps de réponse inférieur à 25 ns ;* *(II) une surface de détection de l'échantillon supérieure à 149 mm^2 ;* *(III) un facteur de multiplication supérieur à 1,3 × 10^3 ;* *(c) un temps de réponse inférieur à 5 ns ;* *(d) une surface de détection de l'échantillon supérieure à 314 mm^2 ;* *(e) un facteur de multiplication supérieur à 4,0 × 10^7.*	31 December 2026 pour la cat. 8 dispositifs méd., y compris les DIV et pour la cat. 9 IMC y compris IMCI

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 (B'Innov) is working on the contract for the "Study to assess requests for a renewal of 16 exemptions to Annex IV of Directive 2011/65/EU (Contract No. 070201/2020/832829/ENV.B.3) since July 27th, 2020.

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, in this case of (sub)categories of categories 8 and 9. In the course of the evaluation, a public online stakeholder consultation was also organized.

The Commission has received requests for the continuation of 16 exemptions of Annex IV of the Directive applicable to electrical and electronic equipment of categories 8 and 9 of RoHS Annex II. This study will provide the Commission required technical and scientific support for the evaluation of the requests for renewal of the 16 exemptions displayed in Table .

Table 3-1: Overview of the reviewed exemptions

No. on Annex IV	Exemption wording	Scope and expiry date of the exemption
Equipment utilising or detecting ionising radiation		
1	Lead, cadmium and mercury in detectors for ionising radiation	*Expiry due to Art. 4(3) in combination with Art. 5(2)(b): maximum 7 year validity period reached in 2021*
2	Lead bearings in X-ray tubes.	
3	Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate.	
5	Lead in shielding for ionising radiation.	
Sensors, detectors and electrodes		
1a	Lead and cadmium in ion selective electrodes including glass of pH electrodes.	*Expiry due to Art. 4(3) in combination with Art. 5(2)(b): maximum 7 year validity period reached in 2021*
1b	Lead anodes in electrochemical oxygen sensors.	
1c	Lead, cadmium and mercury in infrared light detectors.	
Others		
11	Lead in alloys as a superconductor and thermal conductor in MRI.	*Expiry due to Art. 4(3) in combination with Art. 5(2)(b): maximum 7 year validity period reached in 2021*
13	Lead in counterweights.	
14	Lead in single crystal piezoelectric materials for ultrasonic transducers.	
15	Lead in solders for bonding to ultrasonic transducers.	
17	Lead in solders in portable emergency defibrillators.	
26	Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions: (a) solders on printed circuit boards; (b) termination coatings of electrical and electronic components and coatings of printed circuit boards; (c) solders for connecting wires and cables;	*First review in 2011 to 2013* *Expiry on 30 June 2021*

No. on Annex IV	Exemption wording	Scope and expiry date of the exemption
	(d) solders connecting transducers and sensors. Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C.	*26, 29, 31(a) and 39 have been evaluated in previous technical assessments*
29	Lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments.	
31(a)	Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.	*Expires on 21 July 2021 for the use in medical devices other than in vitro diagnostic medical devices; (later expiry dates for other (sub)categories of EEE)*
39	Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is present: (a) a compact size of the detector for electrons or ions, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable; (b) a two-dimensional spatial resolution for detecting electrons or ions, where at least one of the following applies: (i) a response time shorter than 25 ns; (ii) a sample detection area larger than 149 mm^2; (iii) a multiplication factor larger than $1,3 \times 10^3$. (c) a response time shorter than 5 ns for detecting electrons or ions; (d) a sample detection area larger than 314 mm^2 for detecting electrons or ions; (e) a multiplication factor larger than $4,0 \times 10^7$.	*Expires on 21 July 2021 for medical devices other than in vitro diagnostic medical devices and monitoring and control instruments; (later expiry dates for other (sub)categories of EEE)*

3.2. 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 other chemical safety concern):

- Substances that may have serious and often irreversible effects on human health and the environment can be added to the candidate list of Substances of Very High Concern (SVHCs). Following the identification as SVHC, a substance may be included in Annex XIV of the REACH Regulation (Authorisation list): "List of Substances Subject to Authorisation". If a SVHC is placed on the Authorisation list, companies (manufacturers and importers) that wish to use it or 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 is not adequately controlled, it shall prepare a restriction dossier. ECHA can also take the initiative to prepare a restriction dossier for any substance in the authorisation list if the use of that substance in articles poses a risk to human health and the environment that is not adequately controlled. The provisions of the restriction may be made subject to total or partial bans, or conditions for restrictions, based on an assessment of the risks and the assessment of the socio-economic elements.

The approach adopted in this report is that once a substance has been included into the Annexes related to authorisation or restriction of substances and articles under the REACH Regulation, the environmental and health protection afforded by REACH may be weakened in cases where an exemption would be granted for these uses under the provisions of RoHS.

Substances for which an authorisation or restriction process is underway may be discussed in some cases in relation to a specific exemption, in order to check possible overlaps in the

scope of such processes and of requested RoHS exemptions and to identify the need for possible alignments of these two legislations.[1]

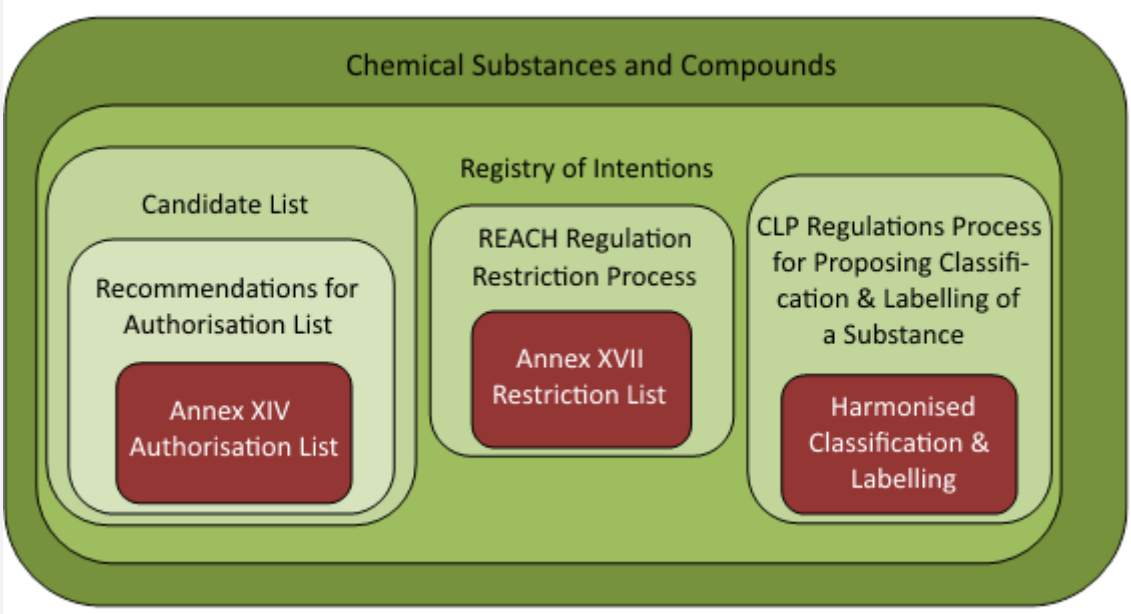
When evaluating the exemption requests, with regard to REACH compliance, we have checked whether the substance / or its substitutes are:

- 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



[1] 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

Before reaching the "Registry of Intentions" as shown in the figure above, there are additional activities and processes to identify substances of potential concern conducted by ECHA together with the Member States and different ECHA Expert Groups.[2] 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).[3] If the Substance Evaluation concludes that the risks are not sufficiently under control with the measures already in place and if a Risk Management Option (RMO) analyses does not conclude that there are appropriate instruments by other legislation / actions, the substance will be notified in the Registry of Intentions.

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

- Member States Competent Authorities (MSCAs) / ECHA, on request by the Commission, may prepare Annex XV dossiers for identification of SVHCs, 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 inclusion of a substance into Annex XIV (the Authorisation list), involves ECHA issuing a Recommendation of substances for Annex XIV. The previous ECHA recommendations for inclusion in the Authorisation List are available at the ECHA website at https://echa.europa.eu/previous-recommendations;
- Once a decision is made, substances may be added to the Authorisation List available under Annex XIV of the REACH Regulation. The use of substances appearing on this list is prohibited unless an Authorisation for use in a specific application has been approved. The Annex can be found in the consolidated version of the REACH legal text;
- In parallel, if a decision is made concerning the Restriction on the use of a substance in a specific article, or concerning the restriction of its provision on the European

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

[3] 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

market, then a restriction is formulated to address the specific terms, and this shall be added to Annex XVII of the REACH Regulation. The Annex can be found in the consolidated version of the REACH legal text; and

As of June 2020, the consolidated version of the REACH legal text, dated 28.04.2020, was used to reference Annexes XIV and XVII: The consolidated version is available at the EUR-Lex website: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20200428. Relevant annexes and processes related to the REACH Regulation have been cross-checked to clarify:

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

In this respect, restrictions and authorisations as well as processes that may lead to their initiation, have been reviewed, in respect of where RoHS Annex II substances are mentioned (i.e. lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) as well as bis (2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DiBP).[4]

[4] 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.

4. Exemption 1 of Annex IV: Pb, Cd and Hg in detectors for ionising radiation

The exact wording of the current exemption IV-1 is as follows:

"*Lead, cadmium and mercury in detectors for ionising radiation*"

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date was scheduled for 21 July 2023, and for IMCIs for 21 July 2024.

Declaration

In the sections preceding chapter "4.4 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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and definitions

JBCE	Japan Business Council in Europe
CdTe	Cadmium Tellurium
CdZnTe	Cadmium Zinc Tellurium
COCIR	European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries
CT	Computed Tomography
PET	Positron emission tomography
SPECT	Single-photon emission computed tomography
WEEE	Waste Electrical and Electronic Equipment

4.1. Background

COCIR (2020a) and (JBCE 2020a) requested the renewal of exemption 1 of Annex IV for the maximum validity period of seven years on 2 and 6 January 2020 respectively. No other stakeholders than the applicants contributed to the online consultation.

4.1.1. History of the Exemption

Goodman, Paul (2006) assessed that this exemption would be required if EEE of category 8 was to be included into the scope of the RoHS Directive, which was not yet the case in RoHS 1 (Directive 2002/95/EC). When EEE of category 8 was included into the scope of RoHS Directive 2011/65/EU (RoHS 2), exemption 1 was listed on Annex IV when it was officially published in 2011. Applications for renewal were submitted in time, and exemption 1 will be reviewed for the first time to adapt it to scientific and technical progress.

4.1.2. Summary of renewal request by (JBCE 2020a)

The below table gives an overview of the exemption renewal requests and the requested wordings. All applicants request the renewal of exemption 1 for the maximum 7 year period for EEE categories 8 and/or 9.

Table 4-1: Overview of exemption requests

Applicant	Proposed Wording	Substances and Applications
JBCE (2020a)	*Cadmium in detectors for ionising radiation*	- Category 8 medical devices other than in-vitro diagnostic -medical devices - Cat. 9 monitoring and control instruments including monitoring and control instruments in industry.
COCIR (2020a)	*a. Cadmium in cadmium telluride and cadmium zinc telluride X-ray detectors for digital imaging* *b. Lead in coatings of ionization chambers of medical X-ray devices*	- Category 8 medical devices other than in-vitro diagnostic medical devices - Category 9 monitoring and control instruments other than monitoring and control instruments in industry

Summary of the renewal by JBCE

(JBCE 2020a) request the renewal of the exemption for category 8 medical devices other than in-vitro diagnostic medical devices and for cat. 9 monitoring and control instruments including monitoring and control instruments in industry for the maximum seven years validity period.

According to JBCE (2020a), *"By the transmission ability, X-rays and gamma rays are utilized to see inside the human body or objects in the field of medical diagnostics, non-destructive testing, food inspection, baggage screening and so on." Therefore, a detector for X- and gamma-ray should have some essential requirements. JBCE states these as follows:*

- *High sensitivity: Higher sensitivity of the detector enables reduction of radiation dose, leading to lower risk of the patient, medical staff and operators. This is critical for the citizen's human health.*

- *High spatial resolution: High spatial resolution is an ability to see the fine object clearly, and this is the fundamental function of the "imaging detector" to find the small pathological change of the patient, abnormality of the object, contaminations of the foreign substance, explosives in the baggage and so on.*
- *High energy resolution: The energy information of the radiation can give the new additional functions to the radiation imaging. It is used not only for removing the scattering ray to improve the image quality, but also for material discrimination ability by the multi-energy imaging.*
- *Room temperature operation: If the detector cannot be operated at room temperature, it requires a cooling system and the whole device size becomes too large or the device cannot be realized. It is practically very important.*

JBCE is applying for the renewal of the exemption of cadmium in detectors, because they meet *"the above four technical requirements and are used for category 8 and 9 applications, contributing to the society, such as human health, safety of the plant, reliability of the products, security at the border and so on."*

In the summary JBCE also states that "So far only a few semiconductor materials, such as silicon (Si), amorphous selenium (a-Se), germanium (Ge), CdTe and CdZnTe have been used as the direct conversion type detectors and some other semiconductors are the new candidates. However, only CdTe or CdZnTe can satisfy 4 important requirements and there are no alternatives of them so far. If this exemption is expired, the medical diagnosis will become poor and the radiation exposure risk to the patient or the medical staff will increase.

Summary of renewal request by COCIR (2020a)

COCIR (2020a) request the exemption renewal for lead and cadmium for 7 years for cat 8 for medical devices other than in-vitro medical devices and for monitoring and control instruments other than industrial monitoring and control instruments.

According to COCIR, *the "[…] renewal request includes uses of two of the RoHS substances in two different types of detector. One type contains cadmium and the other contains lead.*

Cadmium telluride and cadmium zinc telluride are used in semiconductor flat panel detectors for imaging using ionising radiation. They are used for X-ray imaging as well as γ-radiation imaging with PET (Positron Emission Tomography) and SPECT (Single Photon Emission Computed Tomography). They have the advantage of giving superior image quality with lower radiation doses. These materials are superior overall to all other detector materials and so this exemption needs to be renewed to allow their use to continue.

These detectors are also used in category 9 applications because of their superior image quality and so this exemption also needs to be renewed for non-industrial monitoring and control instruments. The health advantage to patients from the use of CdTe and CdZnTe in reducing the radiation dose to the patients is likely to be much more important than the very small potential of cadmium contamination at end of life.

Lead is used in ionisation chambers that are used to regulate the quantity of X-radiation that patients are exposed in EU hospitals and clinics. These chambers have been specifically designed to be used in most types of X-ray system sold in the EU and research has shown that all alternative materials and designs are either inferior or unsuitable.

Alternative materials can only be used if the entire X-ray system is completely redesigned and this will take many decades before all existing systems can be replaced.

4.2. Technical description of the requested exemption

4.2.1. Amount of cadmium and lead used under the exemption

The applicants state that a CdTe semiconductor contains 46.7 % cadmium and in a nominally Cd0.9Zn0.1Te semiconductor are 43 % cadmium.

COCIR (2020a) state further that lead metal (99.9 %) is in ionisation chamber coatings.

According to JBCE (2020a) and COCIR (2020a), quantity of cadmium is taken from a study carried out for the European Commission on the possible inclusion of categories 8 and 9 in scope of RoHS in 2006 [Goodman, Paul (2006)] and assumes that the annual amount of 300k g has doubled since 2006.

COCIR (2020a) state that 1.6 kg lead enter the market per year. The quantity calculation leading to that number by a manufacturer of ionisation chambers is confidential.

Therefore, the amount of substance that will enter the market is:

- 600 kg cadmium per year
- 1.6 kg lead per year

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

The restricted substances for this exemption are cadmium, mercury and lead. Mercury is no more needed for this exemption. Cadmium is used in flat panel detectors for X- and gamma rays and lead are used in ionization chambers to regulate x-ray radiation. Both substances can be used simultaneously in medical applications, but not necessarily. Therefore, in the following, the substances will be described and treated separately due to their slightly different areas of applications.

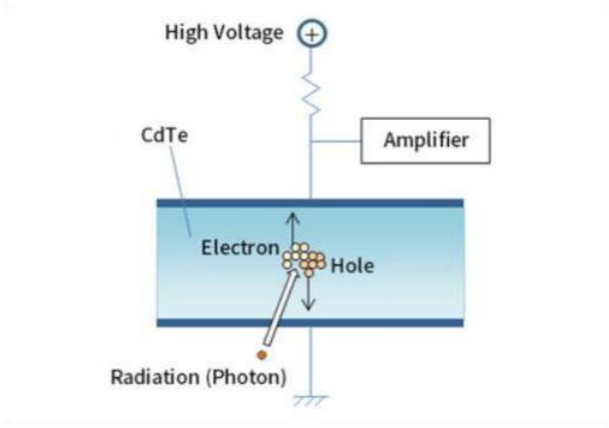
Cadmium in detectors for ionizing radiation

In order to decide which substance is the best fit for a detector of X- and gamma rays, four requirements are stated by the applicant JBCE. As mentioned above, a detector needs high sensitivity, high spatial resolution, high energy resolution and room temperature operation.

<u>High Sensitivity</u>

JBCE explains when an irradiated photon such as x- or gamma ray is absorbed in the crystal, it generates the electron-hole pairs. The electrons and the holes are driven by the internal electric field to the anode and the cathode electrode, respectively (see Figure 4-1). Through amplifying the electrical charge in the read out circuit, the photon can be detected.

Figure 4-1: Functional principle of CdTe semiconductor radiation detector



Source: (JBCE 2020a)

The semiconductors with high densities and high atomic numbers show the highest absorption efficiency as shown in Table 4-2.

Table 4-2: Physical parameters and performance of semiconductor radiation detectors

related pefromance		Si	a-Se	Ge	GaAs	CdTe	CZT	HgI_2	TlBr
Sensitivity	Density (g/cm^3)	2.33	4.39	5.32	5.32	5.85	5.8	6.36	7.56
	Atomic number	14	34	32	31, 33	48, 52	48,30,52	80, 53	81, 35
	Absorption (%) of 100keV X-ray by 1mm thick detector	4%	24%	26%	26%	62%		89%	95%
Energy Resolution	Electron mobility lifetime product (cm^2/V)	0.42 77K	$3x10^{-6}$	0.72 77K	10^{-4}	$2\sim3x10^{-3}$	$10^{-3}\sim10^{-2}$	$1x10^{-4}$	$3x10^{-3}$
	Hole mobility lifetime product (cm^2/V)	0.22 77K	$6x10^{-5}$	0.84 77K	$4x10^{-5}$	$3\sim5x10^{-4}$	$\sim10^{-5}$	$4x10^{-5}$	$\sim10^{-4}$
	Energy Resolution at 122keV (keV)	0.55 77K	-	0.4 77K	-	3.5	4.4	3.2	6.1
	Energy Resolution at 662keV (keV)	0.9 77K	-	0.9 77K	-	7.5	11.8	5.96	11.2
Room Temperature Operation	Band gap (eV)	1.11	2.3	0.665	1.43	1.44	1.44∼1.6	2.13	2.68
	Resistivity (Ωcm) at 300K	$2.3x10^5$	$1x10^{12}$	47	$1x10^9$	$1x10^9$	$1x10^{10\sim11}$	$1x10^{13}$	$1.5x10^{10}$
Toxicity[55]	LD50 (mg/kg)	3,160	6,700	—	>15,000	>15,000		18	35[56] LDLo
	Toxicity(oral) GHS category	Not a dangerous sunstance	3	Not a dangerous sunstance	—	4		2	2

Source: (JBCE 2020a)

Spatial Resolution

The spatial resolution is mainly important for the imaging detector because the higher the spatial resolution is the clearer the image of the detector will be.

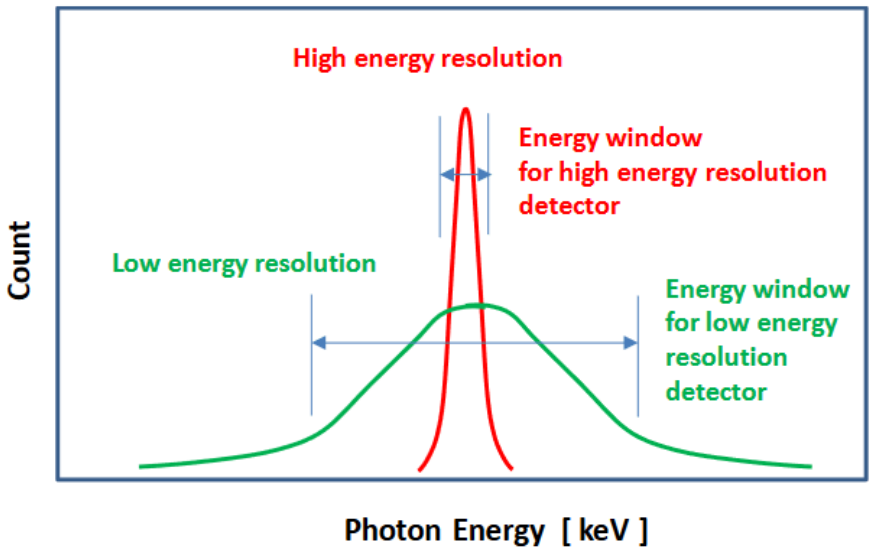
JBCE describes that *the radiation is directly converted to the electric charge, this type is called Direct Conversion type. The electric charge can reach the pixel electrode right below the absorbed position without spreading, so the sharp image can be obtained. An appropriate semiconductor thickness can be selected by the energy of photon without the risk of blurring the image. The alternative of an indirect conversion type is using a scintillator and has a lesser spatial resolution.*

Energy Resolution

JBCE explain in the application that *the energy resolution of the detector is determined by the mobility–lifetime products (μτ-products). If the Mobility Life-time Product (cm2/V) value is higher the charge collection increases, which improves sensitivity.*

If the detector has higher energy resolution, sharper image can be obtained by using the narrower energy window as in Figure 4-2.

Figure 4-2: Schematic of the relation between energy resolution and energy window



Source: (JBCE 2020a)

Room Temperature Operation

Leak current can be minimized if the detector is cooled down to liquid nitrogen temperature. Cooling down is costly and elaborate. *JBCE state this with the example of Ge in their application. But other semiconductor detectors can be used in room temperature due to the larger band gap and high resistivity. If the bandgap is not high enough, electrons in the*

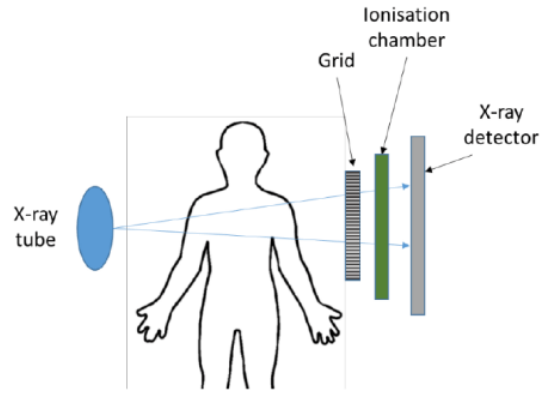
valence band are easily activated to conduction band due to the thermal energy and the leak current increases. This leak current becomes the cause of the noise.

Lead in ionisation chambers

COCIR (2020a) state that *ionisation chambers measure the quantity of X-radiation for automatic exposure control to ensure that the correct radiation dose is used to obtain a clear image. These are used in most X-ray imaging systems to compensate for the thickness and density of the parts of the patient being examined. Figure 4-3 shows the position of the ionisation chamber within the medical X-ray system schematic.*

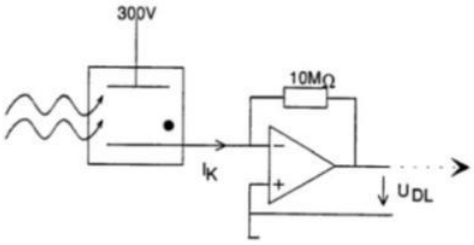
Lead is used as the negative electrode of the ionization chamber. X-rays ionise the air inside the chamber which allows secondary electrons to be emitted from the negative lead coated electrode and travel to the positive electrode. This generates a current through the chamber and the associated circuit, which determines the quantity of ionisation in the chamber from the X-radiation exposure. A typical circuit is shown in Figure 4-4.

Figure 4-3: Position of ionization chamber within the medical X-ray



Source: COCIR (2020a)

Figure 4-4: Principle of operation of an ionization chamber



Source: COCIR (2020b)

The chambers monitoring circuit include a capacitor that is charged at a rate which is determined by the quantity of ionisation in the chamber from the X-radiation. When it is charged to a certain voltage, it initiates current flow that actuates a contactor which shuts down the X-ray tube and stops X-ray exposure.

X-ray ionisation chambers are made of plastics which are transparent to X-rays and have printed graphite patterns as the positive and negative electrodes (graphite is also

transparent to X-rays). The negative electrode is then coated using physical vapour deposition (PVD) with a 3µm thick coating of lead (effectively transparent to X-rays at this thickness).

4.3. Justification for the requested exemption

4.3.1. Substitution and elimination of cadmium in detectors for ionizing radiation

Both applicants state that the substitution of cadmium leads to different semiconductor detectors. *All detectors worth considering have less energy and spatial resolution, need more radiation or need to be cooled, which means that radiation doses for patients get higher and radiation time increases.* JBCE (2020a) gave a comparison of radiation detectors used for X-ray detection (see Table 4-3).

Table 4-3: Comparison of radiation detectors

	Direct Conversion Type							Indirect Conversion Type
	Si	a-Se	Ge	GaAs	CdTe, CZT	HgI_2	TlBr	
Sensitivity	X	X	X	X	O	O	O	
Spatial Resolution	O	O		O	O			X
Energy resolution	O	×	O 77K		O	O	O	
Room temperature operation	O	O	X	O	O	O	O	
Toxicity						X	X	
Note			Cooling System required			Minamata convention	Very toxic material	

Source: (JBCE 2020a)

COCIR (2020a) write in their renewal application that *comprehensive research by a medical equipment manufacturer has evaluated semiconductors for CT (Computed Tomography) detectors. This work assessed 23 materials by assessing variables such as their absorption performance, count rate, diffusion radius (affects spatial resolution) and charge carrier loss (likelihood that an X-ray results in a charge reaching the pixelated electrode).Elements with k-edge of 80 –90 keV were reported to be less suitable for CT as this is close to the X-ray energy used for CT, which makes mercury compounds (83.1 keV) and lead compounds (88.0 keV) less suitable. This assessment resulted in three materials that are potentially suitable; CdTe, lead sulphide and germanium, however of these, lead sulphide and germanium must be cooled to low temperature which requires additional, quite bulky, cryocooling equipment or the use of liquid nitrogen. Liquid nitrogen cooling is not technically practical for a CT detector as the detector rotates around the patient. Also, of the 23 semiconductors assessed, only a few materials, including CdTe are commercially available of suitable thickness and size.*

4.3.2. Substitution and elimination of lead in ionization chambers

COCIR (2020a) state that *the substitution of lead in ionisation chambers is only possible with tin. But substituting the lead by tin means a redesign of the imaging systems, which only can be done by new designs and not on existing systems. This can take up to 10 years.*

COCIR (2020a) explain in the application that *light elements (such as graphite) generate very weak signals (graphite emits only 2 % of the emission from lead of similar thickness) and the signal is too small to give accurate control. As each element emits secondary electrons with different energies, there is no possible drop-in replacement for lead as every alternative element will generate a different signal. As the ionisation chamber design, control circuits and especially the calibration curves were developed with lead, it is not possible to use a different metal coating and achieve the same automatic exposure control; patients' images will be over or under-exposed if a different metal were used.*

COCIR also gives a comparison of ionisation chambers to phototimers. Ionisation chambers have mostly replaced the previously used method of automatic exposure control using phototimers. Phototimers use scintillator panels that convert X-rays into light and then the light output is measured with photomultipliers or photodiodes. As most X-rays should be absorbed to be measured, these are positioned after the X-radiation has passed through the patient. This has disadvantages that have resulted in the change to ionisation chambers, as summarised in Table 4-4.

Table 4-4 Comparison of ionisation chambers with phototimers

Characteristic	Ionisation chamber	Phototimer
Position	After X-rays emerge from patient.	After X-rays emerge from patient.
Effect on X-ray beam	Does not block X-rays so no scattering or image generated	Must absorb radiation to measure dose. Scattering does occur which requires lead shielding and can affect image quality
Behaviour with implants	No effect as energy from X-ray tube is measured before reaching patient	Can block X-radiation so that patient receives a dangerously high dose and image is over-exposed
Shielding	Not needed	Lead shielding required

Source: (JBCE 2020a)

If implants block X-radiation, the phototimer registers a too low intensity of the X-ray which as a result increases the intensity so that the patient may be exposed to a dangerously high dose.

COCIR (2020a) compare the detection efficiencies and detection limits of commonly used types of detectors. COCIR (2020b) give a few examples concerning the comparison of different detectors. The data in Table 4-5 of COCIR's exemption renewal request shows that the efficiency of CdTe and CdZnTe detectors is 60 % whereas flat panel detectors with scintillators are only 40 %. This allows the radiation dose to be reduced by about 30 %. In fact, the difference is even larger because, as shown in

Table 4-6, CdTe and CdZnTe semiconductor detectors can detect single photons, so are able to count number of photons per pixel, in comparison a flat panel with scintillator has a detection limit of 104 photons/mm. Therefor it is much less sensitive at low levels of X-ray energy. To be able to achieve a reading with a flat panel with scintillator patients would have to be exposed for longer due to the lower sensitivity.

Table 4-5: Detection efficiency of commonly used types of detectors

Material	Detection Efficiency %
Silicon	~5%
Sodium iodide scintillator	~40%
Cadmium telluride and cadmium zinc telluride	~60%

Source: COCIR (2020a)

Table 4-6: Detection limits of common types of X-ray detection media

Detector	Detection limit, photons / mm^2.
Photographic film	10^6
Flat panel detector with scintillator	10^4
CMOS CdTe semiconductor detector	1

Source: COCIR (2020a)

COCIR (2020b) further state that a recent verification test during clinical lung imaging using CdZnTe confirmed that exposure can be reduced to 1/5 (20 %) of the radiation dose, compared to state-of-the-art non-CdZnTe technology. Other sources from a preclinical prototype CT based on CdTe sensors show for certain applications a reduction in dose of about up to 30 % at the same image quality.

4.3.3. Roadmap towards substitution or elimination of cadmium in detectors for ionizing radiation

Both applicants state that they believe that *there will be no substitute available within the next 7 years and even after that the development of a new detector will last more than 20 years.*

COCIR (2020a) further state that *the current development of GaAs can be compared to the stage of development of CdZnTe in the 1990's due to its performance and yield. Development of CdZnTe required since the 1990s an additional 10 years of development for niche applications and 25 years for mainstream medical applications such as CT.*

COCIR further describe that *for CT detector application (energy range 20 keV to 140 keV) one would need a sensor of 5 mm in thickness (for comparable absorption to 1.6 mm CdTe). Such a thickness in a quality being sufficient for CT X-ray detectors is not yet available – even at research level. For manufacturing GaAs in X-ray detector grade quality, one has in principle two possibilities, either slicing a big ingot in wafers and performing post-growth doping with chromium or by using epitaxial growth techniques. Both, the Post-growth doping and the epitaxial growth are limited to low thickness as of about 500 µm^2. This is still less than the required 5 mm. All other disadvantages of GaAs demonstrating that GaAs is inferior to CdTe and CdZnTe. The other materials stated are even further away from being commercially available, in addition to the fact that HgI2 or PbI could not be used without an exemption.*

4.3.4. Roadmap towards substitution or elimination of lead in ionization chambers

The substitution of lead in ionization chambers is only possible with tin and needs a redesign of the system. Therefore COCIR (2020a) state that designing a new X-ray system is extremely complex and typically takes over 10 years from design to construction of prototypes, testing, clinical trials and gaining Medical Device Regulation approval by a Notified body. Each manufacturer is able to develop one new system at a time (due to limitations on the availability of trained engineers) and each manufacturer will have many systems designed for different purposes.

4.3.5. Environmental arguments and socioeconomic impacts

The applicants state that according to WEEE directive requirement, the equipment shall be collected by the responsible company which is in the WEEE registration list and passed to the recycler who shall treat them adequately under the WEEE requirement.

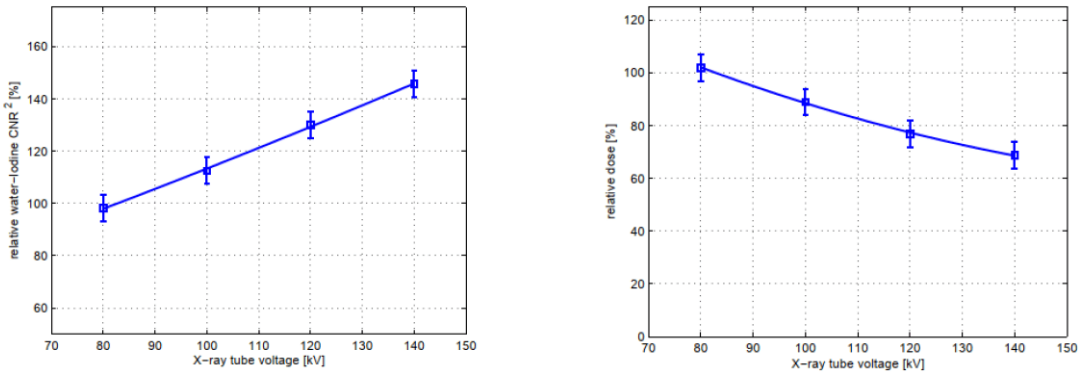
In case of expensive medical devices such as CT, SPECT and PET, they can be refurbished or reused. Even more the materials of old detectors can be recycled in order to produce new detectors.

(JBCE 2020a) state that 480 kg of cadmium can be reused and 120 kg of cadmium can be recycled from the devices which are currently on the market when they are treated once they come back from the market in the coming years.

Additionally, COCIR (2020a) confirms that 480 kg cadmium and 1.3 kg lead can be reused and 120 kg cadmium and 0.3 kg lead can be recycled. JBCE (2021) also gives a calculation

on how the radiation dose of a CdTe based detector can be reduced by optimizing the contrast to noise ratio (CNR2) to the tube voltage. The dose with CdTe photon counting detector can be reduced by 32 % for the same image quality that is obtained by a conventional detector at 140 V, see Figure 4-5.

Figure 4-5: Optimized radiation dose of CdTe detectors – an example



Source: JBCE (2020b)

JBCE (2020a) further state that *without the possibility of using a Cd-based detector, the diagnosis in medical field becomes poor and the radiation exposure risk to the patient and the medical staff increase. This applies not only to the medical field, but in other applications, such as non-destructive testing, food inspection, baggage inspection, etc. For the society, the accuracy of the inspection is absolutely necessary, and the risk of the radiation exposure should be decreased at the same time.*

COCIR (2020a) adds that *possible substitutes of a detector for ionised radiation require higher radiation doses, which can be harmful to patients, and inferior image quality which may prevent early or accurate diagnosis.*

COCIR (2020a) further states that the use of a ionisation chamber is not a reliability issue. But the chamber is used to control the X-ray imaging properly and to receive a well exposed image immediately. Otherwise repeated imaging exposes the patient unnecessarily with radiation.

4.4. Critical review

4.4.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the 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.

Lead

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by"* the REACH Regulation if the requested exemption would be granted/renewed.

REACH Annex XIV (2021)[5] lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- *Lead chromate (entry 10);*
- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

The application in the scope of the exemption at hand use lead only and not any of the above lead compounds.

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16[6] and entry 17[7] restrict the use of lead carbonates and lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds[8] such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*

The above applications are not applicable to the use of lead in the applications in the scope of the exemption at hand.

- *Entry 28[9] addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*

[5] ECHA, https://echa.europa.eu/authorisation-list?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

[6] 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

[7] 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

[8] 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

[9] 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

- *Entry 30[10] addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they 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 above restrictions are not applicable to the use of lead in the exemption at hand. The substances are part of an article (professional use medical devices) and thus are not placed on the market or used as substances, constituents of other substances or mixtures supplied to the general public.*
- *Entry 63[11] restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72[12] stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

Lead in the scope of the exemption at hand is thus not used in wristwatches or any other jewellery in the scope of entry 63, nor are conditions foreseeable where lead components or the related equipment may be placed in the mouth by children. Further on, EEE in the scope of the RoHS Directive 2011/65/EU is excluded from the scope of entry 72.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status (October 2021) 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 the respective criteria of Art. 5(1)(a) apply.

Cadmium

With regards to **Annex XIV of the REACH Regulation**, cadmium in general or in compounds is not mentioned in the list of substances that require an **authorisation** for use.

With regards to **Annex XVII of the REACH Regulation**, cadmium is mentioned in a few of the listed restrictions.

Paragraph 1 of entry 23[13] 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.*

[10] 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

[11] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[12] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

[13] C.f. ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e2518

2. *Shall not be used for cadmium plating[14] 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 exemption at hand, Cd(Zn)Te is neither used in polymers nor in platings or as brazing filler, and its use under the exemption is not related to jewellery. The above stipulations are therefore not applicable.

Due to their carcinogenicity, *entry 28[15] 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.*

Neither CdTe nor CdZnTe are mentioned so that the restrictions related to entry 28 do not apply.

Entry 72[16] lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It refers among others to cadmium and its compounds as listed under entries 28, 29 and 30 (germ cell mutagenic substances) and restricts their use in clothing and textiles. The entries list several cadmium compounds, among others cadmium sulphide and cadmium nitrate.

Like entry 28, this entry does not address Cd(Zn)Te as it is applied in exemption 1.

To conclude, none of the entries currently listed under REACH would apply to the case at hand. The Use of Cd in Cd(Zn)Te detectors 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.

4.4.2. Substitution or elimination of cadmium in X-ray detectors

According to the applicants, the elimination or substitution of cadmium in the radiation detectors would result in the use of different semiconductor detectors or even use a scintillation detector. The applicants discuss that both alternatives would be followed by complete redesign of the system and a lower resolution, which would mean longer

[14] 'Cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface

[15] ECHA, https://echa.europa.eu/de/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

[16] ECHA, https://www.echa.europa.eu/web/guest/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

exposition times and thus higher exposure to X-rays and lower quality of X-ray photographs, c.f. section 4.3.1 This is highly impractical for medical und security purposes.

The applicant was requested to give an example for an alternative detector that needs cooling. JBCE (2021) show how a cooling system of a lung counter. In this case, the measurements are made with a static detector, but are much more difficult to use with rotating detectors like used in CTs.

Figure 4-6: Lung counter with a cooling system

Source: Canberra[17] in JBCE (2020b)

The applicant described the advantages of CdTe detectors and was asked to provide more details substantiating these statements.

COCIR (2020b) add on request that for the applications described in the exemption request the use of a cooling system is not technically practical. *Additionally, those materials which use Germanium and which require cooling, have a higher diffusion radius which leads to a reduced spatial resolution (pixel size) compared to Cd-based materials, so could not be described as achieving the same performance. CdTe and CZT are wide band gap room temperature semiconductor radiation detectors that do not need cooling.*

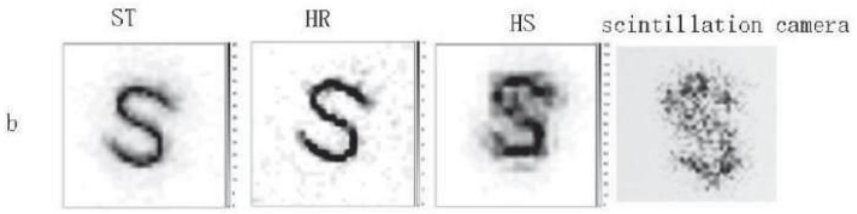
JBCE (2020b) also give an example of the comparison of a CdTe based detector with a conventional NaI (sodium ionide) scintillation camera[18].

In Figure 4-7 it is described that the three on the left were taken with the CdTe gamma camera and the one on the right was taken with conventional NaI scintillation camera.

[17] C.f. Canberra in JBCE 2020

[18] JBCE 2020b cites the following article: T Oda, et all. “Evaluation of Small Semiconductor Gamma Camera” Kakuigaku (NuclearMedicine) 6:pp 1-12, 2009

Figure 4-7 Comparison CdTe based detector with NaI scintillator camera



Source: JBCE (2020b)

This example shows that the resolution of the CdTe detector is much better than the one from the NaI scintillator and JBCE state that the radiation dose is halved.

Both applicants refer to a new detector that is still in development. It is a detector based on a Perovskite hybrid, which is a lead based crystal. This substance is already used in solar cells, which are not included in the scope of RoHS. There is a project called PEROXIS[2] that works on the development for this detector with the aim to develop the next generation of highly sensitive X-ray detectors that will enable better diagnostics and treatment for better patient outcomes. The project is due to finish by the end of 2022. JBCE (2021) and COCIR (2021a) request to take into account this development and include lead into the scope of the future exemption IV-1.

COCIR (2021a) say that such detectors might already be placed on the market in 2026. They claim that lead should therefore remain in the exemption wording so that no new exemption would have to be requested for these detectors prior to 2026. They also state in the context of these new detectors that there may be other applications of lead in detectors out there and that probably the manufacturers do not even know that the wording is going to be changed so they ignore they should come out.

The applicants upon request could not give details as to the performance of the lead containing Perovskite detectors compared to CdTe or CdZnTe detectors. In the consultants' point of view, new developments can be taken into account in principle. In the case at hand, however, the applicants could not provide properties showing that these detectors have superior performance or other advantages compared to the cadmium detectors for which the exemption renewal was requested. In the absence of such evidence, the consultants cannot recommend the exemption to be renewed for lead in line with Art. 5(1)(a). COCIRs' request in this context cannot be followed to further on including the use of lead in detectors in the exemption scope because manufacturers or users of such detectors did not know of the exemption review. Following this proposition would in consequence block revocations or changes of exemptions and shift the responsibility of producers and users to follow up on the legislation of relevance for their activities to the consultants and the COM.

The consultants therefore recommend that COCIR, JBCE or other applicants request a new exemption or the amendment of exemption 1 when they can substantiate their application with sufficient evidence and in time to enable them to be placed on the market latest after the two year approval phase. The actual performance and properties of lead-containing Perovskite detectors should be clear latest, probably even before, the beginning of this approval phase.

4.4.3. Substitution or elimination of lead in ionization chambers

According to COCIR (2020a), elimination or substitution of lead in ionisation chambers is possible by tin. COCIR state that "tin is the only alternative to lead which one manufacturer has been able to develop for use in newly designed and calibrated imaging systems. Secondary electron generation differs significantly between lead and tin. As a result, tin-based chambers can be installed only in new designs of x-ray systems whereas lead-based chambers must be used in all other existing X-ray systems on the market, which are most existing systems."

COCIR was asked since when these lead-free chambers are available, which manufacturer developed this system and in which X-ray devices it was used. *COCIR (2021b) said that this new technology has been developed by Siemens Healthcare GmbH for a few new radiology systems by use of a lead-free chamber. The first x-ray model using this new technology was placed on the market in 2013 by Siemens. To date there are no technical parameters which preclude the use of lead-free ionization chambers beyond the requirement that the system is specifically designed for being used with these lead-free chambers (to allow for different calibration algorithms etc.). After such a redesign taking into account the specific properties of the ionization chamber, each X-ray can be operated with this lead-free ionization chamber.*

COCIR (2021b) highlight that lead-free chambers are not available on the market to be purchased. It is a new technology that has been developed by one single manufacturer. Most manufacturers of x-ray devices simply purchase lead-based ionization chambers. The time to develop a similar technology and to ensure it is reliable, should also be taken into account.

Development of the chamber itself, the generator and the radiology systems, would need to be undertaken. The resulting changes in the image chain (X-Ray-Tube, Generator, Ionizing Chamber, Software and Calibration) effectively results in a new device as changing in one part affects the others. Every combination of the available flat panel detector energy dependent behaviour of the chain radiation-ionization chamber-generator-detector would have to be measured/found. After having found the right combination values the calibration algorithm has to be developed in the generator/system-software.

The development on system level firstly requires adaptation of the adjustment, calibration procedures and eventually reflecting those in the system software (system service software). The entire component chain (chamber, generator and system service software) then would need to be integrated, tested and undergo regulatory approval tests such as EMC, electrical safety typically by authorized test houses.

For Siemens Healthcare GmbH which has models utilising lead-free chambers the following timeframes could be expected for the redesign of a device:

- *Development: Integration of chamber and definition of interface electronic (value): 3-4 years*
- *Development of the generator respectively modification of the generator electronics: 2-3 years*

However, manufacturers which do not have this experience or an already working lead-free chamber , could take significantly longer as the function lead provides to such devices is so integral to the function of the device.

For global approvals, after successful testing of the component changes, results need to be shared with specific authorities for renewal of the respective country licenses, which can require confirmation test by local authorities e.g. China.

COCIR (2021b) state that the innovative part is always a small one. The ionization chamber is part of the image chain (tube, generator, chamber, collimator, detector). This technology has a design cycle that is far longer than the device itself and is used unchanged in successive generations. The chamber in particular plays a critical safety role and, for instance, unlike tubes and detectors, cannot be changed without redesigning the whole image chain. To use lead-free ionization chambers the whole calibration process of the image chain for every system variation would have to be to be significantly changed. It is a huge development effort. First have to find out a way to design and manufacture such chambers, or work with manufacturers of lead-free chambers, in a way to ensure absolute reliability.

Secondly, the redesign of the image chain is not even possible at the level of single product redesign as it would require more time than what is required to redesign the product (it can be assimilated to design a new car engine, versus redesigning a car model. Cars are designed to adapt to the new engine, it is not the engine that is redesign to adapt to cars).

Therefore, the introduction of such lead-free technology could only happen at a very slow pace, at the moment when companies launch a redesign of the image chain. It can be additionally considered that the lead-free technology does not offer any clinical advantage compared to the lead based one.

The consultants understand the above efforts are needed, but at the same time the legal obligation to substitute or eliminate the use of lead has been established via the RoHS Directive including cat. 8 medical devices. It seems that one manufacturer has undertaken successful efforts to develop lead-free ionization chambers and operate them in newly designed X-rays devices. Since 2013, no other manufacturer seems to have followed this example.

In the light of the above, the consultants recommend renewing the exemption to leave time to ensure the reliability of lead-free substitutes by redesign of X-ray devices and develop lead-free ionization chambers if not available on the market. Given the fact that one manufacturer has lead-free ionisation chambers in use, even though not yet in all X-ray models, the exemption should be renewed for three years only. The manufacturers can by then prove compliance efforts or explain plausibly why such efforts still were not possible taking into account that one manufacturer has undertaken such compliance efforts.

4.4.4. Inclusion of ionization chambers into the scope of exemption 1

According to COCIR (2020a), *ionisation chambers measure the quantity of X-radiation for automatic exposure control to ensure that the correct radiation dose is used to obtain a clear image.* They can thus be understood as detectors and thus EEE. In this function, they might be interpreted as lead shielding. But the chambers are exposed to the radiation that passes through the patient instead of shielding the patient from X-rays, and their function prevents the generation of too much X-ray rather than shielding the patient from generated X-ray. Additionally, the lead shieldings addressed in exemption IV-5 are layers/pieces of lead metal and not EEE like the ionization chambers.

Since their function can be understood as detectors for ionization radiation, ionization chambers are covered by the current exemption 1. COCIR proposed specifying the exemption for cadmium-containing detectors and the ionization chambers, and the consultants welcome this proposal because it specifies and defines clearer the exemption scope.

Even though the ionization chambers can be interpreted as a detector for X-rays, their function is different from the cadmium-containing detectors which generate the image, while the ionization chambers control the intensity of generated X-rays. The proposed wording for the renewed exemption addressing the chambers - *Lead in coatings of ionisation chambers of X-ray detectors* – reflects the situation that the monitoring chambers are operated in conjunction with the detectors creating the image. Additionally, since the chambers were understood to be covered by exemption 1 so far, it might create confusion if they are now listed in a separate exemption. As the consultants do not see an urgent need to separate the ionization chambers, it will be kept in the scope of exemption 1.

4.4.5. Environmental arguments and socioeconomic impacts

Having a low radiation dose is a key point in protecting the patients and users of ionized radiation. The Cd-containing detectors contribute to reducing the dose and thus reduce the risk of cancer. Likewise, the usage of an ionisation chamber contributes to better control the intensity and thus the exposition to X-ray radiation.

In the consultants' view these arguments are plausible. Not renewing exemption 1 would thus have adverse impacts on health care in the EU/EEA.

4.4.6. Conclusions

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

- *their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II* ***is scientifically or technically impracticable****;*
- *the* ***reliability*** *of substitutes is not ensured;*
- *The total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.*

JBCE and COCIR request the renewal of exemption 1 for the maximum seven years validity period. They plausibly explain that the use of cadmium in X-ray detectors results in higher image qualities and allows reducing the X-ray dose to which patients are exposed during X-ray examinations. Compared to other detectors which do not use RoHS-restricted substances, the Cd-containing detectors are superior. The substitution of elimination of cadmium is scientifically and technically not practicable.

COCIR requests to include lead in ionization chambers into the scope of the exemption. The substitution of lead by tin in these chambers is, however, scientifically and technically practicable, even though with considerable effort since a comprehensive redesign of the entire X-ray would be required, and possibly the development of an own lead-free ionization chamber. One manufacturer has, however, already started lead substitution with first

models of X-rays placed on the market in 2013, even though not all X-ray models yet seem to have been redesigned accordingly. So far, no other manufacturers have substituted lead in ionization chambers.

In synopsis of the situation, the consultants recommend renewing the exemption since the full conversion of X-rays to operate with lead-free ionization chambers takes time to ensure the reliability of the substitutes so that the renewal should be justifiable by Art. 5(1)(a). The exemption should, however, only be renewed for three years accommodating the fact that one manufacturer has lead-free solutions available already since 2013.

4.5. Recommendation

Based on the information submitted by the applicants, the consultants recommend renewing the exemption. Substitution or elimination of cadmium in CdTe and CdZnTe detectors are scientifically and technically not yet practicable and is not foreseeable for the coming seven years.

The substitution or elimination of lead in ionization chambers is scientifically and technically practicable, but the X-ray devices need a far-reaching redesign to ensure the reliability of the substitutes. Renewing the exemption would therefore be justified by the second criterion of Art. 5(1)(a) for the Cd-containing detectors and for the ionization chambers.

Substitution or elimination of cadmium in the detectors are not foreseeable in the next seven years. One manufacturer has already started the substitution of lead in ionization chambers and has been placing first models of X-rays with lead-free chambers on the market since 2013. It is therefore recommended to grant the exemption for three years only. The consultants recommend the following wording for the exemption in agreement with the applicants.

	Exemption	Scope and dates of applicability
1(I)	*Cadmium in cadmium telluride and cadmium zinc telluride detectors for ionising radiation*	Expiry on - 21 July 2028 for cat 8 medical devices others than in-vitro diagnostic medical devices, and for cat. 9 monitoring and control instruments including industrial monitoring and control instruments
1(II)	*Lead in coatings of ionisation chambers of X-ray detectors*	Expiry on 21 July 2024 for cat 8 medical devices other than in-vitro diagnostic medical devices

4.6. References

COCIR (2020a): Exemption Renewal Form - Exemption 1 Annex IV.

COCIR (2020b): Answer to Questionnaire 1 (Clarification) received at 08.09.2020.

COCIR (2021a): Answers to Questionnaire 2 from Riccardo Corridori (COCIR) to Saskia Huber (Fraunhofer IZM) received at 10.08.2021.

COCIR (2021b): Answers to Questionnaire 3 (Clarification) received at 05.10.2021.

Goodman, Paul (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report July 2006, amended 19 Sep 2006. ERA Report 2006-0383. ERA Technology Ltd. Online verfügbar unter https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf.

JBCE (2020a): Exemption Request Form.

JBCE (2020b): Answer to Questionnaire 1 (Clarification) received at 01.09.2020 by e-mail.

JBCE (2021): Answer to Questionnaire 2 (Clarification) received at 25.08.2021 by e-mail.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

RoHS Directive 2011/65/EU: 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 (recast). RoHS 2. European Union. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065.

5. Exemption 1(a) of Annex IV: Pb and Cd in Ion-selective Electrodes

The exact wording of the current exemption 1(a) of Annex IV is as follows:

"Lead and cadmium in ion selective electrodes including glass of pH electrodes"

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date was scheduled for 21 July 2023, and for IMCIs for 21 July 2024.

Declaration

In the sections preceding section 5.4 "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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and definitions

Ba	Barium
BaO	Barium oxide
Cd	Cadmium
CdS	Cadmium sulphide
IMCI	Industrial monitoring and control instruments
ISE	Ion-selective electrode
ISFET	Ion Sensitive Field Effect Transistor
IVD	In-vitro diagnostic medical devices
Pb	Lead
PbO	Lead oxide
pH	'potential of hydrogen', 'power of hydrogen', a scale used to specify the acidity or basicity of an aqueous solution
RoHS 1	Directive 2002/95/EC
RoHS 2, RoHS	Directive 2011/65/EU

TCE thermal coefficient of expansion

5.1. Background

JBCE (2020a) and JBCE (2020b) (amendment of original renewal application) requested the renewal of exemption 1(a) on 17 January 2020 and 6 July 2020 respectively (amendment) for the maximum validity period of seven years with the following modified wording:

Lead in pH glass electrodes and ion selective electrodes equipped with a pH glass electrode with complex shape as following:

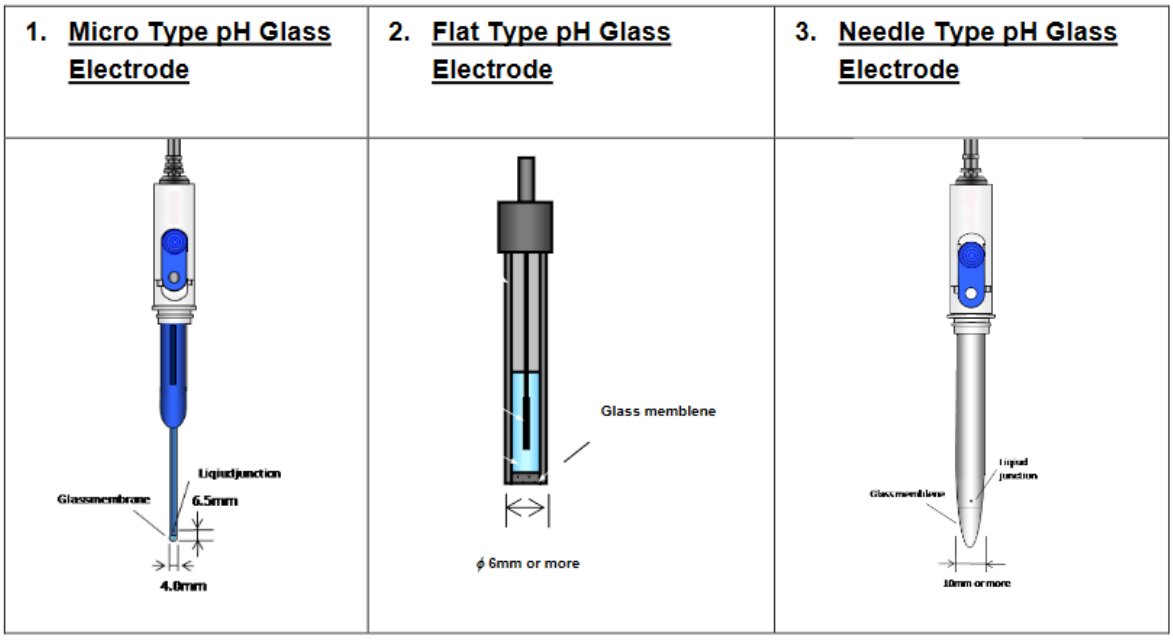
I) Micro type pH glass electrode
Composite electrode that has a spherical or tube-shaped pH responsive glass membrane with a diameter of 4.0 mm or less and a reference electrode with a liquid junction at a position vertically within 6.5 mm from the tip;

II) 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;

III) 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.

JBCE (2020a) request the above renewed wording for EEE of cat. 9 monitoring and control instruments including industrial monitoring and control instruments (IMCI). JBCE (2020b) added the illustration in Figure 5-1 to demonstrate the types of glass pH glass electrodes addressed in their proposed wording:

Figure 5-1: Types of pH glass electrodes addressed in the proposed new wording of exemption 1(a) of Annex IV



Source: JBCE (2020b)

No contributions were received during the stakeholder consultation.

5.1.1. 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. Applications for renewal were submitted in time, and exemption 1(a) was reviewed for the first time to adapt it to scientific and technical progress.

5.1.2. Summary of renewal request

JBCE (2020a) state that *"The current exemption is for both lead and cadmium in ion selective electrodes and pH glass electrodes, however JBCE requests renewal only for lead as it has no knowledge of electrodes that contain cadmium [Goodman (2006) stated that cadmium concentration in aqueous solutions was measured with an electrode sulphide membrane at the time, the consultants].*

pH meters are used by a wide variety of purposes including use in laboratories, process control, quality control, workplace safety, environment (pollution) analysis. Over the last 14 years, pH electrode manufacturers have carried out research into lead-free glass pH electrodes and this work has been successful for many designs. However, where complex or unusual shapes of electrodes are required, lead-free glass causes cracks during the manufacturing process that result in premature failures. Therefore, this exemption is needed for these designs. pH electrodes are also used as components inside electrodes for analysis of substances, such as ammonia and this exemption is also needed for these electrodes. Lead-free pH glass electrodes are available on the market. However, lead in glass of pH glass electrode is required to create intermediate layer for the connection between stem tube and pH-responsive glass or pH glass membrane. Some complicated shapes explained in this document cannot be formed without lead and currently there is no alternative technology that allow glass to be substituted."

5.2. Technical description of the requested exemption

5.2.1. Amount of lead used under the exemption

JBCE (2020a) state that they do "not have access to all EU data. pH glass electrodes and ion selective electrodes are made by many manufacturers and are used in a wide range of final products and markets, it is therefore impossible to provide a precise figure of the amount of lead included in glass of all pH electrodes supplied in the EU. However due to the developments of lead-free alternatives for some designs of electrodes it would be reasonable to expect that the annual quantity of lead used is reduced from the previous exemption request even if the exact amount cannot be calculated.

The amount entering the EU market annually from manufacturers of JBCE members has been calculated to be approximately 14 g."

5.2.2. Applications in the scope of the requested exemption

According to JBCE (2020a), pH glass electrodes are used in pH meters that are employed for a wide variety of purposes including use in laboratories, process control, quality control, workplace safety, environment (pollution) analysis. JBCE (2020a) explain that pH electrodes are also used as components inside electrodes for analysis of substances, such as ammonia, and this exemption is also needed for these electrodes (ion selective electrodes). Both applications are described in more detail in the following.

pH meters

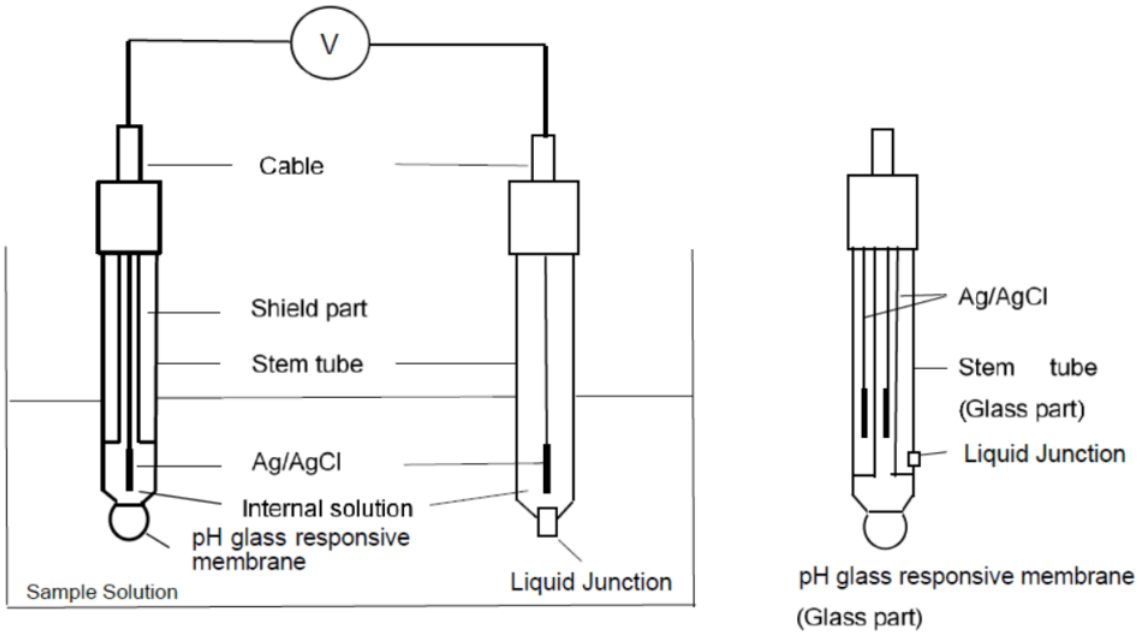
According to JBCE (2020a), the "pH meter is one of the most widely used instruments with a wide variety of purposes. The applications listed below are categorized and are not exhaustive:

- *Use in laboratories of universities, companies, research institutes, educational institutions and quality control in manufacturing industries;*
- *Process control in the industrial facilities: use and control for production and manufacturing lines;*
- *Quality control; control of pH in food, drinking water and sewerage;*
- *Use for workplace control and safety for safety check before work; and*
- *Use for environment (pollution) analysis."*

JBCE (2020a) explain the principle of pH measurement using a pH meter is that "the silanol groups formed in the hydrated layer on the pH-responsive glass surface respond to hydrogen ions, and the potential generated across pH-responsive glass affected by the hydrogen ion concentration is measured with a potentiometer".

Diagrams of pH measurement with pH glass electrode and a reference electrode, as well as a structure of pH glass combination electrode (pH electrode combined with a reference electrode) are shown in Figure 5-2.

Figure 5-2: Configuration example of a pH electrode

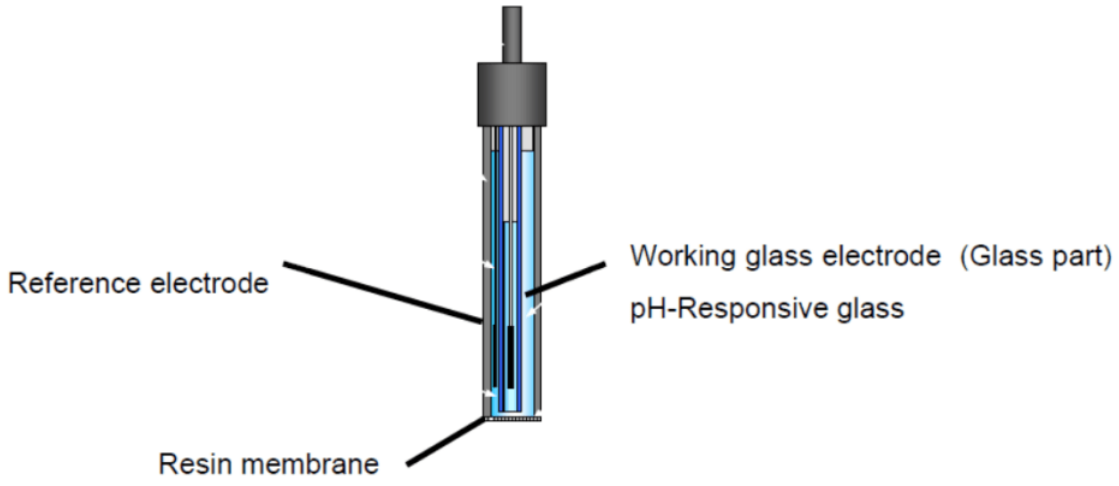


Source: JBCE (2020a)

Ion selective electrode

According to JBCE (2020a), "diaphragm type ion selective electrode (ammonia electrode) contain a pH glass electrode and a reference electrode. In this case, ammonia gas migrates through the membrane, and is changed to ammonium ions in an alkaline internal solution. Ammonium ions are measured by the change in pH and converted into ammonia concentration". The structure of an ion selective electrode equipped with a pH glass electrode is shown in Figure 5-3.

Figure 5-3: Configuration example of ion-selective electrode equipped with a pH glass electrode



Source: JBCE (2020a)

Function of lead in the described applications

JBCE (2020a) explain that in pH glass electrodes, there is pH responsive glass and a stem tube glass, which are joint as shown in Figure 5-2. JBCE (2020a) explain that "the pH responsive glass is a glass that selectively responds to hydrogen ions and has a special composition containing about 30 mol % of an alkali metal such as lithium. This glass generally has a linear thermal expansion coefficient of 100 × 10^{-7} / degree or more due to its high alkalinity. The glass is joined by heat with a stem glass tube which is a different kind of glass with electrically insulating character. Typical thermal expansion coefficient of the stem glass tube is 94 × 10^{-7} / degree."

JBCE (2020a) continue to explain that "at the joint of the two different glasses with different thermal expansion coefficients, it is easy for cracks to occur shortly after manufacturing due to temperature change or static fatigue. To prevent the cracks, after the stem tube glass and pH-responsive glass are joined by heat, air pressure is manipulated to expand and contract the pH responsive glass several times so that an intermediate layer is formed between the two different types of glasses. When there is enough intermediate layer formed, no cracks occur, and the electrode is able to be manufactured without failure."

However, JBCE (2020a) explain further that "it is difficult to form an intermediate layer in the case of electrodes that have complicated shape, for example flat responsive glass type, microelectrode type, or needle tip type. The complicated shapes of these electrodes allow unique functionality which would not be able to be achieved without this shape, which is discussed further below. Since the shape of responsive glass of these electrodes are complicated, it is necessary to join the responsive glass membrane and stem glass tube in a very short time, otherwise the shape of the glasses is deformed due to the heat. Due to the limited time to form an intermediate layer between the response glass membrane and the stem glass tube, cracks can easily occur."

JBCE (2020a) state that when lead containing glass is used as stem glass tube, "no cracks occur, even if there is a limited processing time to allow for an intermediate layer to be formed. The reason is that lead is an element which has a low chemical potential, and so rapidly diffuses into different types of glass at the time of bonding to form an intermediate layer even in a short time. This is the reason why lead is needed for electrodes with complicated shapes."

Specific electrode types requiring the exemption

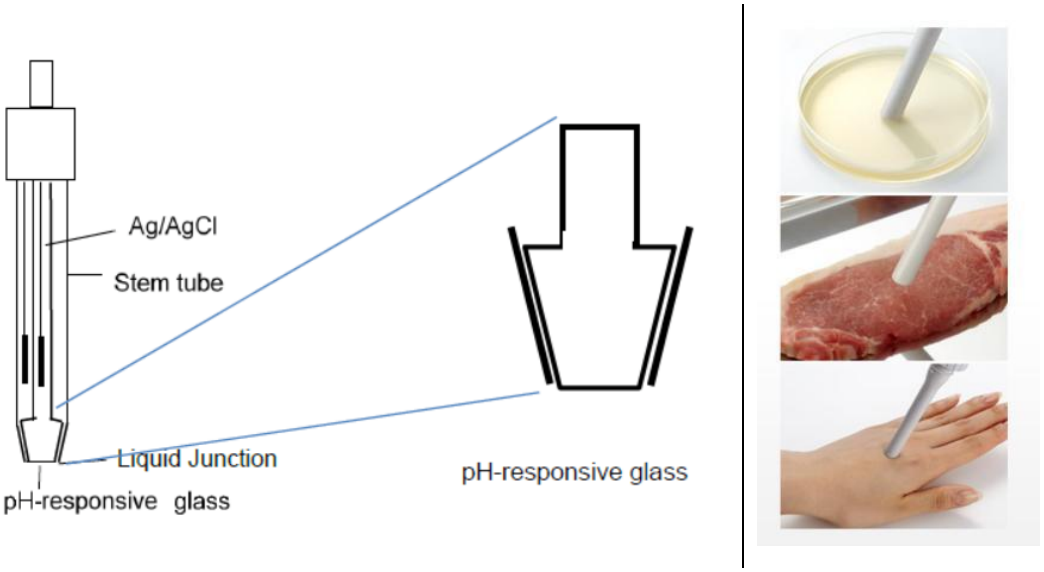
Flat type electrode

According to JBCE (2020a), the "flat type electrode is used for measuring the pH of a thin film such as paper, and is measured by penetrating a small amount of water into paper. Measurement is performed by bringing a film into contact with the surface of a flat object. Ammonia electrode has a flat pH responsive glass electrode inside. The flat membrane is joined to stem glass tube. The place where cracks are likely to occur is the joint between the responsive glass and the stem tube. The reason of the cracks is that the upper part of the joint portion of the stem tube is on the thread during manufacture and heat cannot be applied to the stem tube with a burner. The responsive glass and the stem tube have

different thermal coefficient of expansion (TCE) values and so cracks are likely to occur, unless lead glass is used as the stem glass tube."

JBCE (2020a) provided the images in Figure 5-4 for illustration.

Figure 5-4: Flat type example configuration (left) and application examples (right)



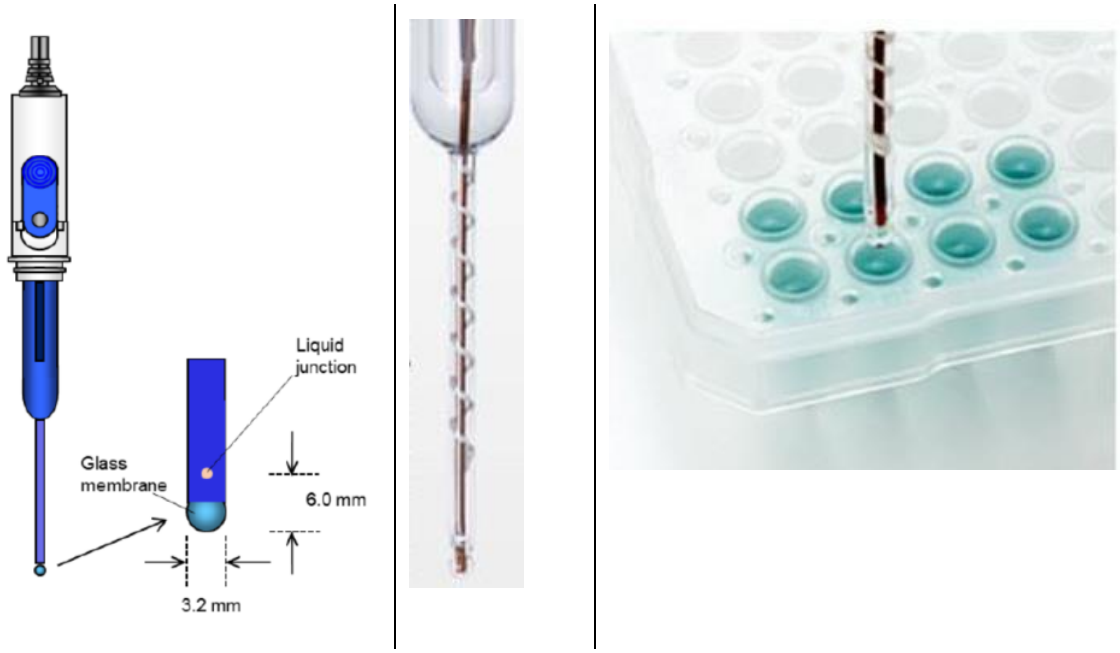
Source: JBCE (2020a)

Microelectrode type

JBCE (2020a) stated that "since the pH responsive glass membrane is small, it is necessary to make the glass composition rich in lithium oxide to reduce the responsive glass resistance to 300 MΩ or less, which is necessary for the electrode to function correctly as well as being a measurement method standard of the Japan Measurement Act. A large amount of lithium oxide inevitably increases the linear thermal expansion coefficient. Since the linear thermal expansion coefficient difference with the stem tube glass is large, cracks are likely to occur. Lead is what eases the stress between the two glass types."

JBCE (2020a) provided the images in Figure 5-5 for illustration.

Figure 5-5: Microelectrode type example configuration (left), close up of the pH responsive glass electrode (middle), and application example (right)



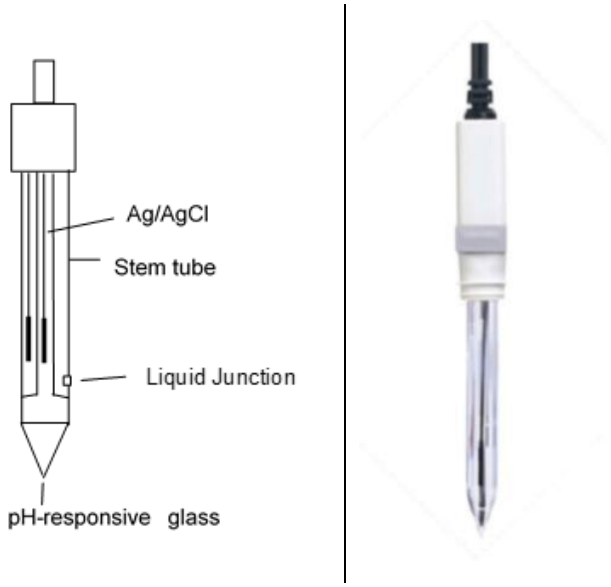
Source: JBCE (2020a)

Needle type

JBCE (2020a) stated: "In case of needle type, the stem tube is rotated with a lathe, the responsive glass is melted with a burner and placed on the stem tube. The shape is processed into the needle shape while gradually stretching the molten glass and therefore is unable to be heated further to join the glasses and form an intermediate layer without the use of lead. The place where the crack is likely to occur is the joint between the responsive glass and the stem tube, unless lead glass is used. This electrode has a sharp tip, to allow pH measurement by inserting it into a soft solid such as cheese or yogurt."

JBCE (2020a) provided the images in Figure 5-6 for illustration.

Figure 5-6: Needle type example configuration



Source: JBCE (2020a)

5.3. Justification for the requested exemption

5.3.1. Substitution of lead in pH glass electrodes

Lead-free glass

According to JBCE (2020a), "over the last 14 years, pH electrode manufacturers have carried out research into lead-free glass pH electrodes and this work has been successful for many designs. Electrodes that are simple in shape, such as general purpose electrodes are possible to process already with lead-free glass. However, where complex or unusual shapes of electrode are required, lead-free glass causes cracks during the manufacturing process that result in premature failure. Therefore, this exemption is needed for these designs."

JBCE (2020a) state that "lead-free pH glass electrodes are available on the market. However, lead in glass of pH glass electrodes is required in order to create an intermediate layer for the connection between stem tube and pH-responsive glass or pH glass membrane. Some complicated shapes explained in [section 5.2.2] cannot be formed without lead and currently there is no alternative technology that allow glass to be substituted."

Adding a more in-depth explanation, JBCE (2020a) state that "the thermal expansion coefficient of lead glass is close to that of pH responsive glass", stating that generally, the difference of the coefficient should be within 10 % for joining different kinds of glass firmly. JBCE (2020a) provided a table that shows the thermal properties of typical lead glass and lead-free glass (Table 5-1).

Table 5-1: Comparison of thermal properties of lead glass and lead-free glass

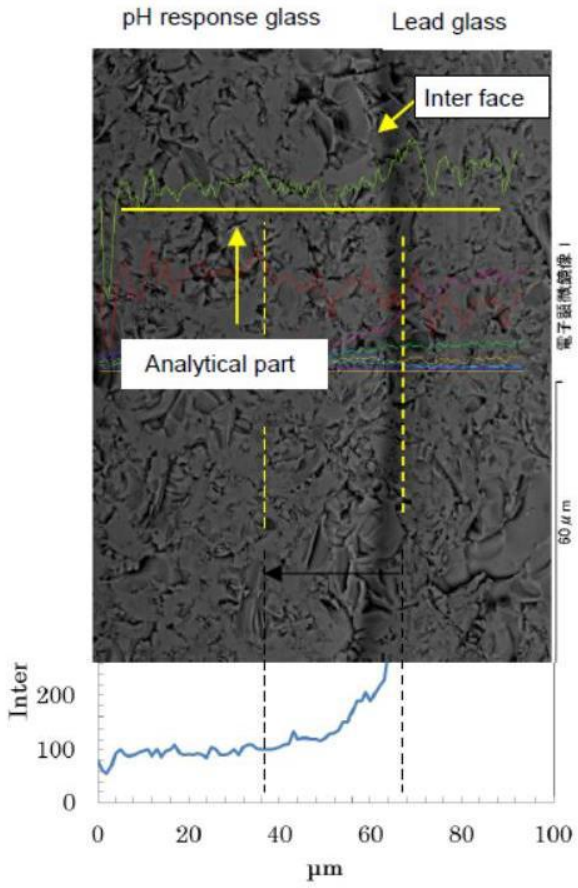
Glass Type	Stem GLASS		
Characteristic	L-29(NEG) *1 Lead Glass	PS-94(NEG) *2 Lead free glass	Schott AR GLASS *3 Lead free glass
Thermal expansion coefficient at 30-380℃ ($\times 10^{-7}$/K)	94	94.5	91.0
Density $\times 10^{3}$kg/m3	3.05	2.57	2.50
Strain point ℃	395	440	-
Annealing temperature ℃	435	480	530
Softening point ℃	625	665	720
Working point ℃	965	980	1040
WT% of PbO	29	None	None

Source: JBCE (2020a), citing third sources

JBCE (2020a) further explain that "since the thermal expansion coefficient of our pH responsive glass is 95 to 110 × 10^{-7} / K, bonding with lead glass is possible without any problem. Lead free glasses seem to have no problem because of their similar thermal expansion coefficients, however, they have different thermal characteristics other than expansion coefficient. For example, the softening point is higher at 665 °C and 720 °C, whereas lead glass is 625 °C, which differs by 40 °C or more. This difference means that the rate of shrinkage is different in the cooling process, so that higher strain stress is generated and cracks between different glasses are more easily occurred. This is the reason why lead-free glass is difficult to use for stem glass."

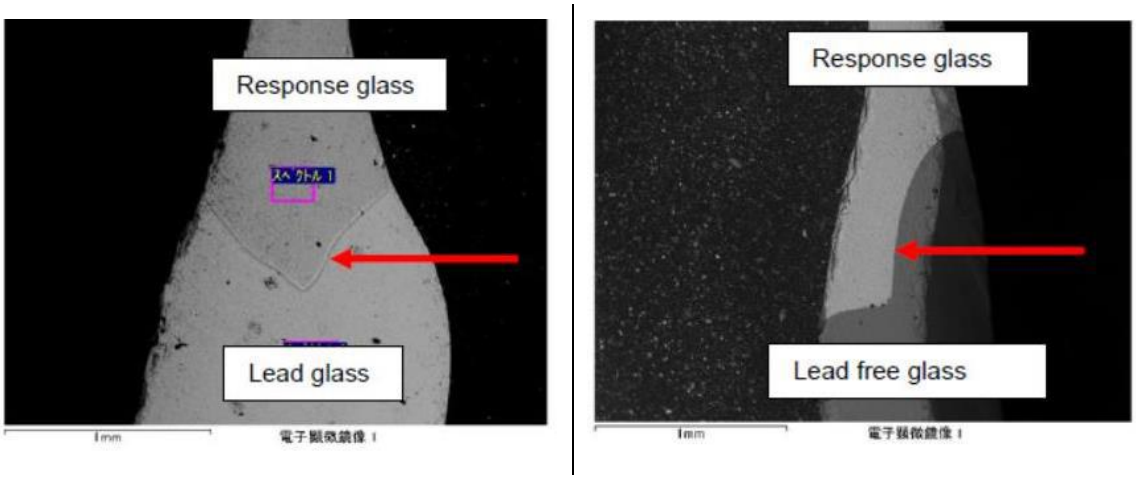
According to JBCE (2020a), another reason for the use of lead is that "lead glass is easily bonded to pH responsive glass firmly. This is because lead glass diffuses toward pH responsive glass and forms an intermediate layer between the two glasses". Figure 5-7 shows the result of line chemical analysis of lead in the bonding interface determined by EDX (energy dispersive X-ray analysis), which shows a distribution of lead in the glass. Figure 5-8 (left hand image) is a SEM (electron microscope) photograph of the joint of lead glass and pH responsive glass. As shown in the image, lead diffuses and makes a bonding interface layer which is seen on the image as a double line. In contrast, in using lead free glass, the interface is a sharp boundary as shown on the image as one clear line Figure 5-8 (right hand image). According to JBCE (2020a), "this means that the compatibility between the two glasses is small and does not have enough intermediate layer. In this case the bonding is performed only at the interface, and the bonding strength is weak and cracks can more easily occur."

Figure 5-7: Analysis of lead distribution in the joint between lead glass and pH response glass



Source: JBCE (2020a), citing an unnamed JBCE member company

Figure 5-8: SEM photographs of the joint between lead glass and pH response glass showing the diffuse interface layer (left) and SEM photograph of the joint between lead free glass and pH response glass (right)



Source: JBCE (2020a), citing an unnamed JBCE member company

JBCE (2020a) describe that "since there is no diffusion of elements such as lead when lead-free glasses are used, the joint interface becomes clear and cracks are likely to occur. The pH glass electrode measures the pH of an aqueous solution of acid or alkali. Ions contained in these measurement samples can enter the glass bonding interface and cause cracks after several weeks to several months (cracks that generate cracks over time are referred to as static fatigue cracks)."

JBCE (2020a) further state that "analyzing these phenomena by fluorescence analysis and optimizing the processing conditions can be improved to a large extent the ability to withstand crack formation. Conventional shape pH glass electrodes are able to be manufactured by blowing glass which has lead below the regulated value. However, pH electrodes which have a special shape (as described in section 5.2.2) has been devised to increase the alkali content of the response glass to lower the electrical resistance, and but this has the disadvantage of having a larger linear thermal expansion coefficient than lead glass. If a lead-glass support stem tube is used, the difference in expansion coefficient does not become a problem, but if a lead-free glass is used, the difference in TCE causes cracks. Because there is no lead diffusion (intermediate layer), static fatigue cracks are likely to occur at the joint bond between the tube glass and the responsive glass."

JBCE (2020a) argue that "one difficulty is that lead-free glass is much less flexible at the highest temperature that can be used to bond the stem glass tube to the pH sensitive glass. If the temperature is raised to further soften the glass, the stem glass becomes too soft and distorts so it is impossible to make complex shapes. Trials with the complex pH electrode types shown in section 5.2.2 resulted within a few hours of making the bonds, cracks will form within the bonds due to the stresses within the glass as it cools.

As a consequence of a higher softening temperature the more complex geometries of Flat type electrodes, Needle type electrodes and Microelectrode type lead free glasses are unable to be used as the higher temperature causes the deformation of the electrode during manufacturing."

Barium glass

When asked whether substances other than lead have been investigated to fulfil the same function in the stem glass of glass electrodes, JBCE (2021a) stated to not be aware of any "*examples of research for adding other elements in a stem tube that can achieve the same functionality as lead. The glass of stem tubes used for pH electrodes is commercially available product for a wide range of applications, not dedicated to pH electrode application. The development of stem tubes dedicated to pH electrode is not feasible for a large-scale production because the demand of pH electrode is far smaller than demand for other applications. Therefore, a glass responsive membrane that can be adapted to commercially available stem glass is being developed.*"

When specifically asked about whether barium glass might be a substitute for lead glass (this was stated by another company, cf. Table 5-6 in section 5.4 "Critical Review"), JBCE (2021a) stated: *"Barium is one of the general additives when making the glass, so we believe the main purpose of adding barium is not to achieve the same functionality as lead"*. JBCE (2021a) further clarified that in the glass-forming process, lead (specifically: lead oxide) is a glass-forming intermediate, while barium (specifically: barium oxide) is a glass

modifier. JBCE (2021a) explain the difference as follows: *"Since glass modifiers have weak bonds, metallic cations (such as Ba) can diffuse inside a glass during the high temperature fabrication process but will not contribute in bridging the glass network. On the other hand, "glass forming intermediates" such as lead oxide (PbO) are essentials for the formation process of glass. Lead cations (Pb) act as bridges in the glass network for the diffusion of different kinds of others elements by heat during the formation of the glass. PbO is therefore essential to bond glasses with different thermal characteristic, such as a relatively large variability in thermal expansion coefficient."* Therefore, according to JBCE (2021a), as barium is classified as a "modifier", not as a "glass-forming intermediate", barium does not have the same function than lead in the glass.

JBCE (2021a) provided a table with a classification of glass-forming inorganic substances, taken from the Glass Engineering Handbook (Table 5-1).

Table 5-2: Classification of glass-forming inorganic substances

Glass-network formers	Glass-forming intermediates	Glass modifiers
SiO2	TiO2	Li2O
B2O3	TeO2	Na2O
P2O5	Al2O3	K2O
GeO2	Bi2O3	MgO
BeF2	V2O5	**BaO**
	Sb2O3	CaO
	PbO	SrO
	CuO	LiCl
	ZrF4	NaCl
	AlF3	BaF2
	InF3	LaF3
	ZnCl2	
	ZnBr2	

Source: JBCE (2021a), stating the Glass Engineering Handbook as source

With respect to the glass-forming intermediates other than lead oxide, JBCE (2021a) provided the following comparison of required properties (**Table 5-3**). In this comparison, every compound has a negative impact in its application in pH electrodes.

Table 5-3: Comparison of glass-forming intermediates in necessary properties

	pH sensitivity	Alkaline error	Water proof	workability	Other disadvantages
Al2O3 Bi2O3 Sb2O3 AlF3 InF3 ZnCl2 ZnBr2	Low sensitivity	Cause of error	No negative impact	No negative impact	N/A
V2O5	No negative impact	No negative impact	Less water proof[1]	No negative impact	N/A
CuO	No negative impact	No negative impact	No negative impact	Less workability	N/A
TiO2 TeO2 ZrF4	No negative impact	No negative impact	No negative impact	No negative impact	Cause of less formability
PbO	No negative impact	No negative impact	No negative impact	No negative impact	N/A

Source: JBCE (2021a)

5.3.2. Elimination of lead

JBCE (2020a) describe ISFET electrodes and the use of fluorescent dyes as alternative technologies to lead-containing glass electrodes. The listed methods are stated to be shown as examples and not exhaustive.

Ion Sensitive Field Effect Transistor (ISFET) electrodes

JBCE (2020a) explain that instead of pH responsive glass membranes, metal oxide semiconductors can be used to measure the "potential generated depending on hydrogen ion concentration in a sample. It can be used in almost the same measurement range as the conventional electrode with responsive glass membrane. Since the surface is stronger than a glass membrane, and because there is no need to use glass for stem tube, the strength and the design of the liquid contact part is advantageous compared to conventional glass electrodes." JBCE (2020a), however, also point out problems with ISFET:

a. The ISFET resin body and semiconductor are susceptible to damage
b. The shape of ISFET electrodes cannot be completely flat
c. ISFET have a limited measurement range
d. Measurements are affected by light
e. Lower battery life of portable ISFET instruments

These four issues are described in more detail the following sections.

a. The ISFET resin body and semiconductor are susceptible to damage

JBCE (2020a) states that one disadvantage of ISFET is that its plastic body is damaged by many organic solvents or other similar substances: ISFET has a resin body, which can be damaged by organic solvent, chlorine and other chemicals that can permanently damage the ISFET chip. When asked to specify which components of an ISFET electrode are damaged by which substances, JBCE (2021a) specified the following three factors:

- *"A pH-sensor based on an ISFET chip is very sensitive to electrical static discharges (ESD) such as every Field-Effect transistor-based technology. Unlike most integrated circuits, which are operating in a closed, well-protected, environment, ISFET are often exposed to very high intensity ESD events. For example, very low conductivity waters or hands of someone manipulating the pH sensor can generate ESD events of dozens of kV that may deteriorate permanently an ISFET chip. Despite ESD-protection integrated in the ISFET pH sensor, some applications are not suitable for ISFET due to the high occurrence of ESD-events. On the other hands, glass-made pH electrodes are totally insensitive to ESD." JBCE (2021a)*
- *"The sensing layer of an ISFET is a metal oxide (for example, Al_2O_3 or Ta_2O_5) deposited during the CMOS process. Despite being chemically inert in most aqueous solutions, metal oxide materials will be dissolved in highly concentrated alkali solutions (such as 1M NaOH or KOH), with a etching rate increasing exponentially with the temperature." JBCE (2021a)*
- *"The body of the pH sensor, the substrate of an ISFET chip or the hydrophobic coating used to protect the ISFET connection can be damaged by long exposure in organic solvents." JBCE (2021a)*

When asked to explain the reasons why the body of ISFET electrodes is made from resin, and whether other materials, such as ceramics or glass, might be used alternatively, JBCE (2021a) responded that *"In the encapsulation process of the ISFET sensor, the ISFET chip and several additional components (such as a glass thermistor or a SMD capacitor) are mounted directly inside the plastic body, which has been designed on purpose to fit each component. This would be probably extremely difficult to fabricate a ceramic-based body that can accommodate such a complex geometry with the tolerance on size and the reproducibility that can be achieved with the current polymer body. We also believe that glass might not be suitable because some steps of the encapsulation process require some mechanical constraints on the sensor that can ultimately break a glass material."*

The consultants identified ISFET electrode products that use materials such as PEEK (Polyether ether ketone), FFKM (perfluorinated rubber) and ceramics[19]. When asked whether such products would have similar issues with damage from organic solvents or other substances, JBCE (2021a) responded: "*We agree that polymer materials you proposed can increase the chemical resistance for the body of the ISFET pH sensor, although some fluorinated materials may not bonded with adhesives. On the other hand, we believe that changing the material of the sensor body will not be effective to overcome*

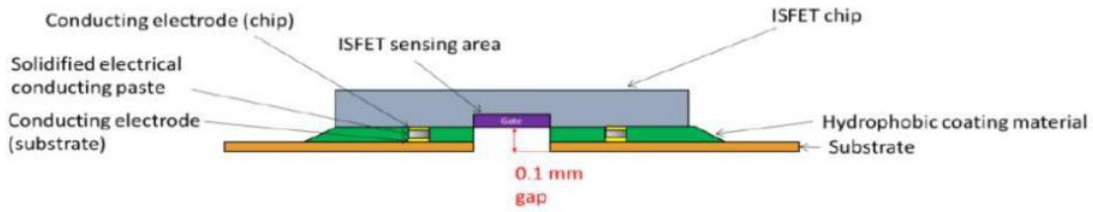
[19] Digital non-glass sensor Memosens CPS47D: https://www.de.endress.com/en/field-instruments-overview/liquid-analysis-product-overview/pH-digital-sensor-cps47d (last accessed: 2nd August 2021)

essential issues of the ISFET which are ESD events and low lifetime in strongly alkaline solutions. In addition, changing the material of the body will not remove the requirement of using a hydrophobic coating material in order to connect the ISFET chip with the substrate. A coating material will not have increased chemical resistance by changing the material body. ISFET pH sensor made with a PEEK or a FFKM body will certainly share most of limitations in the ISFET technology we stated earlier […]."

b. The shape of ISFET electrodes cannot be completely flat

Another disadvantage of ISFET described by JBCE (2020a) is that the shape cannot be completely flat, therefore ISFET cannot be applied in use cases where a completely flat electrode is required. The consultants identified suppliers ISFET pH electrodes that are designed to take pH measurements from the surface of solid samples via their flat-tipped sensor[20] and have the semiconductor-based sensor located less than 100 µm from the flat surface of the tip[21]. When asked about these product examples, JBCE (2021a) stated that the sensing area of the ISFET electrode must be in contact with the measured samples (typically water) but the conducting electrodes (the terminal to take out the electrical signal from a field effect transistor) must be kept strictly isolated from liquids to protect the sensor against malfunctions. This protection is typically performed by depositing a thin layer of a hydrophobic coating material, which leads to the sensing area of the ISFET chip being around 0.1 mm depth the level of the substrate. JBCE (2021a) provided the illustrating schematic produced in Figure 5-9.

Figure 5-9: Schematic of an ISFET



Source: JBCE (2021a)

JBCE (2021a) stated that "While the gap of 0.1 mm might be considered small compared to previous generation of ISFET products, this cannot prevent the formation of air bubble on the top of the sensing area during measurement. Air bubbles can be ultimately removed by stirring the solution. However, since there are some applications in which it is impracticable to stir during measurement, an ISFET pH electrode is not always an alternative to glass pH responsive electrode due to the 0.1 mm gap existing on the top surface of ISFET pH electrode."

When asked whether ISFET electrodes can generally be designed to be used in applications which require the three complex shapes relevant for this exemption request

[20] Horiba Flat ISFET pH Electrode - 0040-10D: https://www.agriculturesolutions.com/horiba-flat-isfet-ph-electrode-0040-10d (last accessed: 2nd August 2021)

[21] 0040-10D LAQUA Electrode pH ISFET https://www.alphaomega-electronics.com/en/electrodes/4599-0040-10d-laqua-electrode-ph-isfet-ion-sensitive-field-effect-transistor.html (last accessed: 2nd August 2021)

(flat, microelectrode, or needle type), JBCE (2021a) stated that *"It might be technically possible. However, the microelectrode design cannot accommodate the ISFET chip that is bigger than the 3 mm diameter of the pH sensing area. We address that the flat electrode cannot be done perfectly flat using ISFET for reasons explained on the previous point."*

c. Limited measurement range

JBCE (2020a) stated that while pH electrodes fitted with a glass membrane feature a measurement range of pH -2 to 16, ISFET has a more limited measurement range of pH 0 to 14.

d. Lower battery life of portable ISFET instruments

Another disadvantage mentioned by JBCE (2020a) is that "when using a common measuring equipment for conventional glass electrode, ISFET requires another signal conversion circuit, which increases the size of instruments and electric power consumption. Lifetime of batteries of portable instruments is shorter than the instruments with glass pH electrodes."

e. Measurements are affected by light

Lastly, according to JBCE (2020a), "the measured value is affected by light during measurement because of its semiconductor property, and so ISFET is not suitable for outdoor measurement or measurements in bright areas."

Optical measurements using fluorescent dye

JBCE (2020a) describe that "in this method, pH is measured by measuring the amount of emitted fluorescence according to the hydrogen ion concentration in sample solution. Since it is not necessary to use reference electrode, there is no concern that potassium chloride (KCl) solution derived from reference electrode will flow out to sample solution, which is particularly useful for measurement in a closed system.

However, this method also has some problems. One is that the range in which pH can be measured is narrow, and in some cases only pH 4 to 10 can be measured. Its measurement resolution is also low, making it difficult to see the difference in the order of 0.01 or 0.001. In addition, since it is affected by the influence of sample temperature and concentration of ions contained therein, it can be used only to know trends in limited situations. As described above, fluorescent method cannot be an alternative method of conventional glass electrode."

Comparison of glass membrane and potential alternatives

JBCE (2020a) provide a table comparing glass membrane and its potential alternatives regarding several aspects in **Table 5-4**.

Table 5-4: Comparison of glass membrane and potential alternatives

	Glass membrane	ISFET	Fluorescence
Response location	pH Response glass	Semiconductor (metal oxide compounds)	Fluorescent dye
Necessary equipment	Voltmeter (high impedance)	Signal coverter circuit	Fluorescence measurement
Measurement range	-2 to 16	0 to 14	4 to 10
pH resolution	0.001	0.001	0.1
Body material	Glass or Plastic	Plastic	Plastic
Influencing factors	-	Outer light	Outer light Ion concentration Temperature

Source: JBCE (2020a)

5.3.3. Roadmap towards substitution or elimination lead

JBCE (2020a) point out that for the three types of pH electrodes, micro size, needle type and flat type, that use lead glass in the scope of this exemption request, efforts are underway to make these without lead or reduced lead content.

With respect to the stages necessary for substitution of lead in the glass of these three electrode types and the timeframe needed for completion, JBCE (2020a) stated that glass of pH electrodes and ion selective electrodes require the intermediate layer in the glass and that there is currently no known way of creating an intermediate layer in the complex geometries described in section 5.2.2 without lead. Therefore, JBCE (2020a) cannot provide a specific time frame for searching for the composition of a lead-free glass substitute. JBCE (2020a) state, citing a third party report[22], that new product development time for many Category 8 and 9 products is over 4 years and can be 7 years or longer. This is considered an expected timeframe by JBCE (2020a) as instrument manufacturers will need to undertake engineering changes and evaluate the functionality of the alternative solution. The change would also mandate the update of global approvals, one of which is the submission of change of products as required by the Measurement Act of Japan. JBCE (2020a) cannot specify the period of the schedule but due to the complex nature of the product expect this to be over 7 years.

[22] ERA Technology (2006) , Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report, 2006, p.29 https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf (last accessed: 3rd August 2021)

5.3.4. Environmental arguments and socioeconomic impacts

JBCE (2020a) state that if this exemption is not renewed, "reliable pH electrodes could no longer be sold in the EU which will prevent many EU industries from operating and pollution could not be prevented (e.g. as water quality could not be monitored). EU industry would be at a very significant competitive disadvantage and there would likely be significant loss of EU jobs."

5.4. Critical review

5.4.1. REACH compliance – Relation to the REACH Regulation

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

Lead

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by"* the REACH Regulation if the requested exemption would be granted/renewed.

REACH Annex XIV (2021)[23] lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- *Lead chromate (entry 10);*
- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

The applications in the scope of the exemption at hand do not use any of the above lead compounds.

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16 and entry 17 restrict the use of lead carbonates and lead sulphates in paints;*

[23] ECHA, https://echa.europa.eu/authorisation-list?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

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

The above applications are not applicable to the use of lead in oxygen sensors.

- *Entry 28*[24] *addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30*[25] *addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they 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 above restrictions are not applicable to the use of lead in glass electrodes. Further, the substances are part of an article and thus are not placed on the market or used as substances, constituents of other substances or mixtures supplied to the general public.

- *Entry 63*[26] *restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72*[27] *stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

Lead oxides are constituents of leaded glass. In the scope of the exemption at hand, lead oxides are, however, not used in wristwatches or any other jewellery in the scope of entry 63, nor are conditions foreseeable where the oxygen sensors or the related equipment may be placed in the mouth by children. The same applies to entry 72, where it is not expected that leaded glass electrodes might be used in textiles, clothing or shoes in the scope of entry 72.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the 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 the respective criteria of Art. 5(1)(a) apply.

[24] 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

[25] 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

[26] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[27] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

Cadmium

With regards to **Annex XIV** of the REACH Regulation, cadmium in general or in compounds is not mentioned in the list of substances that require an **authorisation** for use.

With regards to **Annex XVII** of the REACH Regulation, cadmium is mentioned in a few of the listed restrictions.

Paragraph 1 of entry 23[28] of Annex XVII refers to cadmium and several of its compounds including cadmium sulphide. Under this entry, several restrictions are mentioned for cadmium and the compounds, among others:

- *A list of various polymers in which cadmium may not be used unless required in colour for safety reasons.*
- *Shall not be used for cadmium plating[29] metallic articles or components of articles used in equipment and machinery in certain branches and applications, e.g. cooling and freezing, food production, etc.*
- *Shall not be used in brazing fillers unless used for safety reasons*
- *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 exemption at hand, cadmium is neither used in polymers nor in platings or as brazing filler, and its use under the exemption is not related to jewellery. The above stipulations are therefore not applicable.

Due to their carcinogenicity, *entry 28[30] 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.*

As cadmium sulphide in ISE is a constituent of an article as opposed to substance or mixture, the exemption would not weaken the protection afforded by entry 28.

Entry 63 restricts the use of lead and its compounds as part of jewellery articles and provide a list of affected lead compounds, including

- *Cadmium sulphide (CdS), solid soln. with zinc sulphide, copper and lead-doped*
- *Cadmium sulphide (CdS), copper and lead-doped*

[28] C.f. ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e2518

[29] 'Cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface

[30] ECHA, https://echa.europa.eu/de/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

Cadmium sulphide is not used as part of jewellery in this exemption.

Entry 72[31] *lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It refers among others to cadmium and its compounds as listed under entries 28, 29 and 30 (germ cell mutagenic substances) and restricts their use in clothing and textiles. The entries list several cadmium compounds, among others cadmium sulphide.*

Like entry 28, this entry does not address cadmium as it is applied in exemption 1.

To conclude, none of the entries currently listed under REACH would apply to the case at hand. The use of cadmium in ISE 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.

5.4.2. Scientific and technical practicability of substitution or elimination of lead

Scope clarification

JBCE (2020a) requested the renewal of exemption 1(a) with a slightly modified wording that does no longer mention cadmium, as *JBCE has no knowledge of electrodes that contain cadmium*. JBCE (2020b) amended the renewal request specifying the exact applications for which the exemption is needed in the following updated wording. When asked, JBCE (2020c) agreed to a slight rewording that specifically highlights the stem glass as the part of the pH glass electrodes that requires the addition of lead, as other parts of the pH glass electrodes (e.g. the pH-responsive glass) do not require lead (changes in the requested formulation are underlined):

"Lead in the stem glass of pH glass electrodes and ion selective electrodes equipped with a pH glass electrode with complex shape as following:

I) 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;

II) 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;

III) 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."

The consultants note that no application was received for a renewal of the exemption for cadmium to be used in electrodes in scope of this exemption. Cadmium-selective electrodes traditionally use a cadmium sulphide membrane, as reported by Goodman (2006). The consultants requested three relevant companies to provide information on whether

[31] ECHA, https://www.echa.europa.eu/web/guest/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

cadmium may still be needed in this application, from which two responded. (Metrohm 2021c) stated that to their knowledge, cadmium would only be used in cadmium-selective electrodes, adding that Metrohm does not offer such electrodes, and that none of their electrodes contain cadmium. Another company, that did not agree to be named, stated that their ion selective electrodes for cadmium offered on the EU market do in fact contain cadmium sulphide (CdS). Another company stated that the cadmium-selective electrodes in their portfolio are free of cadmium. The latter two responses were received after the draft report for this review had been submitted. Therefore, further in-depth investigation was not feasible.

Substitution of lead glass with lead-free glass

Lead-free glass

The core technical reason argued by JBCE (2020a) why lead-free glass cannot be used in the three types of glass electrodes for which the exemption is requested is that *the intermediate layer required for the bonding of the stem glass and the pH responsive glass cannot form sufficiently when using lead-free stem glass*. Two characteristics of lead are highlighted by JBCE (2020a) that make the use of lead indispensable:

- *Lead is an element which has a low chemical potential, and so rapidly diffuses into different types of glass at the time of bonding to form an intermediate layer even in a short time.*
- *The thermal expansion coefficient of lead glass is close to that of pH responsive glass, and its softening point (625°) leads to a shrinkage rate during the cooling process that prevents higher strain stress, thereby avoiding cracks.*

When asked, JBCE (2021b) specified that the required softening point on the stem tube for bonding pH responsive glass membrane is between 625 and 700 degrees Celsius. Therefore, the physical requirements for a lead-free glass as a potential substitute for lead glass are:

- Thermal expansion coefficient of 95 to 110 × 10−7 K^{-1} ±10 %
- Softening point between 625°C and 700°C

JBCE (2021b) also confirmed that there are no other required physical properties for the glass, and that "*joining is possible as long as the physical characteristics (thermal characteristics) are within the above required range*".

During the evaluation of the exemption request, the consultants identified a few lead-free glass types, including SG036 and Schott 8366, the properties of which are compared with the requirements stated by JBCE in Table 5-5.

Table 5-5: Comparison of required physical properties with lead-free glass types

	TCE	Softening point
Requirements stated by JBCE	95-110×10^{-7} K^{-1} ± 10 %	625-700 °C
SG036 lead-free glass	105x10^{-7} K^{-1}	675 °C
Schott 8366 lead-free glass	92x10^{-7} K^{-1}	675 °C

When asked about SG036, JBCE (2021b) explained that the TCE in the specification sheet of SG036 is defined differently from the definition used by JBCE: "*Thermal Expansion you referred as 105 is calculated based on the amount of change between Room Temp (20 deg C) and Set Point (about 485 deg C). TCE definition we are adopting is change between 100 to 300 deg C. Our required TCE range is 95-100 between 100-300 deg C.*" The specification sheet of SG036 also states the TCE between 0°C and 300°C to be 92.5x$10^{-7}$$K^{-1}$, which is also below the required range stated by JBCE.

Concerning the glass type Schott 8366, JBCE (2021b) stated: "*is also one of the candidates, because the softening point seems to be within (close to) our required range." JBCE further explained that since the market demand for pH electrodes is extremely small and unsteady compared to other applications, the procurement of Schott 8366 for pH electrodes is problematic with respect to timing. According to JBCE's knowledge, the next lot of 8366 is planned to be manufactured around Summer 2022. Further, JBCE state that "Even after getting 8366, it will take 5-7 years for us in order to evaluate the lot-to-lot variation, and to optimize our production process.*" It should be noted that the TCE is also slightly below the required range stated by JBCE.

The consultants can follow the argument that both lead-free glass types are not within the required TCE range specified by JBCE and may therefore not be considered "drop-in" replacements for currently used lead glass. Both glasses, however, may be considered as potential candidates to substitute lead glass in the future, if production processes can be optimized by JBCE.

In correspondence with Metrohm, another supplier of pH glass electrodes and ion selective electrodes (cf. Table 5-6), they stated to have *transitioned from lead to barium glass for most types of electrodes*. When asked whether using barium instead of lead glass would also be feasible for JBCE, the applicant stated that *barium is one of the general additives when making glass and that the main purpose of adding barium is not to achieve the same functionality as lead*. Further investigating barium as a potential substitute for lead, the consultants identified scientific literature discussing the substitution of lead glass with barium-containing glass in technical applications as opposed to decorative and other applications of such glasses. (Lityushkin et al. 2000) positively evaluated the substitution potential of high-lead glass with barium-containing glass in the production of light sources, stating: "*Glasses known as barium crystal with BaO mass content up to 20 % and total content of alkaline oxides up to 18 % have recently gained wide acceptance. The TCLE* [thermal coefficient of linear expansion; the consultants] *of such glasses is (99 - 109) x* 10^{-7} *K […]. They have low softening point and viscosity* 10^{10} *Pa sec (510- 520°C), rather high temperature* T_k*-100 (290-300°C), and are easily melted, molded, and heat-treated.*" While

the TCE seems to be well aligned with TCE of the pH responsive glass of 95 - 110 × $10^{-7}K^{-1}$, as stated by JBCE (2020a), the softening point deviates from that of the pH responsive glass (625°C) by more than 100 °C.

This difference in the softening point is larger than the difference pointed out by JBCE (2020a) when comparing lead glass to commercially available lead-free glass. *JBCE (2021b) confirmed that the softening point of the described glass was lower than the required range (625 to 700 °C), and added that it is likely not on the market, as the only commercially available stem glass tubes were in the range of 91 to 94 x 10^{-7} K^{-1}.*

Adding to the above, the substitution potential of the described glass with high barium in the lighting industry does not necessarily indicate the feasibility of substitution in pH electrodes, as these are entirely different applications with different requirements.

Market-available lead-free pH glass electrodes

The consultants investigated whether other manufacturers and suppliers of pH meters or glass electrodes offer lead-free products corresponding to the three complex electrode shapes relevant for this exemption renewal request. Eight suppliers that operate within the EU were contacted. Answers were received from five companies and are summarized in **Table 5-6**. Only the names of companies are explicitly stated that engaged in more in-depth discussions leading for relevant conclusions for the exemption evaluation, other companies are not named in the table.

Table 5-6: Summary of company inquiries for lead-free pH glass electrodes

Company	Relevant products	Response	Conclusions
Hanna Instruments	pH electrodes, ISE	All pH glass electrodes are manufactured with lead-free glass	Offer lead-free flat type, micro type and needle type electrodes
Metrohm	pH electrodes, ISE	Transitioning from lead glass to barium glass for many electrode types, incl. flat-type electrodes.	Offer lead-free flat type, micro type and needle type electrodes
Company 3	pH sensors for water	All products are lead-free, but only “standard products” - cannot make statement on the three complex shapes.	No conclusions for the specific electrode types relevant for this exemption request.
Company 4	pH meters incl. with flat electrode	Initially confirmed to manufacture all electrodes without added lead.	Did not respond to request to confirm that the electrode types relevant for this exemption request

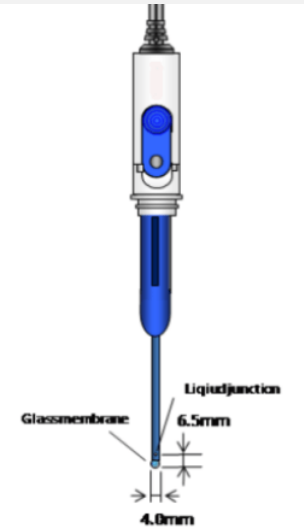
			are indeed manufactured without added lead.
Company 5	Glass products	Insufficient insights into electrode manufacturing	n/a

(Hanna Instruments 2021a) stated that the glass used in their pH electrode production is lead-free and provided information on the properties of the used glass type SG036 (see TCE and softening point data cited in Table 5-5). The company offers flat type, micro type and needle type electrodes in their product catalogue and confirmed that all electrodes are manufactured using the lead-free glass.

(Metrohm 2021a) stated to have transitioned from lead glass to barium glass for most of their pH electrodes, stating that many glass electrodes were already manufactured using barium glass. In further correspondence, (Metrohm 2021a) confirmed that their flat, micro and needle type electrodes are manufactured without the addition of lead.

A comparison of electrode types in the scope of the requested renewed exemption and those offered by Hanna Instruments and Metrohm is provided in the following tables.

Table 5-7: Comparison of Micro Type pH Glass Electrodes

JBCE specified electrode	Example electrode from Metrohm	Example electrode from Hanna Instruments
		
"*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*	Combined electrode that has a spherical pH responsive glass membrane with a diameter of 3 mm and a reference electrode with a liquid junction at a position	Combined electrode that has a spherical pH responsive glass membrane with a diameter of 3 mm and a reference electrode. *Source: https://hannainst.de/707-*

vertically within 6.5 mm from the tip."	vertically within 7 mm from the tip. *Source: https://www.metrohm.com/de-de/products-overview/60224100*	*hi1093b-kombinierte-mikro-ph-elektrode.html*

Table 5-8: Comparison of Flat Type pH Glass Electrodes

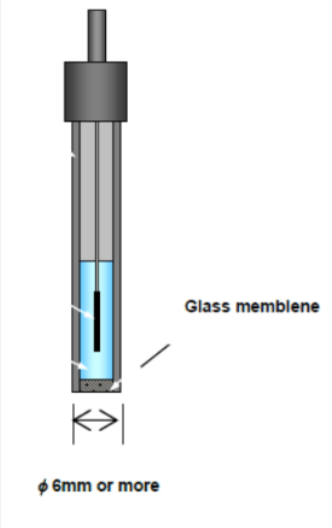
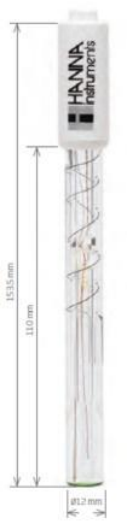
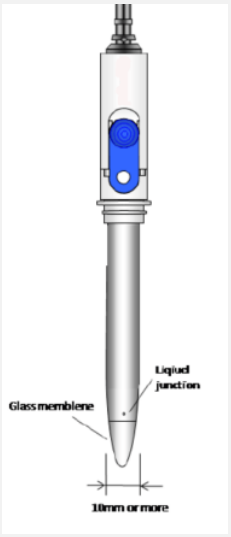
JBCE specified electrode	Example electrode from Metrohm	Example electrode from Hanna Instruments
		
"*pH glass electrode with a flat pH response membrane at the tip of a glass tube with a diameter of 6.0 mm or more.*"	pH glass electrode with a flat pH responsive membrane at the tip of a glass tube with a diameter of 12 mm. *Source: https://www.metrohm.com/de-de/products-overview/60256100*	pH glass electrode with a flat pH responsive membrane at the tip of a glass tube with a diameter of 12 mm. *Source: https://hannainst.de/731-hi14143-ph-elektrode-mit-flacher-spitze-quick-din-anschluss.html*

Table 5-9: Comparison of Needle Type pH Glass Electrodes

JBCE specified electrode	Example electrode from Metrohm	Example electrode from Hanna Instruments
		
"*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.*"	Combined electrode that has a conical pH response membrane with a diameter of 6 mm. *Source: https://www.metrohm.com/de-de/products-overview/60226100*	Combined electrode that has a conical pH response membrane with a diameter of 10 mm (at the tip). *Source: https://www.hannainst.com/fc2100-digital-ph-temperature-electrode-for-dairy.html*

When asked to point out technical differences between the JBCE electrodes (using lead) and the electrodes from Metrohm and Hanna Instruments (using no lead), JBCE (2021c) stated: "*there does not seem be significant difference between HANNA instruments and our required pH electrode performance in comparison*" when specifications are compared, and further: *"[…] mechanically, the electrodes offered by Metrohm and Hanna Instruments closely match our specification. However, we believe that it will take 5-7 years for us in order to evaluate the lot-to-lot variation, and to optimize our production process in order to bond our pH responsive glass membrane with necessary property to the lead-free stem glass."*

Only with respect to the micro type pH electrode, JBCE found the measurement range to be different, in that the JBCE reference electrode has a wider measurement range (the specific Hanna Instruments electrode has a measurement range of pH 0-12). JBCE (2021c) provided a table comparing basic specifications of the leaded electrodes described by JBCE with the lead-free products by Metrohm and Hanna Instruments, reproduced in Figure 5-10.

Figure 5-10: Specification comparison of the lead vs. lead free electrodes

	Flat type			Needle type			Micro type		
	Leaded	HANNA	METROHM	Leaded	HANNA	METROHM	Leaded	HANNA	METROHM
model number		HI14143	6.0256.100		FC2100	6.0226.100		HI1093B	6.0224.100
Measurement range	0-12pH	0-12pH	0-13pH	0-12pH	0-12pH	1-11pH	0-14pH	0-13pH	1-11pH
Temperature range	0-50°C	0-50°C	0-60°C	0-60°C	0-60°C	0-60°C	0-60°C	0-50°C	0-60°C
Size	Φ12 x 150mm	Φ12x153.5mm	Φ12x125mm	Φ12x150mm	Φ10x163.5mm	Φ6x98mm	Φ3x151.5mm	Φ3x150mm	Φ3x113mm

Source: JBCE (2021c)

Due to the above information, the consultants consider the basic specifications of the leaded and lead-free electrodes to be very similar. With respect to the measurement range of the micro type electrode*, (Hanna Instruments 2021b) stated that the measurement range of the micro type electrode HI1093B is actually pH 0-14 and therefore equal to the lead electrode*.

With regards to differences that may justify the exemption, *JBCE (2021b) added that they found differences in the measurement performance caused by the difference in the pH responsive glass membrane, stating:* "*We strongly believe that "the reliability of substitutes is not ensured", because pH responsive glass membrane we use (which has better performance) is not suitable to bonding to the stem glass which HANNA Instruments uses."*

When asked whether non-confidential data can be shared to substantiate these claims, JBCE (2021c) provided a further statement in combination with the data table reproduced in **Table 5-10** and the diagram reproduced in Figure 5-12.

The consultants note that the tested Hanna Instruments electrode (type HI10832) is a lead-free micro electrode, having a spherical tip with a diameter of 3 mm, shown in Figure 5-11 (rotated by 90°).

Figure 5-11: Hanna Instruments electrode HI10832

Source: Hanna Instruments[32]

[32] HI10832 in the Hanna Instruments online shop: https://hannainst.de/2338-hi10832-halo-ph-elektrode-fuer-laboranwendungen.html [last accessed: 16 September 2021]

Table 5-10: Performance comparison of the lead vs. lead-free electrode

Performance parameters		Leaded	HANNA-HI10832 (Lead free)
Sensitivity (%)	pH4.01-pH6.86	99.4	97.3
	pH6.86-pH9.18	99.4	99.2
	pH4.01-pH9.18	99.4	98.2
Repeatability (mV)	pH6.86	1.3	5.3
	pH4.01	1.3	2.2
	pH9.18	1.1	5.3
Responsiveness (mV)	pH6.86	0.7	-0.6
	pH4.01	0.3	-0.1
	pH9.18	0.3	0.4
Alkaline error (mV)	0.1 M NaOH	12.8	12.9
Tap water response time(s)	Tap water	12.2	199.0
Resistance of glass ($\times 10^8 \Omega$)	3.33 M KCl	1.19	5.62

Source: JBCE (2021c)

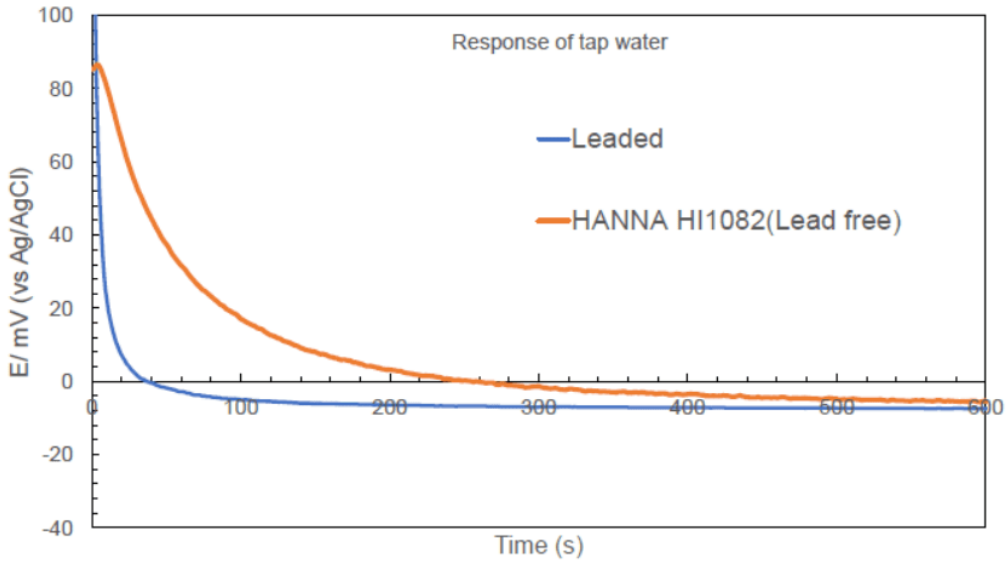
Upon request, JBCE (2021d) stated that *the buffer solutions were compliant with the Japanese Industrial Standard JISZ8802 at 25°C*. JBCE (2021d) also explained that test results in the category repeatability are to be interpreted as follows:

"Regarding the relationship between mV and pH, it follows Nernst equations as described in BN EN60746-1.

- *In the case of 5.3mV is converted to 0.089 pH (at 25 deg C).*
- *In the case of 1.3mV is converted to 0.021 pH (at 25 deg C).*

We strongly believe that the sensitivity is very essential to detect the proper condition in the aquatic ecosystem. For some of fish species, small change of pH value will cause increasing mean percentage mortality."

Figure 5-12: Response data comparison of the lead vs. lead-free electrode

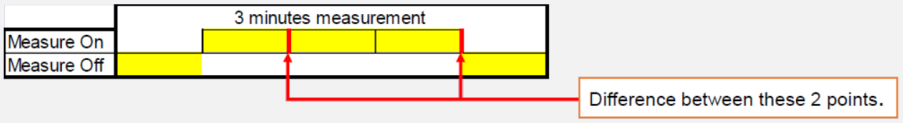


Measured by BS EN 60746 "Expression of performance of electrochemical analyzers", (2003)
10 min measurement of tap water, after the standards solution(pH4) measurement.

Source: JBCE (2021c)

JBCE (2021c) provided measurement conditions for each of the performance parameters reported on in the above figures. The parameters in which the lead-free electrode is shown to perform worse are repeatability and tap water response time. These are defined by JBCE (2021c) as reproduced in Table 5-11.

Table 5-11: Measurement condition for repeatability and tap water response time

Aspect	Definitions provided by JBCE (2021c)
Repeatability (mV)	*"Measure the buffer solutions pH7, pH4, pH9 for 3 minutes each. Difference between reading value at one minute, and at 3 minutes."* 
Response of tap water (T90)	*"Measured by BS EN 60746 "Expression of performance of electrochemical analyzers (2003).* ▪ *10 min measurement of tap water, after the standards solution (pH4) measurement. Then calculate the 90 % of the electric potential at 10 min later after starting the tap water measurement.* ▪ *Then calculate the elapsed time to reach the above 90 % of the electric potential from the starting time of the tap water measurement."*

When asked whether the reduced repeatability and tap water response of the lead-free electrode was directly caused by the electrode's characteristic of being lead-free, JBCE (2021d) stated: *"Adding lead does not contribute to the response time, but adding alkaline metal elements or alkaline earth metal elements do contribute. So, it is necessary to add a large amount of alkaline oxide as glass modifiers. In general, the coefficient of thermal expansion of glass is determined by the property and amount of each oxide component. As alkaline metal elements or alkaline earth metal elements have a large coefficient of thermal expansion, the coefficient of thermal expansion of the response glass membrane increases when it is optimized to perform with higher response time. Therefore, the better performance response glass membrane makes it difficult to bond with lead-free glass."*

When requested to comment on the data provided in the above figures, *confirmed the longer response time of the sensor HI1082, which was stated to be due to the internal design of the sensor, including diaphragm type, electrolyte, and other factors. This was said to be also the case for the sensors HI14143 und FC2100. While Hanna Instruments stated that the response time is not directly causally related to the stem glass being lead-free, as this is not the ion-sensitive component of the pH electrode, they did not disagree with the above explanation provided by JBCE. (Hanna Instruments 2021b) could not immediately provide their own measurement data for the parameter "repeatability", citing the short time available for responding. (Metrohm 2021b) suspected that not the glass type of the electrode, but the composition of the membrane (diaphragm) was the decisive factor to determine the "repeatability" and "response time".*

In the consultants' view, the test result data on one electrode from one supplier does not allow drawing conclusions on the entire range of available lead-free electrodes from several manufactures. When asked whether test data on other lead-free electrodes was available, JBCE (2021d) stated: *"To our best knowledge, Methrom has not been identified as a supplier of lead-free pH electrode. So, we have never evaluated ones from Methrom. We are planning to evaluate, once we get it. However, as long as we confirmed, there is no stock in Japan, so it will take around 2 to 3 months to get."* (Hanna Instruments 2021b) stated that it cannot be assumed that other lead-free electrodes also have a higher response time and lower repeatability.

Elimination of lead

Other technologies that may be used instead of glass electrodes are ISFET electrodes and optical sensing using fluorescent dyes. JBCE provided a range of reasons arguing that currently, neither technology can substitute pH glass electrodes in all applications.

ISFET

The applicant pointed out a range of disadvantages of ISFET compared to glass electrodes that may hinder them to substitute glass electrodes in all applications. Among those, those that appeared most relevant to the consultants were researched further:

a. *The ISFET resin body and semiconductor are susceptible to damage:* This argument appears plausible. However, it should be noted that glass membranes are also susceptible to physical damages to the glass. ISFET electrodes are often advertised by manufacturers and suppliers to be useful in cases in which the more fragile glass

electrodes cannot be used. However, glass may be more resistant to the types of damage (i.e. ESD, organic solvents, etching by alkali solutions) described by JBCE.

b. *The shape of ISFET electrodes cannot be completely flat*: The consultants identified market-available ISFET electrodes that are advertised to be of flat shape, however, JBCE correctly pointed out that the sensing element of the electrode is commonly offset from the surface by 0.1 mm. *JBCE argued that air bubbles tend to form in the gap, which disturb the measurement and which cannot always be dispersed by shaking or stirring the measured solution.* This argument appears plausible to the consultants.

c. *ISFET have a limited measurement range*: It was confirmed in a non-exhaustive market research that ISFET electrodes are advertised to measure the range of max. pH 0 to 14 and do not cover the extreme ends of the spectrum (pH -2 up to +16) so that this argument is technically correct and can be followed.

With respect to shapes other than flat type, JBCE (2021a) stated that "*it might be technically possible. However, the microelectrode design cannot accommodate the ISFET chip that is bigger than the 3 mm diameter of the pH sensing area*". When asked whether ISFET packages could be manufactured as small as with a 3 mm diameter, JBCE (2021b) stated: "*To our best knowledge, it is achievable to manufacture less than 3mm ISFET chips (sensing area). However, it needs to be larger size than 3mm when making it the ISFET package*. *To make smaller ISFET package result in sacrificing the durability, because the smaller package size, the less reliability on ESD [electrostatic discharge; the consultants] resistance.*"

As to the needle type, JBCE (2021b) responded "*Needle type can be made if the dent is acceptable." When asked to elaborate in this statement, JBCE (2021c) stated that although needle type electrodes with ISFET exist in the market, not all types of measurement allow the operator to check whether air bubbles exist on the tip of the sensor. JBCE also state to believe that the dent on the tip of the electrode will sometimes cause electrode failure, because debris and particles may easily get stuck there, and brushing them into the sensor may damage it when cleaning the electrode.*

In the consultants' view, the arguments presented by JBCE are plausible. Electrodes fitted with ISFET may be suitable for some applications, but due to the wider measurement range and higher geometric flexibility, they may not substitute glass electrodes in all applications.

Fluorescence

Regarding pH measurement via fluorescent optical sensors, *JBCE (2020a) argued that due to the narrow measurement range of pH 4-10 as opposed to -2 to 16 using glass electrodes, it cannot substitute glass electrodes in all use cases*. The argument of limited measurement range could be confirmed in a non-exhaustive survey of publicly available information. This is also confirmed by other publications such as (Gotor et al. 2017), stating that the working range of fluorescent pH indicators is commonly 2 pH units, which only allows for the determination of pH values in specific pH windows. (Gotor et al. 2017) further explain that researchers have conceived various strategies to broaden the pH range of optical

indicators, but that "*among the large amount of optical pH sensors reported, only very few cover a range of ≥10 pH units and all of these systems rely on the combination of dyes*".

In the consultants' view, therefore, the argument provided by JBCE appears plausible, and it seems measurements using fluorescent optical sensors can indeed not substitute glass electrodes in all applications.

5.4.3. Environmental arguments and socioeconomic impacts

The reasons for the requested renewal of this exemption are solely technical and no arguments have been presented that favour pH glass electrodes using leaded glass over its alternatives in environmental or socio-economic terms. JBCE (2020a) stated that *reliable pH electrodes for specific applications could no longer be sold in the EU if the exemption expired and that the EU industry would be disadvantaged and jobs may be lost.* The consultants can follow this line of argument.

With respect to the amount of lead entering the EU market through this exemption, JBCE only provided an estimate for the products of its member companies (14 grams per annum) and did not provide any data on the entire EU market. Goodman (2006) did also not report amounts of lead placed on the market through pH glass electrodes per se, but reported 200 grams of lead from ion-selective electrodes per annum. It is not immediately clear whether this number also includes pH glass electrodes, which can be considered a type of ion selective electrode that is selective for hydrogen.

Due to the fact that lead has been substituted in many pH glass electrodes including in ion-selective electrodes since then, the consultants assume that the order of magnitude of lead entering the EU market through products in scope of this exemption request is likely in the range of a few dozen or hundred grams up to several kilograms. However, this is to be considered a best guess in the absence of factual data.

As glass electrodes can reasonably be assumed to be used by professionals rather than private consumers, it can be reasoned that it is more likely that an appropriate collection and recycling pathway is taken at their end of life. Therefore, the uncontrolled release of glass bound in the glass matrix becomes less likely.

5.4.4. Conclusions

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

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

In their initial exemption renewal request, JBCE described the progress over the past 14 years and stated that the transition to lead-free glass has been successful for pH electrodes that are simple in shape. The applicant consequently narrowed the scope of the exemption request to three specific and well-defined types of electrodes: those with a flat shape, micro electrodes, and needle type electrodes. Extensive descriptions and evidence on material level was presented to demonstrate why lead-free glass cannot substitute lead-containing glass in the manufacturing of those complex-shaped electrodes. The applicant further narrowed the scope of the exemption request by stating that cadmium is no longer needed in the wording of the exemption, as JBCE are unaware of any electrode that uses cadmium.

Initially, JBCE primarily argued with the lack of manufacturability of three specific types of pH glass electrodes when using lead-free glass. However, during the evaluation, the consultants identified other suppliers that stated to manufacture the same three specific types of pH glass electrodes without the use of lead. Two of them, Hanna Instruments and Metrohm, engaged in extensive communication and provided documents to support their statements. JBCE confirmed that the products from those two manufactures closely match the specifications of the three specific types of glass electrodes for which the renewal of this exemption was requested.

The main argument by JBCE after this point was that “the reliability of alternatives is not ensured”, which JBCE demonstrated with measurement data from a lead-free electrode from Hanna Instruments compared with a lead electrode from an unnamed manufacturer, in which the lead electrode performs better in the tests on “repeatability” and “tap water response time”. *Hanna Instruments confirmed the longer response time of their lead-free electrode.*

In the consultants’ view, JBCE could have performed measurements with other lead-free electrodes, such as the flat and needle type electrodes from Hanna Instruments, in order to evaluate whether these could deliver the required performance. This does not seem to have taken place.

Regarding the elimination of lead through the use of alternative technologies, the consultants can follow the arguments presented by the applicant. ISFET and optical measurement with fluorescent dyes both have limitations compared to glass electrodes. Limitations include the limited measurement range of both methods, limited shape, and susceptibility to damage in the case of ISFET.

In conclusion, the technical barrier described by JBCE – the lack of manufacturability of glass electrodes with complex shapes using lead-free glass – has been disproven in the consultants’ view. Other manufacturers, such as Hanna Instruments and Metrohm, in fact offer such electrodes using lead-free glass. Nevertheless, the secondary argument presented by JBCE – the reduced responsiveness and repeatability – was not disproven, even when requesting the manufacturers of lead-free electrodes to comment. It should be noted, however, that JBCE based this argument on testing a single lead-free electrode by one supplier. Now that JBCE is aware of the fact that more suppliers of lead-free electrodes exist, more comparative testing can be carried out.

The consultants conclude that the available information does not allow the conclusion that lead-free glass electrodes can substitute leaded glass electrodes in all applications and find it reasonable to renew the exemption with the new wording. However, it should be noted that the real-life relevance of the performance differences of lead-free glass electrodes compared to leaded glass electrodes (i.e. repeatability, tap water response time and the ability to measure extreme ends of the pH spectrum) in the various applications of such electrodes could not be unambiguously clarified. In a possible next review, it should be clarified whether these aspects indeed prevent the substitution of leaded glass electrodes in practice and in which specific applications.

The consultants further conclude 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.

Scope and timing of the renewal request

As explained under section 5.4.2 “Scope clarification”, no application was received for a renewal of the exemption for cadmium to be used in ion selective electrodes. After the submission of the draft report, the consultants received information that cadmium is in fact contained in some ion selective electrodes that detect cadmium ions. In this late stage of the review process, it was not feasible to further investigate whether cadmium-free ISE are available for all types of measurements that are conducted using cadmium-containing ISE.

The applicant requested the renewal of exemption 1(a) only for the use of lead in EEE of cat. 9 IMCI. As a result, the renewed exemption would no longer cover the use of cadmium in these appliances, which might cause shortages of ISE containing cadmium and of the respective IMCI for specific measurements.

For cat. 9 IMCI, the expiration date is on 21 July 2024, i.e. the current review started three years before the exemption would have expired. The fact that no request to renew the exemption for cadmium was submitted can be interpreted in two ways: Either, cadmium is no longer needed, or companies that still require the exemption for cadmium were not aware that the review of this exemption is taking place three years ahead of its expiry. For this reason, the consultants consider it reasonable to suggest two options for the wording of the renewed exemption.

For cat. 8 IVD, exemption 1(a) expires on 21 July 2023, and as the request for renewal does not pertain to category 8 devices, the exemption in its current wording could continue to apply to category 8 IVD until 21 July 2023 with the possibility to request further renewal in due time.

5.5. Recommendation

The available information suggests that substitution and elimination of lead in pH glass electrodes and ion selective electrodes equipped with a pH glass electrode is not yet feasible in all cases as the reliability of substitutes is not ensured. In the consultants’ view, Art. 5(1)(a) would therefore allow granting an exemption.

In reference to the section “Scope and timing of the renewal request” above, the consultants suggest two options for the wording of the exemption.

- Option A builds on the stakeholders’ and their associations’ responsibility to follow with due diligence the developments in the context of regulations which are applicable to their products. It therefore only takes account of the exemption request situation, i.e. that no renewal was submitted for cadmium in ISE applied in cat. 9 IMCI. This approach results in the below exemption wording and timing:

Exemption wording option A

	Exemption	Scope and dates of applicability
1(a)	*Lead and cadmium in ion selective electrodes including glass of pH electrodes*	*Expires on* - *21 July 2021 for cat. 8 other than in vitro diagnostic medical devices* - *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.*

- Option B, besides the renewal request from JBCE, takes into account that the renewal request was submitted 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. Some stakeholders and their associations despite due diligence may not have been aware of the consequences that might arise from this situation. Considering that this is the first larger review of Annex IV exemptions, this may be justifiable. If

the COM wishes to follow these considerations, the consultants recommend renewing the exemption for cadmium in ISE in cat. 9 IMCI as exemption 1(a)(I) for the originally foreseen validity period until July 2024:

Exemption wordings option B

	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.*

The consultants recommend renewing the exemption for lead in ISE in cat. 9 in the scope of exemption 1(a)(I) in option A or 1(a)(II) in Option B for a period below the maximum possible as suppliers may be able to demonstrate substitutability within a shorter time than the maximum validity period requested by the applicant.

For the next review of this exemption, the consultants expect that the applicant will be able to provide comparative measurement data on the performance of all or most available lead-free pH glass electrodes with the geometric specifications of the electrodes in the scope of

the renewed exemption, as such and as part of ion selective electrodes. It should be demonstrated whether any insufficient performance compared to specific lead electrodes (naming manufacturer, product identifier and the electrode geometries) still exist that hinder substitution. It is also expected that the applicant can provide a list of applications in which glass electrodes are needed for measurements of the extreme ends of the pH spectrum (below zero and above 14). Further, in case the “repeatability” and “tap water response time” of lead-free electrodes still do not match the performance of lead electrodes, and this is brought forward as an argument for another renewal of this exemption, the applicant is expected to provide technical insight into the relevance of these parameters in specific real-life applications where the substitution with lead-free electrodes is prevented due to their subpar performance in these two test criteria.

5.6. References

Directive 2002/95/EC: Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 1). RoHS 1. Fundstelle: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0095:EN:NOT, zuletzt geprüft am 04.12.2013.

Directive 2011/65/EU: 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 (recast). RoHS 2. Fundstelle: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065.

Goodman (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report (amended). ERA Report 2006-0383. Unter Mitarbeit von Paul Goodman. ERA Technology Ltd. Online verfügbar unter http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf.

Gotor, Raúl; Ashokkumar, Pichandi; Hecht, Mandy; Keil, Karin; Rurack, Knut (2017): Optical pH Sensor Covering the Range from pH 0-14 Compatible with Mobile-Device Readout and Based on a Set of Rationally Designed Indicator Dyes. In: *Anal. Chem.* 89 (16), S. 8437–8444. DOI: 10.1021/acs.analchem.7b01903.

Hanna Instruments (2021a): Correspondence on exemption 1(a) of RoHS Annex IV, 16.08.2021. Email an Christian Clemm (Fraunhofer IZM).

Hanna Instruments (2021b): Correspondence on exemption 1(a) of RoHS Annex IV, 08.09.2021. E-Mail an Christian Clemm (Fraunhofer IZM).

JBCE (2020a): Request for renewal of exemption 1a of RoHS Annex IV. Online verfügbar unter https://www.rohs.biois.eu/Ex_1a-IV_JBCE_Renewal-Request.pdf.

JBCE (2020b): Update of the request for renewal of exemption 1(a) of RoHS Annex IV. Online verfügbar unter https://www.rohs.biois.eu/JBCE_IV-1c.pdf.

JBCE (2020c): Answers to questionnaire 1 (clarification questionnaire) for RoHS exemption 1(a) of Annex IV. Clarification questionnaire. Online verfügbar unter https://www.rohs.biois.eu/Ex-1a-IV_JBCE_Questionnaire-1_Clarification.pdf.

JBCE (2021a): Answers to questionnaire 2 for RoHS exemption 1(a) of Annex IV, zuletzt geprüft am 30.07.2021.

JBCE (2021b): Answers to questionnaire 3 for RoHS exemption 1(a) of Annex IV. JBCE (5-6), zuletzt geprüft am 26.08.2021.

JBCE (2021c): Answers to questionnaire 4 for RoHS exemption 1(a) of Annex IV. JBCE, zuletzt geprüft am 09.06.2021.

JBCE (2021d): Answers to questionnaire 5 for RoHS exemption 1(a) of Annex IV. JBCE, zuletzt geprüft am 15.09.2021.

Lityushkin, V. V.; Kovalenko, A. I.; Sivko, A. P.; Smirnova, L. P.; Filimonova, M. A. (2000): Barium-containing glass as an efficient substitute for high-lead glass in the production of light sources. In: *Glass Ceram* 57 (5-6), S. 193–194. DOI: 10.1007/BF02681275.

Metrohm (2021a): Correspondence on exemption 1(a) of RoHS Annex IV, 18.08.2021. Email an Christian Clemm (Fraunhofer IZM).

Metrohm (2021b): Correspondence on exemption 1(a) of RoHS Annex IV, 17.09.2021. Email an Christian Clemm (Fraunhofer IZM).

Metrohm (2021c): Correspondence on exemption 1(a) of RoHS Annex IV, 04.10.2021. Email an Christian Clemm (Fraunhofer IZM).

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

6. Exemption 1(b) of Annex IV: Lead anodes in electrochemical oxygen sensors

The exact wording of the current exemption 1(b) of Annex IV is as follows:

"Lead anodes in electrochemical oxygen sensors"

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 other than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date is scheduled for 21 July 2023, and for IMCIs for 21 July 2024.

Declaration

In the sections preceding section 6.4 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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and definitions

BOD	Biological oxygen demand
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
CPAP	Continuous positive airway pressure
CE	Counter electrode
DIN	German Institute for Standardization
DO	Dissolved oxygen
ECMO	Extracorporeal membrane oxygenation
EEE	Electrical and electronic equipment
IMCI	Industrial monitoring and control instruments
ISO	International Organization for Standardization
ITG	International Technologies Gambert
IVD	In-vitro diagnostic medical devices
JBCE	Japan Business Council in Europe

MRI	Magnetic resonance imaging
NO	Nitrogen oxides
Pb	Lead
ppb	Parts per billion
ppm	Parts per million
RE	Reference electrode
RoHS 1	Directive 2002/95/EC
RoHS 2, RoHS	Directive 2011/65/EU
WE	Working electrode

6.1. Background

COCIR (2020b) requested the exemption to be renewed using the same phrasing ("Lead anodes in electrochemical oxygen sensors") until the end of 2025 for new instruments that use electrochemical oxygen sensors that contain lead and for the maximum validity period for replacement oxygen sensors.

(JBCE 2020a) also requested the exemption to be renewed using the same phrasing ("Lead anodes in electrochemical oxygen sensors"), but for the maximum validity period (7 years).

Stakeholder contributions were received from ITG (2020a) and JBCE (2020c).

6.1.1. 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. Applications for renewal were submitted in time, and exemption 1(b) was reviewed for the first time to adapt it to scientific and technical progress.

6.1.2. Summary of renewal requests and stakeholder contributions

Renewal requests

Table 6-1 below gives an overview of the exemption requests and the requested wordings.

Table 6-1: Overview of exemption requests

Applicant	Proposed Wording	Duration	RoHS Category and Applications
COCIR (2020b)	Lead anodes in electrochemical oxygen sensors	Until the end of 2025 for new instruments which use electrochemical oxygen sensors that contain lead. Maximum validity period for replacement oxygen sensors.	Cat. 8: Medical devices others than in-vitro diagnostic medical devices "*Respiratory care products that measure oxygen concentration of inhaled and exhaled air for patients, for example in anaesthesia workstations and in ventilators.*" COCIR (2020b)
(JBCE 2020a)	Lead anodes in electrochemical oxygen sensors	Maximum validity period (7 years)	Cat. 9: monitoring and control instruments including those used in industry "*Analysis and measuring instruments for oxygen concentration*" (JBCE 2020a)

Application from COCIR

According to COCIR (2020b), *"This exemption is required to allow the use of electrochemical oxygen sensors for measurement of oxygen concentrations in inhaled and exhaled air of patients who are being ventilated, and when undergoing surgery or MRI scans when under anaesthesia. Electrochemical sensors have many advantages including their very small size and no need for a power supply which provide them with unique functionality critical to patient care.*

Alternative types of oxygen sensor have been assessed, but all alternative types are unsuitable for the aforementioned applications. Lead-free electrochemical sensors have recently become available and have been evaluated. Tests have shown that these are not drop-in replacements and cannot be used with the existing oxygen analyser instruments currently in use in EU hospitals and clinics. Analyser instruments that are connected to the sensors and indicate the oxygen concentration are being redesigned to use new lead-free sensors although these cannot be sold in the EU until redesign, testing a qualification is complete and Medical Device Regulation approval is granted which is not expected before 2025. This exemption will be required after 2025 to allow the currently used lead-based sensors to be used as replacements with the current designs of analyser instruments that are in use in EU hospitals and clinics."

Application from JBCE

The applicant (JBCE 2020a) "[…] request the extension of exemption 1b of Annex IV for Lead anodes in electrochemical oxygen sensors used in monitoring and control devices. There is a wide variety of measurement methods for oxygen concentration. Galvanic oxygen sensors with lead anode are one of measurement methods of oxygen concentration. Galvanic oxygen sensors with lead anode are incorporated into analysis and measuring instruments for oxygen concentration measurement to provide rapid and accurate analysis

and wide ranges of measurement. The technology is used by a wide variety of industry sectors, researchers and for educational purposes.

Galvanic sensors with lead [lead-free, the consultants] anodes are available on the market; however, the technical requirements, such as, measurement range, accuracy and response time are not sufficient for some analysis and measuring instrument for oxygen concentration. The other substitutes are also not feasible technically."

Stakeholder contributions

Stakeholder contributions were received from JBCE (2020c) and ITG (2020a).

Contribution of JBCE

JBCE (2020c) complemented the information provided in their renewal request (JBCE 2020a) and their response to the consultant's first clarification questionnaire JBCE (2020b) by providing information showing that electrochemical oxygen sensors that use lead as the anode (galvanic electrode method) work on the same principle for detecting oxygen gas and dissolved oxygen. It is further stated that "*dissolved oxygen sensor is required higher detectivity compared to the oxygen gas sensor, because the dissolved oxygen sensor has lower saturated value compared to the oxygen gas*".

Contribution of ITG

ITG (2020a) stated to supply a "line-up of lead-free (free of any heavy-metals) oxygen sensors as either drop-in replacement or as customised version into the EU as well as outside EU market" since the year 2013. ITG (2020a) state that their lead-free galvanic oxygen sensors are already well established in the market.

ITG (2020a) stated to "disagree in all respect to the requesters input such as technical requirements (lack of measurement range, accuracy and response times), incompatibilities (as there are, mechanical and electrical interfacing) and the sensor's properties of being a drop-in replacement".

According to ITG (2020a), the basic advantages of their lead-free sensors "when integrated into analysers are size, costs, less expenditure on electronics (processing units, no power supply make them superior for portable use) reasonable gas treatment and head-space. However, former insufficiencies linked to the classical leaded fuel cells (lifetime, drift, toxic and environmentally hazard) are eliminated by the lead-free alternative. What is more, in some points the lead-free variant has caught up or even overtaken competitive oxygen sensor technologies."

According to ITG (2020a), around 70 % of their lead-free sensors are sold "into to the medical field, particularly life-supporting systems (ventilators, anaesthesia machines, ECMOs), ergo-spirometry (breath-by-breath analysis) and home-care therapeutic instruments (CPAP-systems). The remaining part is divided into various industrial applications such as flue gas measurement, process technology, oxygen deficiency (gas-blanketing), quality inspection and others."

ITG (2020a) explained that their lead-free sensor "is still of galvanic type comprising a zinc anode and a counter-electrode consisting of any kind of precious metal. The weak acidic electrolyte (caesium-carbonate as leading constituent) has been designed and tailored in

order to withstands impacts of acidic gases, i.e. carbon-dioxide, aggressive bromides, anaesthesia gases or harsh solvents."

In conclusion, ITG (2020a) stated to see no reason to renew the exemption currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

6.2. Technical description of the requested exemption

6.2.1. Amount of lead used under the exemption

According to COCIR (2020b), the amount of lead entering the EU market annually through applications for which the exemption is requested is approximately 8 to 13.5 kg per year. This is based on the following data and estimations: "Each cell typically contains 8 to 9 grams of lead. Estimated sales in the EU for medical applications is expected to be about 1000 to 1500 sensors per year" COCIR (2020b).

(JBCE 2020a) stated "We do not have information about overall of the market. Our amount of Lead of entering the EU market is 2 kg approximately".

ITG (2020a) stated that the amount of lead entering the EU market annually is largely underestimated by COCIR. Instead of the 1.000 to 1.500 sensors per year, "ITG estimate the market for medical oxygen sensors to be at least 150.000 sensors and the industrial market at 100.000 sensors annually. This is supported by ITG's sales numbers. A typical sensor contains 10 g lead and is replaced annually. This means that 2.5 tons lead are entering the European market but not only 8 to 13.5 kg as COCIR claims." When asked, ITG (2021b) confirmed that their "approximation has deducted the amount of sensors that have been converted to lead free technology already".

Table 6-2: Amount of lead used under the exemption

	Medical sector	Industrial sector
COCIR (2020b)	8 – 13.5 kg / a	n/a
(JBCE 2020a)	n/a	2 kg / a (JBCE members only)
ITG (2020a)	1.500 kg / a	1.000 kg /a

This substantial divergence between the data provided by the applicants and data provided by ITG was further explored by the consultants. When asked to provide a statement on this divergence, COCIR (2021c) stated that *"Oxygen sensors have many other uses. Our estimate of lead use is for use in equipment for measurement of oxygen concentrations of inhaled and/or exhaled air for patients in some types of medical devices like respiratory care products, anaesthesia machines etc." COCIR (2021b) further stated: "COCIR can only estimate the use of lead in the applications of interest of COCIR Members. […] we are not aware of the data estimations provided by ITG. It seems ITG, as a supplier of such sensors,*

has different market data to COCIR, which may be representative of a much wider market segment."

When asked to assess the data provided by ITG, JBCE (2021b) stated: *"To our best knowledge, the typical oxygen sensor contains less than 5 g of lead per unit."*

6.2.2. Applications in the scope of the requested exemption

COCIR (2020b) request the renewal of the exemption for lead for use in electrochemical oxygen sensors for measurement of oxygen concentrations in inhaled and exhaled air of patients who are being ventilated, and when undergoing surgery or MRI scans when under anaesthesia.

(JBCE 2020a) request the renewal of the exemption of lead for use in galvanic oxygen sensors with lead anode that are incorporated into analysis and measuring instruments for oxygen concentration measurement to provide rapid and accurate analysis and wide ranges of measurement. The technology is used by a wide variety of industry sectors, researchers and for educational purposes.

The applications in the medical and industrial sector are described in more detail below.

Electrochemical oxygen sensors in medical devices

COCIR (2020b) explain that "oxygen in patients' breath is measured by small electrochemical sensors that contain lead anodes. These are used very close to the patient's mouth so must be small and lightweight. 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 supplied to patients and in their exhaled breath needs to be monitored to ensure that they are not being harmed by a poor air supply and monitor their medical condition. Oxygen concentrations need to be accurately monitored if a patient is very ill (e.g. needing to be ventilated), during surgery, incubators for infant and premature babies or if patient are anaesthetised during MRI (magnetic resonance imaging) examination. Sensors used during MRI scans must not contain magnetic materials which occur in most types of electronic components (these usually contain nickel as a barrier coating on terminations).

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.

Electrochemical oxygen sensors consist of two electrodes; a high surface area lead anode and an inert cathode which are immersed in an alkali electrolyte. The anode and cathode reactions are:

- *Cathode: $O_2 + 2H_2O + 4e^- \rightarrow OH^-$*
- *Anode: $2Pb + 4OH^- \rightarrow 2PbO + 2H_2O + 4e^-$"*

According to COCIR (2020b), electrochemical reactions at the anode and cathode generate "*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 air-oxygen 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 medical device 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 breathing gases (inhalation / exhalation) is a prerequisite regarding patient safety for the correct control of anaesthesia procedures. Beside the requirement regarding measurement accuracy, rapid response behaviour is also essential and this analysis method of O_2-measurement ensures immediate reaction strategies by the anaesthetist during medical surgery.

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 medical applications, such as with patient ventilators or during anaesthesia. The few exceptions to this are acid gases and CO_2 will react with the electrolyte (potassium hydroxide or potassium acetate are usually used) and users are warned that this should be minimised, but anaesthesia gases have only a minimal effect on this type of sensor."

According to COCIR (2020b), "*for monitoring patients, the following characteristics are essential, for which the use of lead is required:*

- *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 in the concentration range of 0 % to 100 %*
- *Must be usable and accurate in the presence of commonly used anaesthesia gases (such as Halothane, Isoflurane, Sevoflurane and Desflurane), N_2O and CO_2.*
- *Usable at 0 % – 99 % non-condensing humidity*
- *Accuracy should not be affected by typical CO_2 concentrations in exhaled breath*
- *Sensors must not contain magnetic materials when they are used with MRI scanners"*

COCIR (2020c) provided commonly used examples of devices containing the oxygen sensors in the scope of this exemption request:

- *Anaesthesia equipment used in hospital operating theatres to ensure that the patient is breathing correctly*
- *Intensive care ventilators and ventilators used for other locations such as in ambulances, hospitals wards, etc. Ventilators aid monitor breathing and monitor the oxygen concentration in inhaled and exhaled breath.*

Examples images for both types of devices were provided by COCIR (2020c) and are reproduced in Figure 6-1.

Figure 6-1: Examples of medical devices that use oxygen sensors in scope of this exemption request

	
Anaesthesia equipment	Ventilator

Source: COCIR (2020c)

Electrochemical oxygen sensors in monitoring and control instruments in industry

(JBCE 2020a) explain that "electrochemical oxygen sensors are essentially small fuel cells which use oxygen as fuel and have a very small orifice to control the flow of gas into the cell. Within the cell, an electrochemical reaction occurs generating current which is proportional to the oxygen concentration.

For electrochemical oxygen sensors that uses lead as the anode (galvanic electrode method), a noble metal (typically gold or platinum, silver) is used at the cathode."

(JBCE 2020a) explain that the following reactions take place within the sensors:

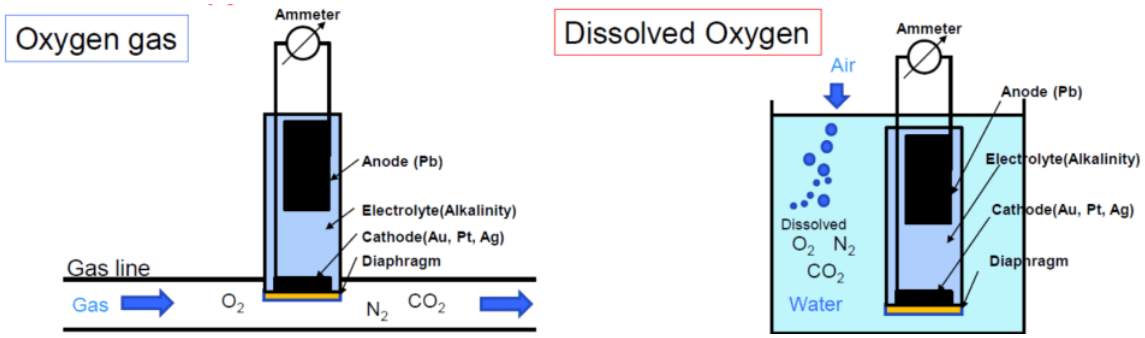
- *at the cathode:* $O_2 + 2H_2O + 4e^- \rightarrow 4OH^-$
- *at the lead anode:* $2Pb + 4OH^- \rightarrow 2PbO + 2H_2O + 4e^-$
- *overall reaction:* $O_2 + 2Pb \rightarrow 2PbO$

(JBCE 2020a) state that "the lead anode is consumed in a way that is similar to a battery and so these devices could be and some are used as batteries."

According to (JBCE 2020a), "*lead has one main advantage that it does not corrode in the cell spontaneously and so does not produce a current in the absence of oxygen. Sensors based on lead have a reasonably long life and can be used typically for 1 to 2 years which is important for sensors which are in hard-to-reach areas where replacement opportunities are limited. Another advantage of this type of sensor is that they do not consume power and so the batteries used in portable oxygen meters have long lives. The design of the device including the galvanic sensor has a circuit configuration in which the potential difference between both ends of the positive electrode and the negative electrode is calculated as an output because the sensor itself is a battery."*

JBCE (2020c) illustrate the functional principle of galvanic electrode oxygen sensors in the schematic diagram in **Figure 6-2**.

Figure 6-2: Schematic diagram of the diaphragm galvanic electrode method for measurement instrument of oxygen gases and air (left) and in liquids (right)



Source: JBCE (2020c)

(JBCE 2020a) explain that "electrochemical oxygen sensors are incorporated with analysis and measuring instruments in order to analyse and measure the concentration of oxygen in liquids and air/gases.

Analytical and measuring instruments are designed to analyse and measure qualitative and quantitative aspects of the compositions, properties, structures, and states of substances. Qualitative and quantitative information of substances is basis of today's science and technology, and its applications are expanding the categories (fields) including living environments, global environments, medical and health care, space exploration and the others.

The applications listed below are categorized and are not exhaustive.

- *Analysis and measurement of dissolved oxygen in liquid is used in the following applications:*
  - *Process control in the industrial facilities: use and control for production and manufacturing lines, as well as environmental protection to ensure hazardous gases are contained*
  - *Use in laboratories; the research, quality control and other applications, applications including the research about anaerobic bacteria and the anti-oxidisation of food package by a wide variety of sectors, researchers and for educational purposes.*
  - *Quality control; control of oxygen concentrations in food packages and of drinking water and sewerage.*
  - *Use for environment (pollution) analysis*
- *Analysis and measurement of oxygen concentration in the air/gas for:*
  - *Process control in the industrial facilities: use and control for production and manufacturing lines.*
  - *Research in laboratories for applications such as monitoring of environmental test laboratories, and control of thermostatic ovens.*
  - *Use for workplace control and security: security checks in workplace, such as, checks before work, and control of laboratories.*
  - *Quality control; control of oxygen concentrations in food packages*
  - *Use for environment (pollution) analysis; oxygen concentrations in the emission gases from vehicles and others*"

6.3. Justification for the requested exemption

6.3.1. Substitution of lead in galvanic oxygen sensors

Reactive metals as anode material

According to COCIR (2020b), "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.

Research has shown[33] that the more reactive metals such as tin, zinc and aluminium are unsuitable as they are thermodynamically unstable in suitable electrolytes. Electrolytes

[33] Lead-Free Galvanic Oxygen Sensors. A Conceptual Approach, Cornel Cobianu, et. al (Honeywell). CAS (International Semiconductor Conference) 2012, Abstract from https://www.semanticscholar.org/paper/Lead-free-galvanic-oxygen-sensors- %E2 %80 %94-A-conceptual-Cobianu-Serban/e4cfb461b42eba465ee2410d5637bf7453079bf6

such as potassium hydroxide (used with lead) and other alkali solutions, acidic solutions such as phosphoric acid and caesium carbonate solution (mildly alkali) have been investigated.

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, commercially available oxygen sensors that use tin anodes in a caesium carbonate electrolyte are being sold in the EU. The applicants of this renewal request have however evaluated these sensors for their specific applications and found that they do not meet their specifications when used with existing designs of analyser instrument.

Regarding zinc specifically, (JBCE 2020a) explain that "as a substitute candidate of lead anode, zinc has a suitable electrode potential and electrochemical potential. However, zinc is a much more reactive metal than lead and corrodes spontaneously, even in the absence of oxygen. This greatly shortens the life of the sensor and gives a continuous but variable background current so that low oxygen concentrations are impossible to measure".

Less reactive metals as anode material

According to COCIR (2020b) "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. Nobel metals such as gold and silver do not respond at all as they do not react with oxygen from air."

(JBCE 2020a) add that "there are research and academic reports with respect to antimony, bismuth, and antimony-bismuth alloys as alternatives to lead anodes, but there is very limited data on the measurement of such devices and there is no in-service data for long term behaviour."

Influence of interference gases

With relevance to the medical sector, COCIR (2020b) stated: "When used for monitoring breathing when a patient is anaesthetised, it is important that the accuracy of the sensor is not affected by anaesthetic gases. Many years of use in hospitals has shown that these gases have no effect on lead in electrochemical sensors, but extensive testing is needed with any potential substitutes to determine whether it will be accurate and reliable before approval can be obtained under the Medical Devices Regulation. Anaesthesia gases are water soluble to a small extent, so small amounts will dissolve in the sensor's electrolyte and could affect its function.

Additionally, when some anaesthetic gases, such as halothane, are exposed to sunlight or UV light they decompose to give halides which may affect the way that the anode dissolves. Therefore, it cannot be assumed that alternative metals to lead will respond in a similar way when used in oxygen sensors for medical applications and so extensive testing is essential."

With relevance to monitoring and control instruments, (JBCE 2020a) stated: "A galvanic cell type sensor using an anode other than lead for measuring oxygen concentration in gas is on the market. However, before changing to a different type of sensor, manufacturers need to ensure that they give accurate results, especially when measuring oxygen in the presence of other gases that might interfere with the sensor's behaviour to give incorrect results. When this interference gas is classified by use, there are various types such as "industrial process equipment", "research", "workplace environment management", "quality control", "environmental measurement", and the like. In addition, there are about 60 kinds of interference gases that might occur, and the concentrations of these gases existing for each application is different and so their effect will be different. The effect of these interference gases on galvanic cell type sensor using an anode other than lead will need to be fully verified by the combination of application and concentration."

(JBCE 2020a) further stated that "Above all, the verification on the lifetime is evaluated for each application (for each type of interference gas), and the expected lifetime requires a long verification period. Furthermore, verification is needed for all likely interference gases, combinations of these gases, all possible concentrations of these gases as well as all possible oxygen concentrations."

Disadvantages of available lead-free electrochemical oxygen sensors

With respect to the medical sector, COCIR (2020b) stated 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.

Due to the internal design of the cell (which is required by the anode material) it is not possible to adjust the way that the output voltage changes as the anode is consumed by electrical means to reproduce the behaviour of a cell with a lead anode. Therefore, lead-free sensors cannot be used as drop-in replacements for the lead anode sensors used in currently available commercial oxygen analysers."

With respect to monitoring and control devices, (JBCE 2020a) stated that "Although some products have already been commercialized with respect to zinc, the low oxygen concentration sensitivity of the ppb range is higher than that of products using lead, and replacement in the full concentration range has not yet been realized.

In the case of oxygen sensors for dissolved oxygen measurement, an anode sensor using zinc is available in some markets, but is limited as it cannot measure low concentrations of dissolved oxygen. In fact, there are applications that require continuous monitoring and batch measurement of low concentrations in process management such as monitoring the amount of dissolved oxygen to prevent corrosion inside a boiler, quality control to prevent oxidation of food, and research applications such as the culture of oxygen anaerobic bacteria. An anode sensor using lead is required in such cases that measurement and monitoring of low concentration oxygen is required."

Contrasting description of lead-free electrochemical oxygen sensors by ITG

ITG (2020a) stated to "disagree in all respect to the requesters input such as technical requirements (lack of measurement range, accuracy and response times), incompatibilities (as there are, mechanical and electrical interfacing) and the sensor's properties of being a drop-in replacement."

ITG (2020a) further stated: "ITG offers and supplies since 2013 a line-up of lead-free (free of any heavy metals) oxygen sensors as either drop-in replacement or as customised version into the EU as well as outside EU market. When compared to the classical leaded-anode counterpart such sensors are characterised by:

- *RoHS is no longer applicable in general to ITG's lead-free sensors;*
- *No hazardous materials, less risk in case of any damage;*
- *Not considered as toxic waste and therefore easier to dispose of;*
- *Ground and airborne transportation is much easier due to harmless electrolyte;*
- *Noticeable longer lifetime relieving logistics supply chain and stocking time;*
- *A significant longer operation time;*
- *Considerably less output signal drift and hence longer calibration intervals possible;*
- *A faster response time;*
- *A lesser linearity error;*
- *Same geometrical dimensions and form-factor and largely electrically equivalent design;*
- *No external electrical power needed to operate."*

Regarding the market update, ITG (2020a) stated that "Since the introduction of this lead-free cell, we have seen a considerably increasing demand in the world-wide market. That market can be divided into two sales of channels, firstly device manufacturers using the cells for the initial assembly of their analysers and secondly through distributors to service the demand of the aftermarket. Whereas the later lags thanks to the longer product life of the lead-free cell a bit behind the first. Around 70 % of the lead-free sensors go into to the medical field as there are all life-supporting systems (ventilators, anaesthesia machines, ECMOs), ergo-spirometry (breath-by-breath analysis) and home-care therapeutic instruments (CPAP-systems). The remaining part is divided into various industrial

applications such as flue gas measurement, process technology, oxygen deficiency (gas-blanketing), quality inspection and others."

ITG (2020a) explain that their line of "lead-free sensor is still of galvanic type comprising a zinc anode and a counter-electrode consisting of any kind of precious metal. The weak acidic electrolyte (caesium-carbonate as leading constituent) has been designed and tailored in order to withstands impacts of acidic gases i.e. carbon-dioxide, aggressive bromides, anaesthesia gases or harsh solvents." Comparing leaded and lead-free sensors in terms of compatibility, handling, and other characteristics, ITG (2020a) point out only three differences: electrically, the recommended load resistor for the lead-free sensor is >1 MΩ, while it is >1 kΩ for leaded sensors, and chemically, lead-free sensors work with weak alkaline electrolytes while leaded sensors work with strong alkaline electrolytes. Lastly, ITG (2020a) report that the lead-free sensor is less susceptible to CO_2 interference than the leaded sensor.

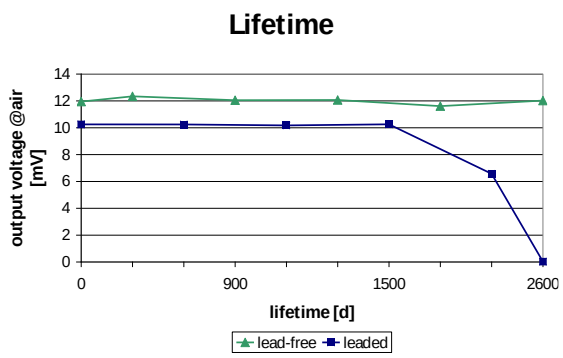
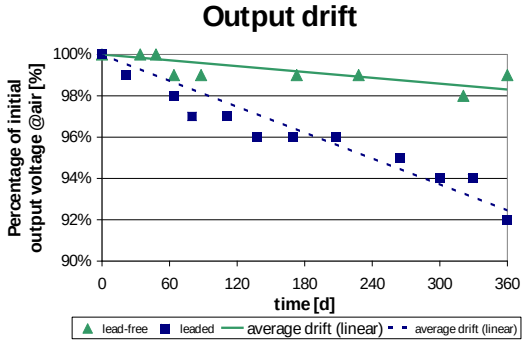
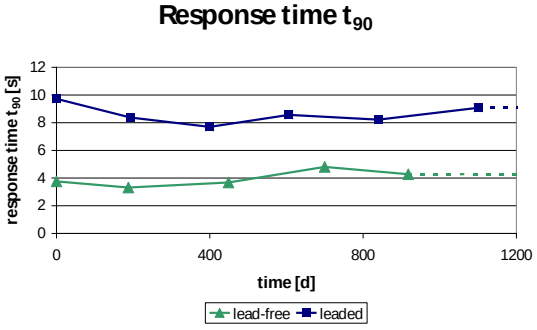
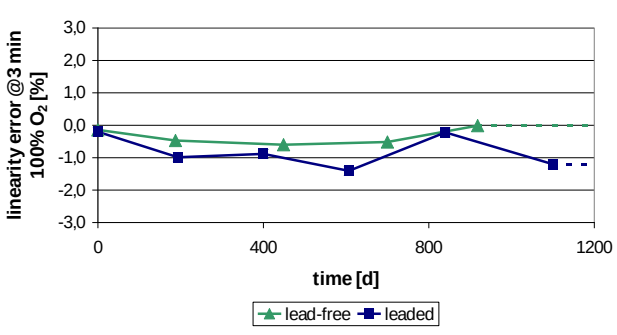
With respect to future developments, ITG (2020a) state that "At present ITG has lead-free galvanic sensors from the very low ppm-range up to 100 Vol. % of oxygen commercially available. With the same technology we see potential to go even further into the sub-ppm range. Furthermore, we strive to downsize the sensor's geometrical dimension to make it more suitable for mainstream measurements (i.e. real-time, to be incorporated into a face-mask) and to set new limits with regard to time response down to 100 msec which then allows an accurate time-resolved measurement of a breathing curve."

Figure 6-3: Illustration of an ITG lead-free sensor

Source: ITG (2020a)

ITG (2020a) stated that lead-free sensors perform better than comparable lead sensors in terms of lifetime, output drift, response time, and linearity error and provide data to substantiate the claims, reproduced in Figure 6-4.

Figure 6-4: Comparison of leaded and lead-free oxygen sensors by ITG

Figure provided by ITG	Description provided by ITG
	*"**Conditions** According to the assumption of the anode, we set up an accelerated lifetime-test at high pressure and 100 % O_2. **Conclusion** Whereas the leaded cell will find its end of life at approximately 2600 days the lead-free cell keeps on going." ITG (2020a)*
	***"Conditions** Average drift within a time period of 12 month at room ambient conditions. **Conclusion** The lead-free cell is much more stable than the leaded sensor and drifts less by the factor of 4.5." ITG (2020a)*
	***"Conditions** Accelerated lifetime test at higher temperature and 100 % O_2. Since almost 3 years the response time is constant within a +/- 1.5s interval. **Conclusion** The lead-free sensor is even faster, 2.5 times than the leaded cell." ITG (2020a)*
	***"Conditions** Accelerated lifetime test at higher temperature and 100 % O_2. Since almost 3 years the linearity error is lower than – 1.5 %. **Conclusion** Tops off the leaded cell as its linearity error is even lower as well as smoother." ITG (2020a)*

Source: ITG (2020a)

6.3.2. Elimination of lead

COCIR stated that many methods of measuring oxygen concentration have been developed but each has different characteristics. The alternative methods described by COCIR (2020b) and (JBCE 2020a) are listed in **Table 6-3**. The more detailed descriptions with advantages and drawbacks of each method provided by the applicants are reproduced in the following sections.

Table 6-3: Alternative methods described by the applicants

Methods described by COCIR	Methods described by JBCE
• 3-electrode electrochemical sensors • Solid metal oxide semiconductor sensors • Mass spectroscopy • Paramagnetic oxygen gas analysers • Optical sensors (several different types)	• Polarographic Sensor • Constant potential electrolytic sensor • Fluorescence method • Zirconia sensors • Paramagnetic oxygen gas analysers

3-electrode electrochemical sensors

Both COCIR and JBCE described a sensor type featuring three electrodes.

According to COCIR (2020b), "One design that has been developed is three electrode cells containing inert lead-free anodes and cathodes with a reference electrode. These have the advantage that the anode is not consumed as the anode reaction is:

$$2H_2O \rightarrow O_2 + 4H^+ + 4e^-$$

These however have the disadvantage that oxygen is generated at the anode and must not reach the cathode as this would give a false high reading. The accuracy of these sensors is also affected by ambient temperature, humidity, pressure and the presence of other gases such as anaesthetics.

One advantage of the lead anode sensors is that they carry their "own" voltage power supply in the anode material (which is the reason for the sensors not working when the anode material is consumed). Electrochemical 3-electrode O_2-sensors require a bipotentiostat, which needs an additional power supply. This is not available at the installation location of the sensor due to a lack of space in the part of the medical device where the sensor is located as this needs to be fairly close to the patient's mouth. Also, the capacity of a small enough battery that would fit into the available space would not allow the operation over 1-2 years.

Experiments with this sensor also showed that electromagnetic requirements cannot be fulfilled without additional means, which are problematic at the installation place of the sensor (e.g. metal housing and control electronics). These also cannot be used with MRI as the control circuits include magnetic materials.

(JBCE 2020a) described constant potential electrolytic sensors featuring three electrodes as follows: "Constant potential electrolysis method uses a sensor to measure the gas

concentration by detecting current produced when gas is electrolyzed at the specific constant potential.

In the case of gas measurement, a constant potential electrolytic sensor may be used. This is a structure in which a working electrode (WE), a counter electrode (CE), and a reference electrode (RE) each composed of a gas permeable membrane and a noble metal catalyst, which are in contact with the electrolyte solution and accommodated in a plastic container. The sensor needs to be driven using an external power supply (potentiostat circuit) and detects the electrolytic current generated between WE and CE while controlling the potential of the WE with reference to RE.

In the case of an oxygen sensor, by setting the potential of the WE to a predetermined negative value with reference to the RE, under an oxygen gas atmosphere, an oxygen reduction reaction occurs on the WE, and at the same time, an oxidation reaction of water occurs on the CE. At this time, ionic conduction occurs in the electrolyte and electronic conduction occurs in the external circuit. The electrolytic current (proportional to the oxygen concentration) generated at this time is converted into a voltage and displayed as the oxygen gas concentration.

A disadvantage of this method is that oxygen is generated at the CE and if this reaches the WE it will give false readings. If oxygen generated from CE stays inside the sensor, it may reach WE, which occurs in that case.

The galvanic sensor is a battery itself, and the potential difference between both ends of the positive electrode and the negative electrode is calculated as an output, so no special circuit is required. The constant potential electrolysis type has three electrodes (WE, CE, RE) of the sensor electrode, and operation is impossible with only the sensor alone. For the operation, it is necessary to apply a potential to WE with respect to RE, and to control this potential to be constant, and this special circuit (a potentiostat) is required. From this, the design as a detector is more complicated in the case of the potentiostatic electrolysis method, and the design variation of the potentiostat circuit may affect the measurement uncertainty."

Solid metal oxide semiconductor sensors

COCIR (2020b) explained that "These are known as lambda probes and 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 spectroscopy

According to COCIR (2020b), "Mass spectrometers can analyse all substances in patients' breath but the response time is too long taking many minutes to obtain a single concentration."

Paramagnetic oxygen gas analysers

Paramagnetic oxygen gas analysers were described by both COCIR and JBCE.

COCIR (2020b) explain that "These rely on oxygen gas being strongly paramagnetic and this method can give very fast response times. However, they have several disadvantages. The response is affected by the concentrations of other paramagnetic gases, which includes CO_2 (in exhaled breath), N_2O (used for anaesthesia) and most other anaesthesia gases. It is also affected by water vapour concentrations (water is diamagnetic so opposes the paramagnetic effect). Because of these limitations, paramagnetic oxygen sensors are unsuitable in anaesthesia applications and can be difficult to use with ventilators.

Paramagnetic sensors have already replaced lead anode based O_2 measurement in diverting (side-stream) respiratory gas monitors. However, due to requirements for the flow of the measurement gas to be very continuous, without pressure and flow peaks, it is not possible to use this type of sensor for the inspiratory O_2 measurement for anaesthesia applications or in main-stream ventilators. This is because the flow rates in the inspiratory part of the devices has a big range. Another disadvantage of this type of sensor is that they need an additional power supply, which cannot be made available near the sensor due to a lack of space. The current peaks and power needed by this principle would require quite a large battery, which is mechanically and dimensionally not possible at the installation location of the sensor."

According to (JBCE 2020a), paramagnetic sensors "have been used for many decades and are widely used in limited applications. They rely on the relatively high magnetic susceptibility of oxygen, which has paramagnetic behaviour. Sensors of the paramagnetic dumbbell type consist of a suspended glass dumbbell which rotates in a magnetic field according to the oxygen concentration of the surrounding gas. There are no consumables and these can measure oxygen in the range from 1 to 100 %.

Their main disadvantages are their larger size and are susceptible to movement such as the angle of instalment; therefore, they are limited to some times of fixed installation. Another limitation is that paramagnetic sensor can also give large errors if other paramagnetic gases, such as, NOs are present. They also cannot be used close to the instruments which are susceptible to the magnetic field due to the powerful magnetic field and can be used only in stationary equipment (due to the delicate "balance" used in these sensors)."

Optical sensors

Both COCIR and JBCE described types of optical sensors, where JBCE focused on fluorescence only.

According to COCIR (2020b), "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 breath including anaesthesia concentrations, 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 ventilators or anaesthesia oxygen monitors where fast response times and high accuracy are essential.

Another type of optical sensor uses an oxygen permeable polymer containing a luminescent compound. The luminescent compounds emit light when excited by exposure to light of a shorter wavelength (e.g. UV), but this is quenched when exposed to oxygen and the change in luminescence intensity is used as a measure of oxygen concentration.

Many luminescent oxygen sensors have been developed and a few types have been commercialised. A recent review reports that many luminescent dyes can be used in aqueous solutions, but some are effective only within specific pH ranges, so are used only to measure dissolved oxygen (not the gas). Many types of dye are not stable as they photo-bleach and become unresponsive. Response time of some types is a disadvantage; one commercial product is claimed to have a response time of less than 30 seconds; however electrochemical sensors respond typically in less than 10 seconds and some are < 5 seconds. A fast response time is essential for monitoring any changes in breathing of ventilated patients and patients under anaesthesia. A few types of luminescent oxygen sensors have much faster response times but only function at very low oxygen concentrations that are not applicable to medical applications.

Luminescent oxygen sensors respond by quenching by oxygen molecules, however many other substances including anaesthesia gases, water vapour, nitrogen oxides and many other contaminants also causes quenching and so these sensors are not sufficiently selective for oxygen to be useful in medical ventilation and anaesthesia applications."

(JBCE 2020a) state that "Fluorescence from a fluorescent material excited by light from a blue light-emitting diode (LED) is quenched by oxygen passed through a dissolved oxygen (DO) permeable layer. The higher the DO level is, the stronger the quenching phenomenon is and the less fluorescence is detected by the detector (light-receiving diodes). Oxygen (DO) enters the light-emitting material layer through a DO permeable layer made of silicon or some other material. This light-emitting material layer contains pyrene and other materials, which are excited by the blue light from the blue LED in the centre and emit fluorescence light. This fluorescence is quenched according to the amount of dissolved oxygen (DO) that reaches the light-emitting material layer, and the remaining fluorescence that was not quenched is received by light-receiving diodes. A light-receiving diode with a blue filter and another with a red filter are used. These diodes only detect the remaining fluorescence and calculate the DO level through mutual subtraction. In principle, higher DO levels cause noise and reduce the measurement accuracy. In this method, a blue LED with an emission wavelength of approximately 360 nm and light-receiving diodes that can detect approximately 0.001 second of light at a wavelength of approximately 800 nm are used.

Organic solvents cannot be analysed because fluorescence pigment melts into organic solvent.

Instruments with fluorescence sensors have 2 electric circuits, which one is for analysis and measurement and another is for power supply, although instruments with galvanic sensors have one electric circuit, which works both for measurement and for power supply."

Polarographic Sensor

According to (JBCE 2020a), "Polarographic type oxygen electrode functions are based on the relation of current and potential (polarogram), by imposing an applied voltage of flat region (plateau region) in a current-voltage characteristics curves."

(JBCE 2020a) argues that *"This type of sensor is not likely to be used for gas measurement. It is not suitable for measuring gas concentration in high temperature as the electrolyte will be evaporated. In contrast, it is suitable for liquid measurement as samples in are not likely to be high temperature as much as those in gas.*

Instruments with polarographic sensors have 2 electric circuits, which one is for analysis and measurement and another is for power supply, although instruments with galvanic sensors have one electric circuit, which works both for measurement and for power supply. More energy is consumed, and more components are required for instruments with polarographic sensors. In addition, output from an electric circuit is possible to cause dispersion of analysis and measurement. An instrument with two electric circuits is possible to cause dispersion more than an instrument with an electric circuit."

Zirconia sensors

With respect to zirconia sensors, (JBCE 2020a) stated that "These are designed for measurement of oxygen in gases and operates when it reaches over 350 to 700 degrees Celsius. Therefore, their use is highly specific to hot temperature uses only, with their main uses in flue gas monitoring and engine management because they can operate at higher temperatures than other types of oxygen sensor. They therefore consume power to maintain their operating temperature and their accuracy can be poor as their response is affected by a variety of other gases.[3] Due to the design it is also possible that the sensor is a safety risk due to its high operating temperature in applications where human contact may occur or it can become clogged with contamination such as oil and dirt and cease functioning."

Comparison of galvanic electrode method and alternative methods

(JBCE 2020a) provided a comparison of the galvanic electrode method, for which the renewal of the exemption is requested, with alternative methods. The comparison is made for two different measurements: (1) analysis and measurement of dissolved oxygen in liquids (Table 6-4), and (2) analysis and measurement of oxygen concentration in air/gas (Table 6-5).

Table 6-4: Comparison of types of oxygen sensors suitable for measurement in liquids

	Galvanic	Poralograhic	Fluorescence
Warm-up time	Negligible	10 min.-1hour	Negligible
Advantages	External power supply for turn- on is not required.	Organic solvents usable	Reagents are not required.
Disadvantages	N/A	Requires a mechanism to apply voltage battery and electicelectric board, requires power supply. See 6. (A). 1. 1.	Organic solvents impossible to measure Requires a mechanism to apply voltage battery and electicelectric board, required for power supply. See 6. (A). 1. 3.
Accuracy and measurement range	0.1ppb-50ppm	0.1ppb-50ppm	1ppb-20ppm

Source: (JBCE 2020a)

Table 6-5: Comparison of types of oxygen sensors suitable for measurement in gases

	Galvanic	Constant potential electrolytic	Zirconia	Paramagnetic
Portability	Suitable	Suitable	Not suitable Large votage and big power supply required, resulting in a big device	
Warm-up time	Negligible	The period depends on the structure of the detector Dozens of min.to several hours approximately.	Heating a sensor takes time. 30min.to several hours approximately.	The stability of measurement takes time. Several hours approximately.
Advan-tages	Intrinsically safe explosion-proof structure can be designed relatively easily. External power supply for turn- on is not required.	No impact from acid gas (carbon dioxide).	Suitable for the measurement of gas in high temperature, for example in engine exhausts.	Intrinsically safe explosion-proof structure can be designed.
Disadvan-tages	None	A drive circuit that controls the precise set potential is required. See 6. (A). 1. 2 .	Requires safe design against high temperatures. Requires external power supply for drive.	Influenced by equipment with magnetic field. Requires an external power supply for driving. Affected by other paramagnetic gases

Source: (JBCE 2020a)

Comparison of lead-free galvanic oxygen sensor versus competitive techniques by ITG

With respect to other techniques to measure oxygen, ITG (2020a) stated that *"by its nature oxygen can be detected with a variety of different techniques. Some of them can be found under Annex 3* [reproduced in Table 6-6 in this report, the consultants] *where those competitive technologies are compared with regard to the key-features commonly demanded from the market. Even some electrochemical operating principles such as amperometric, potentiometric, conductometric, ChemFETs and not to forget fluorescence quenching technologies are used to detect gas-phase oxygen.*"

Table 6-6: Comparison of lead-free galvanic oxygen sensor versus competitive techniques by ITG

Sensor Techniques typical characteristics	lead-free galv. fuel cell	TDL optical sensor	paramagn. Sensor	ultra-sonic sensor
ext. power consumption required	none	yes	yes	yes
motion sensitive	none	none	yes	none
lifetime limitation in medical areas	> 6 years	> 6 years	> 6 years	> 5 years
approximate OEM costs (based on 100 units per month)	60.00 €	2,000.00 €	1,000.00 €	300.00 €
weight	20 grams	3000 grams	50 grams	500 grams
service/ maintenance required after	none	2 years	2 years	none
sample preparation/ pre-treatment/ filtering required	none	yes	yes	yes
humidity affected	none	yes	yes	yes
cross-interferences to anaesthesia gases	none	minor	none	for binary gases only
MRI suitable	yes	none	none	none
warm-up time	none	2 min.	120 min.	none
accuracy (% of full scale)	0.1	0.1	< 1	1 %
Sensitivity drift	less than 1 % per month	+/- 1 % per year	less than or equal 1 % per week	?

Sensor Techniques typical characteristics	lead-free galv. fuel cell	TDL optical sensor	paramagn. Sensor	ultra-sonic sensor
Sensor positioning	independent	independent	≤ 0.05 % O_2 per 1° change	independent

Source: ITG (2020a)

6.3.3. Roadmap towards substitution or elimination lead

COCIR (2020b) stated that "Medical device manufacturers are evaluating new sensors that appear to meet the specifications, but redesign of analysers is also required followed by further extensive testing for accuracy and reliability is needed before they can be evaluated using clinical trials. Once these trials are successfully completed, Notified Body approval in the EU and the equivalent approvals globally can be requested. Typical timescales would be once a suitable sensor becomes available for testing:

- *Testing of sensor* *1 year (currently underway)*
- *Redesign of analysers* *1 year*
- *Testing in ventilators and in anaesthesia workstations* *6 months*
- *Clinical trials ca.* *1 year*
- *Global approvals up to* *2 years*
- *Total elapsed time Up to about* *5.5 years*

In theory, if no difficulties are encountered, analysers suitable for lead-free sensors should be available by the end of 2025, however, EU hospitals and clinics will not be able to use replacement lead-free sensors in current designs of analysers as these function correctly only with lead anode sensors and so the exemption will continue to be required for replacement sensors after this date."

With respect to medical products, ITG (2021a) stated: "ITG sees no reason from the sensor point of view to prolong the exemption for respiratory care. But as not all device manufacturers have adapted a lead free technology yet. ITG supports that this exemption ends end of 2025."

(JBCE 2020a) stated that "galvanic lead-free sensors both for gas and for liquid are available on the market. However, for some specifications, measurement range, response time, operational temperature, and accuracy do not fit the requirements of instruments. Therefore, a period of time for searching for the qualification of the substitute of lead anode is required. We cannot predict the length of the specific period for searching for the substitute of lead anode.

Instrument manufacturers will launch the evaluation of functions as soon as the sensors fit the requirements. ERA Technology explains 'The new product development time for many Category 8 and 9 products over 4 years and can be 7 years or longer'".

An initial timeline provided by (JBCE 2020a) that lacked specific numbers was updated by JBCE (2020b) with a more specific version reproduced in Table 6-7.

Table 6-7: Timeline showing the steps required after an applicable alternative sensor becomes available

	1st year				2nd				3rd				4th				5th				6th				7th			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1.Initial feasiblity evaluation (sensor performance)																												
Sensitivity, response time, accuracy, measurement range (low concentration)																												
Adjusting temperature compensation																												
Lifetime, shelf life evaluation																												
Influence of interfering gases in oxygen																												
2.Evaluation of reliability, durability, transportation, evaluation by end users																												
3.Establishment of production lines and evaluation for production.																												
4 Specific approvals																												

Source: JBCE (2020b)

6.3.4. Environmental arguments and socioeconomic impacts

COCIR (2020b) did not raise environmental arguments to argue for the requested renewal of this exemption. However, socioeconomic were raised by COCIR (2020b) as follows: "EU hospital patients who undergo surgery under anaesthesia, patients being ventilated and patients under anaesthesia having MRI scans would be at risk of harm or death if the electrochemical oxygen sensors that contain lead anodes could no longer be supplied to EU hospitals. There are published statistics on the numbers of surgical procedures carried out annually and most of these rely on anaesthetics. For example, some operations such as cataracts and caesarean sections usually do not use gaseous anaesthetics, but many types of operation usually require use of anaesthesia, such as appendectomies and hip replacements. One study found that 3.2 million people underwent surgery under anaesthesia in the UK in 201311, so the number for the EU is likely to be >10 million people per year and so this number of EU citizens could be negatively affected if this exemption is not renewed. Oxygen measurement using less suitable methods during surgery would increase the risk of harm, potentially including deaths."

(JBCE 2020a) raised the following environmental arguments: "Analysis and measuring instruments for oxygen concentration are used for environment and pollution monitoring. Galvanic sensors are cheaper than the other sensors, can be used for portable instruments,

and enable rapid measurement. Instruments with galvanic sensors are accessible to users to keep monitoring the environment and pollution, and a wide variety of instruments should be available to conserve the environment."

(JBCE 2020a) further describe the following health impacts: "Analysis and measuring instruments for gas are used for the safety control of work place. Galvanic sensors are cheaper than the other sensors, and can be used for portable instruments. Instruments with galvanic sensors are accessible to users to keep workplace safe, and a wide variety of instruments should be available to maintain the working environment."

6.4. Critical review

6.4.1. REACH compliance – Relation to the REACH Regulation

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

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by"* the REACH Regulation if the requested exemption would be granted/renewed.

REACH Annex XIV (2021)[34] lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

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

The applications in the scope of the exemption at hand do not use any of the above lead compounds.

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

[34] ECHA, https://echa.europa.eu/authorisation-list?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

- *Entry 16[35] and entry 17[36] restrict the use of lead carbonates and lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds[37] such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*

The above applications are not applicable to the use of lead in oxygen sensors.

- *Entry 28[38] addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30[39] addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they 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 above restrictions are not applicable to the use of lead in oxygen sensors. Further, the substances are part of an article and thus are not placed on the market or used as substances, constituents of other substances or mixtures supplied to the general public.*
- *Entry 63[40] restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72[41] stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

Lead oxides are constituents of oxygen sensors. In the scope of the exemption at hand, lead oxides are, however, not used in wristwatches or any other jewellery in the scope of

[35] 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

[36] 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

[37] 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

[38] 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

[39] 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

[40] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[41] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

entry 63, nor are conditions foreseeable where the oxygen sensors or the related equipment may be placed in the mouth by children. The same applies to entry 72, where it is not expected that galvanic oxygen sensors might be used in textiles, clothing or shoes in the scope of entry 72.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status (October 2021) 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 the respective criteria of Art. 5(1)(a) apply.

6.4.2. Scientific and technical practicability of substitution or elimination of lead

Scope clarification

Oxygen measurements in the medical sector

When asked, COCIR (2020c) confirmed that the following exemption wording would cover the required applications in category 8:

- *Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and exhaled air for patients in respiratory care products.*

As more insights were gained during the evaluation process, the consultants suggested the following exemption wording:

- *Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled and exhaled air for patients in respiratory care products put on the market before 26th May 2024.*

In response, COCIR (2021c) agreed to the wording with the following slight modifications (underlined):

- *"Lead anodes in electrochemical sensors that measure oxygen concentrations of inhaled <u>and/or</u> exhaled air for patients in <u>medical devices</u> put on the market before 26th May 2024"*

COCIR (2021c) provided the following reasoning on the modified wording: *"The reasons for the requested changes are firstly due to the concern that 'respiratory care products' are limited to a specific type of medical device, which would not include anaesthesia machines. Secondly, some machines only measure oxygen in inhaled path, with the addition of 'and/or' it ensures that there is no uncertainly in interpretation."* The consultants can follow this rationale.

When asked whether it was possible to further narrow the scope of the suggested exemption wording to specific medical equipment, COCIR (2021c) stated that *"All respiratory care products are affected and narrowing the scope further is not possible."*

The question whether replacement sensors were indeed EEE in the sense of RoHS, COCIR (2020c) stated: "*It is COCIR's interpretation that the sensors are consumable and therefore in the scope of RoHS. The RoHS substance restrictions are not excluded by RoHS Article*

4.4 because the replacement sensors are not used for the 'repair, the reuse, the updating of functionalities or upgrading of capacity', so do not meet the requirements of this exclusion."

When requested to confirm whether galvanic oxygen sensors meet the definition of EEE provided by RoHS Art. 3(1) and 3(2), COCIR (2021a) clarified that *"Oxygen sensors are electrochemical devices in which a current is generated between two electrodes (anode and cathode when exposed to oxygen). This electrical current is measured by the medical device to determine the patient's breath-oxygen concentration (some sensors also have internal circuitry). Therefore, these sensors rely on electricity for their main function (to measure oxygen concentration) and so they meet the definition of EEE from Article 3(1) and 3(2). According to the EC FAQ guidance, electrical consumables such as ink jet cartridges are in scope of RoHS because they rely on electricity to function and so electrochemical oxygen sensors, which generate a current output, are in scope for the same reason."*

The consultants can follow the rationale of the applicant and arrive at the conclusion that replacement sensors are considered EEE under RoHS and therefore fall into its scope.

Oxygen measurements with monitoring and control instruments

In the field of monitoring and control instruments, the range of applications of oxygen sensors and their requirements are wider compared to the medical sector. Oxygen measurements take place in various setting (e.g. laboratory, industrial, portable), measuring oxygen in gases as well as dissolved in liquids and a larger range of concentrations, from percentage range down to parts per billion (ppb).

When asked whether lead-free sensors can be used in measurements of % oxygen concentration, JBCE (2021c) stated: *"Yes. Regarding the % range (more than 10,000 ppm (1 %)), there is no performance problem with the specifications of lead-free sensors, so it can be excluded from the scope".* After additional information was provided to the consultants, JBCE was asked whether only sensors "designed for the measurement of dissolved oxygen in concentrations below 30 ppb" would need to be included in the exemption wording, JBCE (2021d) stated to agree with the proposed wording.

When asked whether portable emission testing devices could be excluded from the scope, JBCE (2021c) stated: *"We believe that the portable emission testing device is not suitable word for clear definition of the device which you can carry. It should consist of hand-held devices and transportable devices. To our best knowledge, transportable devices still require the exemption."*

The consultants followed up on whether this meant that "hand-held devices" did no longer require the exemption. *JBCE (2021d) responded: "Yes, some transportable devices still need the exemption, which takes around 7 years to substitute. However, as for handheld devices, we do not need the exemption."* JBCE (2021d) also shared a definition of what constitutes a "hand-held device": *"A handheld device is literally a measuring instrument that can be held in single hand, and is compact, lightweight, battery-powered operation, etc., and does not require a direct AC power for measurement."*

The consultants note that the correspondence with the applicant on handheld devices was solely in the context of emission testing devices. Devices for the measurement of dissolved oxygen may still require the exemption, including handheld, transportable and other types.

When asked whether the exemption phrasing "Lead anodes in electrochemical oxygen sensors designed for (a) the measurement of dissolved oxygen concentration in the ppm and ppb range and (b) oxygen gas measurement with fast response time <x seconds" would cover the required applications and which value for response time would be required, JBCE (2021c) stated: *"your proposed wording "(a) the measurement of dissolved oxygen concentration in the ppm and ppb range", can cover applications that require the exemption for dissolved oxygen measurement. As for your proposed wording "(b) oxygen gas measurement with fast response time <x seconds", our required response time is less than 3 sec (t95) [the time it takes for the sensor to measure 95 % of the maximum analyte level, the consultants]. This is due to the fact that a fast response is an essential requirement for applications such as an exhaust emission inspection for vehicles. Slow response time will cause not only longer time for inspection, but also more exhaust emitting before completing inspection."*

JBCE (2021c) stated to *"agree that the above wording proposal, as long as our required response time is reflected. However, the other variety type of emission measurement applications than vehicle emission requires measuring oxygen in the presence of other gases. This might interfere with the sensor's behaviour to give incorrect results. The effect of these interference gases on lead free oxygen sensor will need to be fully verified by the combination of application and concentration. Therefore, it will take for around 7 years to evaluate and substitute."*

The consultants conclude from the above exchanges with the applicant that sensors for measurements of dissolved oxygen concentration below 30ppb and sensors for oxygen gas measurements where reactions faster than 3 seconds are needed may need to be in scope of a potentially renewed exemption.

Substitution of lead in the medical sector

When asked for which medical applications ITG's lead-free sensors were available and proven in use, ITG (2021a) provided the following information:

- *Ventilators: "Our lead free oxygen sensors are already used and approved in ventilators since 2015. They can be drop in replacements. This may require a software change in the device in some cases." ITG (2021a) added that "In Europe there are at least 100,000 hospital beds with ventilators […]. 60 % of the ventilators have already been converted to lead free oxygen sensors or are in the process to switch during 2021/22."*
- *Infant incubators: "We estimate the number of infant incubators in Europe as 25,000. ITG has a released product since 2019. Infant incubators can be adapted to lead free sensors the same way as ventilators."*
- *Anaesthesia machines: "The European market for anaesthesia machines is estimated as 100,000 devices. For this market ITG has a released lead free sensor since 2017. Devices can be converted to lead free sensors the same way as*

ventilators. We estimate that 50 % of the devices already have lead-free technology (10 % galvanic sensors, paramagnetic, other technology). ITG estimates that 10 – 20 % more will become lead free within the next 2 to 3 years."

- *ECMO (extracorporeal membrane oxygenation): "ECMO/Heart Lung Machines are estimated to be 5,000 devices in Europe. ITG has a released sensor since 2017."*
- *CPAP (*Continuous Positive Airway Pressure): "*Only 20 % of the CPAP devices include oxygen measurement. ITG has a released sensor since 2017."*

When requested to comment on these numbers, COCIR (2021b) stated

- *"The process of transitioning to lead-free sensors in new ventilators is well underway and will be completed by 2025 as requested in the exemption text. 2025 is the best estimation, also considering possible unexpected situations. COCIR and its members have not been able to confirm whether there are 100,000 ventilators in use in the EU. It seems very unlikely that those ventilators that are currently in use in EU hospitals and which use lead anode sensors could be converted to use lead-free sensors for the technical reasons COCIR has explained elsewhere or if this would gain approval from Notified Bodies in the EU.*
- *The 60 % number quoted by ITG seems exceedingly high based on COCIR's knowledge of the large OEMs that have not yet converted to lead-free."*

COCIR was asked whether they had tested the lead-free galvanic oxygen sensors from ITG and other suppliers and what their findings were regarding their performance. In response, COCIR (2021a) raised the following issues, that are each discussed in more detail below, including conflicting statements made by COCIR and ITG:

(a) Reliability of lead-free ITG sensors

(b) Output signal of ITG sensors

(c) Signal drift and lower voltage limits

(d) Effects of anaesthetic gases on ITG sensors

(e) Lead-free sensors from other manufacturers than ITG

(a) Reliability of the lead-free ITG sensors

With regard to the reliability of ITG sensors, COCIR (2021a) stated:

- *"A COCIR member has discussed with ITG their sensors and so has a general knowledge of these sensors. However, research by this manufacturer has found that sensors with lead are more stable than lead-free options. This manufacturer is familiar with the product offered by ITG and had performed some bench scale testing of a small number of the ITG lead-free O_2 sensors. These were tested in a laboratory setting for their specific application to determine initial feasibility of suitability. One of the criteria for suitability is consistent performance over time. 1 out of 3 ITG lead-free O_2 sensors demonstrated erratic behaviour within 3 months of (simulated) use. Testing of their current O_2 sensors containing lead does not display such instability. The stability and accuracy of the performance of the O_2 sensor is critical to the product's operation and patient safety. Suppliers go through a rigorous quality and supply validation process and manufacturers cannot change vendors without an assurance that quality performance will be consistent with expectations. This*

manufacturer also conducted formal tests on ITG lead anode O_2 sensors on 2 separate occasions in their applications and on both occasions the ITG O_2 sensor product failed to meet application reliability requirements. Based on testing, they have concerns on the reliability of ITG lead-free O_2 sensors for their application and do not believe they are a reliable alternative at this time. The primary issue is the concern over the reliability of the lead-free O_2 sensor and its ability to meet the application requirement to operate reliably for at least 1 year."

The consultants requested COCIR to provide evidence to demonstrate that ITG sensors have reliability issues. In response, COCIR (2021c) submitted a test report, in addition to the following statement:

- *"Please see attached report outlining one COCIR members testing [relevant results reproduced in below Table 6-9, the consultants]. Other COCIR members have undertaken informal testing to determine if this option was viable to pursue, via the extensive collaboration with their incumbent O_2 sensor manufacturer to review and analyse comparative testing they have performed on lead-free O_2 sensors. At this point deficiencies have been identified which they are concerned would cause potential patient safety risk, delayed care and increased customer dissatisfaction/complaints."*

The purpose of the test report (COCIR 2020a) is stated to be to *"summarize test data for various lead-free galvanic O_2 sensors on the market that are advertised as drop-in replacements for the lead-anode versions, and to assess the viability of using these sensors as drop-in replacements"*. The lead-free sensors under test are the model MLF-16 from ITG and a model from another manufacturer. According to (COCIR 2020a), *"Sensors were tested for output in air, response time, zero offset, linearity, and output in 100 % O_2 using the TEC sensor test system. The test system is a computer-controlled system that tests an array of sensors by exposing them to air for 1 minute, then 100 % O_2 for 2 minutes, followed by 100 % N_2 for 4 minutes. During the gas exposure times, the voltage output from the sensor is recorded at 4 Hz frequency. Sensor testing was repeated periodically as the test samples aged. Test samples were aged at ambient conditions (21 % O_2, 20 to 25 C, 0.86 atm)."*

The tested criteria are the manufacturer specifications listed in a table in (COCIR 2020a), reproduced in Table 6-8 below. It should be noted that although both a lead-free and a lead-based sensor are listed in this table, only the lead-free sensor was tested.

Table 6-8: ITG MLF-16 and M-16 specifications

Specification	Lead-free Manufacturer Value (MLF-16)	Lead-anode Manufacturer Value (M-16)
Measurement Range	0% to 100% O2	0% to 100% O2
Sensor Life	≥ 2,000,000 %O2 Hours	< 6 years @ ambient air = < 1,100,000 %O2 Hours
Output in Ambient Air	9 to 13 mV	9.6 to 16 mV
Linearity Error	< 3%	< 3%
Response Time	< 7 seconds to 90%	< 12 seconds to 90%
Zero Offset Voltage	< 0.3% Volume O2 in 100% N2	< 0.3% Volume O2 in 100% N2
Recommended Load	≥ 1 MOhms	≥ 10 kOhms

Source: (COCIR 2020a)

(COCIR 2020a) present test results on the ITG MLF-16 sensor in a table reproduced in Table 6-9, explaining: "Ten each of MLF-16 sensors were tested at 237, 252, 298, and 377 days after the sensors were built. Table 6-9 summarizes the results showing which sensors met all specifications (pass) and which sensors failed to meet all specification, with details *on which specification the sensors failed."*

Table 6-9: Test results summary for ITG MLF-16 sensor

Sensor	237 Days (119K %O2 Hrs)	252 Days (127K %O2 Hrs)	298 Days (150K %O2 Hrs)	377 Days (190K %O2 Hrs)
1	Pass	Pass	Pass	Not Tested
2	Pass	Fail Zero Offset, 0.38 mV (0.6% O2)	Pass	Pass
3	Pass	Pass	Pass	Pass
4	Pass	Pass	Pass	Pass
5	Pass	Pass	Pass	Pass
6	Fail Zero Offset, 1.28 mV (2.2% O2)	Pass	Pass	Pass
7	Pass	Pass	Pass	Fail Zero Offset, 0.39 mV (0.7% O2)
8	Fail Zero Offset, 1.06 mV (1.9% O2)	Pass	Pass	Pass
9	Pass	Pass	Fail Zero Offset, 2.48 mV (5.2% O2)	Pass
10	Pass	Pass	Pass	Pass

Source: (COCIR 2020a)

In the discussion section of the test report, (COCIR 2020a) reflect on the results as follows: *"Starting with the first test point at 119,000 % O_2 hours, and at each test point thereafter, sensors were failing the zero-offset specification. However, the sensors were inconsistent and the same sensor did not fail the zero-offset specification more than once throughout the aging and testing process, i.e. the sensors were actually able to recover from one test*

point to another. This may indicate a lack of robustness in the sensor design to isolate the output from normal factors that may influence the results."

(COCIR 2020a) also included test results for a lead-free sensor from the other supplier[42], reproduced in Table 6-10. From the nine sensor units tested, six failed in the test criterion "Air Output" once or repeatedly. (COCIR 2020a) reflected on the results, stating: *"As shown […], there are lifetime issues with the tested sensor. Starting at about 170,000 % O_2 hours, the sensors show a significant drop in output voltage and no longer meet the specification for output in air. This was discussed with the manufacturer and they claim to have corrected the issue. The manufacturer supplied the second set of sensors to be tested, in which they claim to have corrected the problem. However, neither COMPANY [company name redacted by COCIR, the consultants] nor the manufacturer have long term test data to show that the issue has been corrected.*

The samples also had inconsistencies in the zero-offset as they aged. At 198,000 % O_2 hours, two of the samples failed to meet the zero-offset specification, however, at the next time point, they had recovered. This may indicate a lack of robustness in the sensor design to isolate the output from normal factors that may influence the results. Finally, it is noted that two sensors from the second set of sensors that were tested had an output in air that was above the specified value. This may be due to the modifications that manufacturer made to correct the short lifetime issue with these sensors and likely would not create an issue during sensor use."

[42] This supplier is not named as they did not have the opportunity to provide their own data in response

Table 6-10: Test results summary for the other tested sensor

Table 5: Test Results Summary for Envitec OOMLF106 Sensor							
Sensor	**43 Days (22K %O2 Hrs)**	**89 Days (45K %O2 Hrs)**	**168 Days (85K %O2 Hrs)**	**332 Days (170K %O2 Hrs)**	**347 Days (175K %O2 Hrs)**	**393 Days (198K %O2 Hrs)**	**472 Days (238K %O2 Hrs)**
1	Pass	Not Tested	Not Tested	Fail Air Output, 8.29 mV	Fail Air Output, 8.22 mV	Fail Air Output, 7.77 mV	Fail Air Output, 6.94 mV
2	Pass	Not Tested	Not Tested	Fail Air Output, 8.55 mV	Fail Air Output, 8.52 mV	Fail Air Output, 8.08 mV	Fail Air Output, 7.37 mV
3	Pass	Not Tested	Not Tested	Fail Air Output, 6.82 mV	Fail Air Output, 6.86 mV	Fail Air Output, 6.61 mV Fail Zero Offset, 1.33 mV (4.6% O2)	Not Tested
4	Pass	Not Tested	Not Tested	Fail Air Output, 7.37 mV	Fail Air Output, 7.32 mV	Fail Air Output, 7.06 mV Fail Zero Offset, 0.7 mV (2.2% O2)	Fail Air Output, 6.50 mV
5	Pass	Pass	Pass	Not Tested	Not Tested	Not Tested	Not Tested
6	Fail Air Output, 13.16 mV	Pass	Pass	Not Tested	Not Tested	Not Tested	Not Tested
7	Pass	Pass	Pass	Not Tested	Not Tested	Not Tested	Not Tested
8	Fail Air Output, 13.13 mV	Pass	Pass	Not Tested	Not Tested	Not Tested	Not Tested
9	Pass	Pass	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested

Source: (COCIR 2020a)

In the consultants' view, only comparative testing of sensors with a lead anode against lead-free sensors allows conclusions on the performance differences. When comparative data was requested, COCIR (2021b) stated: *"The currently use lead anode sensors were tested before they could be used by COCIR members in their current range of products. These sensors were tested using the same test methods as were used for the tests reported in* Table 6-9 *and Table 6-10, the consultants]. These tests, carried out over the same length of time and test conditions, showed that 100 % of the lead anode sensors passed all of the tests and fully met the manufacturers specifications for the lead-anode sensors […]. Therefore, we did not include a comparative table for lead-anode sensors to show "pass" as the only result. Any lead-free sensors must be at least as good as the lead-anode sensors currently in use."*

COCIR provided an excerpt from a test report for a lead-anode sensor as an example *"to illustrate the comprehensive nature of testing, however some confidential details have had to be removed from this report."* In the consultants' view, the report does not contain sufficient information (e.g. description of tested sensors, pass/fail criteria, units on axis of diagrams, interpretation and discussion of results) to allow a proper comparison with the results on lead-free sensors.

ITG was invited to comment on the test results provided by COCIR. ITG (2021b) stated:

- *"The sensors that were used in this test were samples free of charge that ITG provided a distributor to show to its customers. As COCIR is not willing to reveal where the testing was performed [this was asked in a questionnaire, the consultants] ITG cannot verify if the sensors were transported and stored as specified prior to testing, or what additional testing may have been performed prior to this testing. Inadequate testing, transport and storage can damage the sensors and lead to*

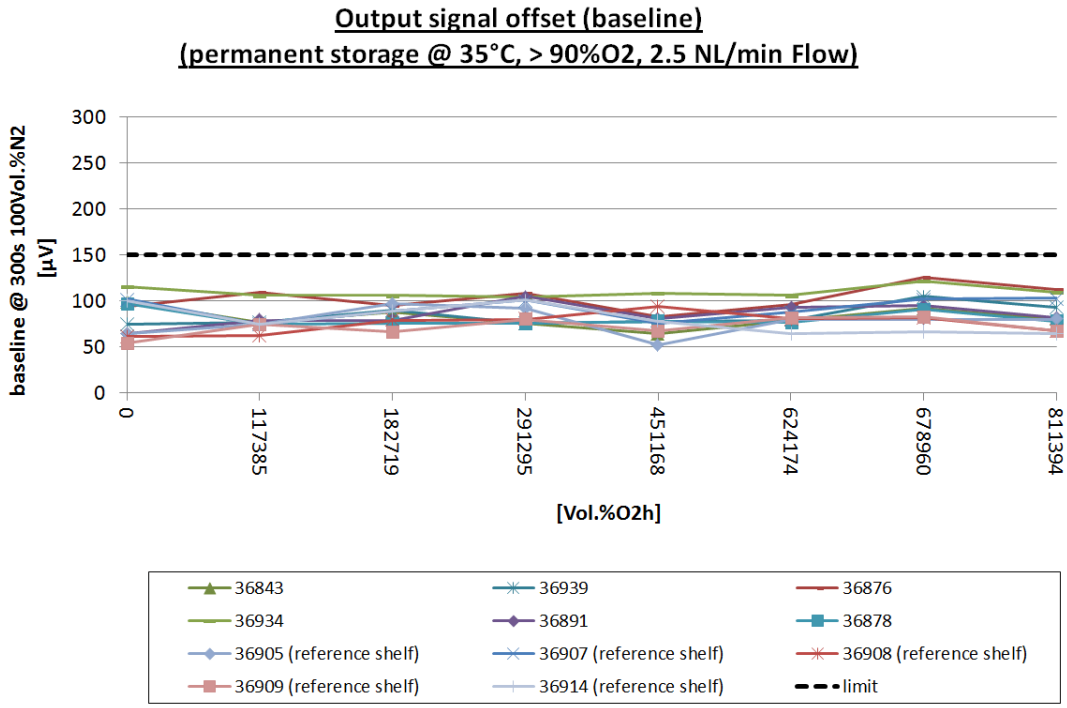
unexpected results. Therefore, transport and storage conditions are specified for such sensors.

- *The testing for the baseline deviates from ITG's specification that requires gassing for 5 minutes with nitrogen instead of only 4 minutes. This could explain why some results are a bit out of spec.*
- *From the measurement graphs [these are not reproduced in this report, the consultants] it can be seen that different sensors at different testing days give deviating results. This is not typical behaviour in case of a faulty sensor. A faulty sensor would give faulty results continuously. Non repeatable faulty results can be caused by the hardware used for testing or by not handling and storing the sensors as specified.*
- *ITG has provided own test results from comparable tests that prove that sensors perform within the specification limits continuously over an even longer test time.*
- *At last ITG disagrees with the purpose of the report as ITG does not claim that its sensors can be used as drop-in replacement. Thus, differences in the specifications of the leaded and the lead-free sensors are allowed and no limitation to use lead free sensors."*

ITG (2021b) provided their own test reports, evaluating the long-term signal stability of the lead-free sensor MLF-16, stating: *"From this reports it can be concluded that our sensors fulfil their specification requirements over their lifetime."*

Figure 6-5 reproduces the results on zero offset testing under accelerated conditions. (ITG 2020b) stated *"All sensors under test show a baseline well below the limit."* All tested sensors produced values below the threshold of 150 µV. These results were produced via accelerated ageing conditions (increased temperature, increased oxygen concentration, continuous gassing) to demonstrate the performance of the sensors over the course of 800,000 hours of simulated use.

Figure 6-5: Test results on zero offset of ITG MLF-16



Source: (ITG 2020b)

COCIR (2021d) was invited to provide an explanation for the diverging findings and stated: *"COCIR's members have many years' experience using and testing oxygen sensors and so do not believe that the differences in results are due to hardware issues. Sensors would be handled as recommended by the sensor manufacturers, but were used in COCIR members equipment. Therefore, COCIR cannot explain why its members obtain different results to ITG. One possibility is that ITG are testing its sensors under ideal laboratory conditions whereas COCIR's members use conditions that represent use in their instruments as are used in hospitals. ITG's data is encouraging and COCIR's members are continuing to work with its sensor suppliers to develop lead free medical devices."*

The consultants note that the test results provided by COCIR and ITG are in conflict. COCIR's results demonstrate unexpected behaviour with respect to the zero offset specification of ITG's lead-free sensors, which they explain with a lack of reliability of the sensors. On the contrary, ITG's results demonstrate that the zero offset specification is met by its sensors. ITG speculate that the divergence in COCIR's test results may not be due to a lack of reliability of the sensors, but due to other factors in the test setup. COCIR speculate that their tests were carried out under conditions closer to real-life usage and therefore are different from ITG's. In this situation, the consultants cannot decide whether there is or is not indeed an issue with the lead-free sensors. Additional test would be required, ideally carried out by an independent laboratory.

(b) Output signal of ITG sensors

COCIR (2021a) stated:

- *"Other COCIR members have assessed ITG MLF 43*[43] *in their applications, however due to the fact that the output of the ITG sensors is a voltage rather than a current (as is required by the medical devices that use a lead anode oxygen sensor), they cannot be used without complete redesign of the medical devices. This would require redesign of the electrical circuitry, reliability and patient-safety testing and gaining re-approvals (the timescale is explained in our exemption renewal request).*
- *The ITG sensors cannot be considered as a 'drop-in replacement' as they cannot be used as consumables in existing medical devices that are used in EU hospitals or in new equipment that was designed to use a lead-based sensor.*
- *Each manufacturer has their own designs of medical device. Some use lead-based sensors that have the same connector design as the ITG sensors whereas others use different connector designs. An issue for one manufacturer is that due to the fact that the ITG MLF43 fits mechanically into their currently produced medical devices, but does not deliver the same signal, there is a high risk of a mix-up by the operator. These sensors are regularly changed by medical personnel, rather than service technicians, as a consumable, and as such has the potential to pose a severe risk of patient safety. If the wrong sensor is used, an incorrect oxygen concentration in patient's breath will be obtained, which would pose a serious risk to the patient's life. This risk can be avoided if different designs of sensor having different connections are used [cf. to Figure 6-6 "Oxycell A" as one option, according to COCIR (2021a)], but there would be a risk to patients if lead-based sensors could no longer be obtained by EU hospitals.*
- *Medical device usage is subject to the EU Medical Device Regulation and as such manufacturers cannot simply replace sensors without going through a rigorous regulatory approval process to validate that the substitute components for the devices work in the same manner as the component and/or material being replaced."*

In response, ITG (2021a) provided the following statements:

- *"In most cases our lead-free oxygen sensors can be used as drop in replacements in various devices without any adaption. Mechanically the lead-free sensors are 1:1 drop in replacements. In case adaptation is necessary the degree depends on the design of the electronic circuit that interfaces with the sensor in the oxygen analyser. Lead free sensors require slightly higher input impedance on the analyser side. In case this is already implemented in the analyser no change of hardware or software is necessary. In case the input impedance of the analyser is to low ITG can compensate for this in the electronic circuit of the sensor. Also, in this case no hardware change of the existing equipment /installed base is necessary. A software update might be necessary. This could come with the need for testing and approval.*

[43] Product specification of ITG O2 lead-free Medical Sensor / Type MLF-43: http://www.it-wismar.de//_documents/specs/MLF-43_spec.pdf (last accessed: 2nd September 2021)

Several European and global customers have completed this process meanwhile. Some more will close this soon."

Further, ITG (2021b) stated:

- *"For the time being 95 % of the medical devices use oxygen sensors with a voltage output, thus most medical sensors come with a voltage output. In cases where sensors with a current output are needed this can be realized by the design of the sensors electronic circuit using respective components to convert the voltage into a current. ITG does not see how the kind of required electrical output of a lead-free sensor could limit its suitability."*

COCIR (2021c) provided more insights on the topic of sensor output signal and the required redesign of analysers:

- *"The sensor output difference means that it is not technically possible to develop a drop in replacement. Medical device redesign is required to convert the output from the new type of sensor into an accurate oxygen concentration. It is also necessary to redesign the circuitry to allow users to calibrate the new sensors. It is always impossible to predict the results of future research into new designs as unexpected results can be obtained. It is possible that new lead-free sensors may not be suitable if the oxygen measurement accuracy is poor and not within accepted limits or if reliability is found to be inferior."*
- *"The decision of what technology is used (voltage/current) is made in the very early design phase of the product, however once this decision has been made a change in later stages is a major change as the sensor system relies on this."*

When asked to comment on the statement made by ITG (2021b) that 95 % of medical devices use oxygen sensors with a voltage output, COCIR (2021b) stated:

- *"COCIR is not aware that 95 % of medical devices on the market use O_2 sensors with a voltage output. Most COCIR manufacturers that require these exemptions are using lead-anode current-output sensors (only one uses voltage output sensors, but this manufacturer has the same reliability issues to resolve before new sensors can be approved in the EU). We can only assume that sensors made by ITG, Cambridge Medical Co and Angst+Pfister are used in different types of medical device that are not made by COCIR's members. We have not been able to find any source confirming or disproving the ITG claim. As already explained "the kind of electrical output of a sensor" limits its suitability in already existing products (no drop-in possible) and can only be accommodated into new designs, as it is happening.*
- *There seems to be confusion around the range of the output of lead-free sensors vs. lead-anode sensors. Restricting the comparison to galvanic type sensors (from ITG) only, they both produce current output that are converted inside the ITG-type sensors to voltage output through a simple resistive element in most cases. The challenge with lead-free sensors is that the sensor output at a given oxygen concentration is often different from that of lead-anode sensors leading to modifications of calibration parameters inside of medical devices. Additionally, the output of a lead-free sensor during fault conditions such as end of life may not correlate with a lead-anode sensor which would impact the diagnostic capabilities of medical devices and would require significant testing to characterize. Finally, since the current output of a lead-free galvanic sensor is significantly lower than a*

lead-anode sensor, a larger resistive element must be used inside of the sensor which will increase the sensor output impedance. This increase in output impedance is likely to cause the electrical interface of the medical device to be incompatible with the lead-free sensor.

- *In order to use a different sensor in an existing ventilator that is in use in an EU hospital, the performance parameters must be identical to the lead anode sensor, and this is never possible as each make and model of sensor is different in terms of its internal impedance output profile, lifetime and fault responses. Lead-free sensors will be used in newly designed ventilators, but industry needs time to design, test and gain approvals for these. However, this is taking quite a long time because the reliability of some sensors has been found to be inferior to the currently used sensors. When this occurs, redesign and testing need to be repeated with a different sensor."*

COCIR (2021b) also clarified that *"This exemption is required by all COCIR members who make the types of equipment described in our exemption renewal request. These are many large OEMs which COCIR believes have a large market share overall. Most COCIR members currently use current output sensors."*

Regarding the different output ranges between lead-anode and lead-free sensor (cf. Table 6-8 on p.135), COCIR (2021b) state: *"The change in voltage range from the lead-free version and lead-anode version is likely to create a problem as a drop-in replacement sensor, particularly on the low end. If the equipment is designed to reject a sensor with an output less than 9.6 mV, then the lead-free sensor may result in extensive failures in the equipment as it may have air output down to 9.0 mV. The 100X increase in the recommended load for the lead-free sensor creates a major hurdle for the sensor to be a drop-in replacement. Without equipment modification, this would likely create significant signal noise for any equipment designed with the 10kOhm recommended load for the lead-anode version."*

When ITG was invited to comment the above findings, ITG (2021b) stated the following: *"ITG disagrees with the purpose of the report as ITG does not claim that its sensors can be used as drop-in replacement. Thus, differences in the specifications of the leaded and the lead-free sensors are allowed."*

(COCIR 2020a) also compared specifications of lead and lead-free sensors from another supplier (Table 6-11) and notes: *"The increase in zero-offset may also present an issue with the equipment using the sensor. It is likely that equipment is designed to reject the sensor if its output is greater than 0.2 mV in 100 % N_2 per the lead-anode specifications, and thus would be rejecting the lead-free version of the sensor which may have up to 0.5 mV in N_2. This also may indicate a decrease in the accuracy of the sensor at low oxygen levels. The 10X increase in recommended load for the lead-free sensor creates a major hurdle for the sensor to be a drop-in replacement. Without equipment modification, this would likely create significant signal noise for any equipment designed with the 10 kOhm recommended load for lead-anode version."*

Table 6-11: Lead-free and lead-anode sensor specifications of another supplier

Table 6: Specification Differences Between Envitec OOMLF106 and OOM106		
Specification	**Lead-free Manufacturer Value (MLF-16)**	**Lead-anode Manufacturer Value (M-16)**
Sensor Life	< 3 years @ standard conditions (21% O2) = 550,000 %O2 Hours	≥ 1,000,000 %O2 Hours
Zero Offset Voltage	< 0.5% Volume O2 in 100% N2	< 0.2 mV in 100% N2
Recommended Load	≥ 100 kOhms	≥ 10 kOhms

In conclusion, in the consultants' view, lead-free sensors appear to indeed diverge in some specifications from their lead counterparts, such as in sensor lifetime, signal output range, response time, zero offset voltage, and recommended load. Therefore, the consultants understand that it may not always be possible or even intended to use lead-free oxygen sensors as drop-in alternatives to lead-anode sensors. The consultants can also follow that suppliers of lead-free sensors are capable to make custom modifications to their sensors to make them compatible, however, it may also be necessary to adapt the software of oxygen analysers. Therefore, the consultants consider that the use of lead-free sensors in existing medical equipment is technically likely possible in many cases, but that it may not be practicable in all cases. On the other hand, the consultants assume that new medical devices may be designed with lead-free sensors in mind, rendering the issues discussed here mostly obsolete.

(c) Signal drift and lower voltage limit

COCIR (2020b) stated that more reactive (than lead) metals as anode material self-corrode and lead to false and incorrect oxygen concentration readings. COCIR (2020b) also stated that lead-free sensors have a completely different behaviour in the way that voltage decreases during operation, and it does not drop below 8.9 V (cf. section 6.3.1).

ITG was invited to respond to these claims. ITG (2021a) stated:

- *"The statements about the chemical processes are not correct. ITG's test results and tests by its customers prove that lead free sensor measure precisely, accurate and reproducible. There are several combinations of metals in suitable electrolytes that are thermodynamically stable. The working principle of a galvanic oxygen sensor includes the combination of a reactive metal anode with an inert cathode which creates a galvanic couple. The current which is generated between anode and cathode is proportional to the oxygen concentration and is the basis to evaluate the measurement signal of a galvanic oxygen sensor. If the right combination of materials (anode, electrolyte and cathode) is chosen neither hydrogen generation nor an incorrect or false oxygen concentration occurs."*
- *"Lead free sensors have a smaller signal drift over time compared to lead sensors. But this is no disadvantage as measurement devices are routinely (e.g. daily or before every use) calibrated with ambient air to compensate for any sensor signal*

drift. This compensates for possible signal drifts so that no false measurements are possible. In case a sensor fails in this calibration the device does not go into operation. There is no general lower limit for the sensor signal at 8.9 mV for a technical reason, not even for lead sensors. This might only be a chosen value in a certain device firmware to trigger an alarm for sensor replacement."

When invited to respond, COCIR (2021c) stated:

- *"Although smaller signal drift over time can be beneficial, this is only an advantage if the behaviour of the software operated in the device is known."*
- *"A lower limit for a sensor signal has to be chosen otherwise the facility to detect 'sensor failure' and/or 'sensor life expired' will not be detected and would be considered a failure/customer complain and result in delayed care. If a calibration limit for a lead-free sensor differs from that of a lead-based sensor, a firmware update may be required for the instrument to respond to different sensor conditions including end-of-life. The 8.9 mV limit may not be a technical requirement but is an example of a limit that could be applied by equipment manufacturers based on recommendations from lead anode sensor manufacturers that would need to be changed if a lead-free sensor was used."*

In the consultants' view, similarly to the previous issue of differences in the output signal between lead and lead-free sensors, this appears to be another technical difference between the leaded and lead-free variants which can be overcome when medical devices are designed with lead-free sensors in mind. Retrofitting of existing medical equipment with lead-free sensors may still be possible, but the consultants cannot unambiguously conclude that it is possible in all cases.

(d) Effects of anaesthetic gases on ITG sensors

COCIR (2020b) raised the issue that extensive testing of lead substitutes is required regarding the effects of anaesthetic gases, e.g. halothane, and their decomposition products, as a barrier to use lead-free sensors.

When asked whether their lead-free sensors were tested against effects from anaesthetic gases and their decomposition products, ITG (2021a) provided the following statement:

- *"ITG has performed extensive testing on possible interferences, even more than required by DIN EN ISO 80601-2-55. ITG has validated its medical lead-free sensors against DIN EN ISO 80601-2-55 and our customers have tested their devices in certified test laboratories as well successfully. Halothane is not used as anaesthetic in Europe since many years. Its use in developed countries has been mostly replaced by newer anaesthetic agents such as sevoflurane. It is no longer commercially available in the United States […]. Beside this device manufacturers take care that no decomposition products are administered to a patient."*

COCIR was asked whether this statement satisfied their requirement that sensors *"must be usable and accurate in the presence of commonly used anaesthesia gases (such as Halothane, Isoflurane, Sevoflurane and Desflurane), N_2O and CO_2"* COCIR (2020b), or if additional testing standards would need to be satisfied, COCIR (2021c) stated:

- *"DIN EN ISO 80601-2-55 is the appropriate standard, but this is a point-in-time test. The main concern is related to the long-term reliability of the lead-free sensor."*
- *"The requirement for qualification is that the sensors must be able to operate in the presence of such gases, rather than if decomposition products are administered to the patient. Medical devices sold in the EU are usually identical to those sold in developing countries where halothane is still used."*

When asked whether their sensors contain any magnetic materials that may prevent the use in MRI machines, ITG (2021a) stated their *"lead free sensors do not contain any magnetic materials. Such sensors are available since 2017."*

In the consultants understanding, this issue has likely been solved by suppliers of lead-free galvanic oxygen sensors, firstly because relevant standards have been applied for testing and secondly evidenced by the use of lead-free sensors in practice.

(e) Lead-free sensors from other manufacturers

With respect to market-available lead-free electrochemical oxygen sensors from other suppliers (other than ITG), COCIR (2021a) stated:

- *"Cambridge Medical Co was determined, when reviewed by COCIR members to have distinct similarities to ITG and so has the same technical issues (i.e. output voltage, not current) identified in the ITG product also applicable to this product.*
- *Honeywell/Envitec were contacted by one COCIR member, but at the time they were contacted, sensors fitting their application was under development, but not yet commercially available.*
- *Hamilton Medical were contacted but replied that they would not offer a drop-in replacement for one manufacturer as their standard design provides an output in the wrong format for their applications. There is also concern around compatibility due to the memo produced by Hamilton Medical.*
- *Angst+Pfister, like Cambridge Medical Co, upon review by COCIR members, these look to have distinct similarities to ITG, with the same issues identified as in the ITG product, also applicable to this product."*

When asked about lead-free electrochemical sensors that, according to COCIR (2020b), "*have recently become available and have been evaluated*", and which prompted COCIR to request a renewal of this exemption only until the end of 2025 instead of the maximum validity period, COCIR (2021a) stated: "*One COCIR member has developed its own in-house sensor solution for a lead free sensor called "Oxycell A" (manufacturer Draeger), which was successfully placed on the market since approx. 2013.*" An illustration was provided by COCIR, which is reproduced in Figure 6-6.

Figure 6-6: Illustrations of the Dräger Oxycell A lead-free sensor

Source: COCIR (2021a)

COCIR (2021a) explained that *"Medical devices that use oxygen sensors that have been designed, tested and approved since 2013 (so available since about 2018/2019 as this timescale is about 5 years) are equipped with those sensors. When the Medical Devices Regulation 2017/745 (MDR) was published, this manufacturer started the Phase-Out of older product lines which means that a design freeze was agreed for these products. Many of these products still need to be available in the EU market as they will be required by hospitals until alternative products are designed, tested and approved. The medical devices from this manufacturer that use the sensors based on this exemption will no longer be placed on the market after their Medical Devices Directive approval certificate expires. The sunset period of the MDR expires 25th May, 2024 (which is why COCIR requested expiry for new medical devices until 2025) thus after that date no new medical devices using the lead-based sensor will be placed in the market. However, hospitals will still need to use lead-based sensors as consumables after this date for use in the medical equipment that hospitals and clinics in the EU already own and will continue to use in the foreseeable future, so the maximum expiry date is needed for these sensors.*"

Providing more information on the Dräger Oxycell A sensor, COCIR (2021b) stated: *"The Draeger Oxycell A […] is a potentiostatic type sensor that has a different theory of operation and requires a significantly different interface than a galvanic type sensor, with or without lead. These are not drop-in replacements and have not yet been (widely) validated in medical applications."*

The consultants confirm that the Oxycell A sensor is described by Dräger informational material as its "newest generation", mentioning its integration in "planned and new device generations", preparing the trend towards miniaturized and non-consuming sensors Draeger (2021). COCIR (2021d) confirmed that Oxycell A matches the description of 3-electrode electrochemical sensors (cf. section 6.3.2), and that the described disadvantages compared to galvanic oxygen sensors do apply (need for an external power and not being suitable for MRI applications).

Substitution of lead in measurement and control instruments

Over the course of several questionnaires answered by JBCE, the applicant commonly distinguished between sensors to measure oxygen in gases and sensors to measure

dissolved oxygen. This is reflected in the following two sub-sections on each field of application.

(a) Dissolved oxygen sensors

JBCE was questioned on the lead-free galvanic oxygen sensors supplied by ITG as well as two other suppliers (Maxel[44] and Angst+Pfister[45]) in terms of whether these had been tested and which properties may prevent the use in relevant equipment of category 9.

Regarding ITG sensors, JBCE (2021a) stated: "*No evaluation because the ITG's sensors are not for dissolved oxygen measurement."* This was confirmed by ITG (2021a), stating that "*For the time being ITG only offers lead free oxygen sensors for the measurement of gases."* JBCE (2021b) clarified that the ITG sensor was never evaluated as *"ITG sensor has no water proof function"*.

Regarding the sensors from other suppliers, JBCE (2021a) stated that "*both Maxell's and Angst+Pfizer's sensors are for oxygen gas measurement like ITG's, not for dissolved oxygen measurement. So we never evaluated them as dissolved Oxygen measurement."* JBCE (2021b) clarified that sensors from these suppliers also *"have not water proof function"*.

When asked to explain which specifications are not met by available lead-free galvanic sensors that are met by leaded sensors, JBCE (2021a) stated "*Although some products have already been commercialized with respect to zinc, the low oxygen concentration sensitivity of the ppb range is higher than that of products using lead, and replacement in the full concentration range has not yet been realized. In the case of oxygen sensors for dissolved oxygen measurement, an anode sensor using zinc is available in some markets but is limited as it cannot measure low concentrations of dissolved oxygen. In fact, there are applications that require continuous monitoring and batch measurement of low concentrations in process management such as monitoring the amount of dissolved oxygen to prevent corrosion inside a boiler, quality control to prevent oxidation of food, and research applications such as the culture of oxygen anaerobic bacteria. An anode sensor using lead is required in such cases that measurement and monitoring of low concentration oxygen is required.*"

JBCE (2021b) explained the reduced capability of lead-free sensors to measure oxygen concentration in the ppb range as follows: *"The dark current of low oxygen concentration by lead free sensor which is close to zero on the ppb range, is higher than that of leaded sensor. Dark current means that the residual electric current flowing in a DO [dissolved oxygen, the consultants] electrode device when there is no oxygen in sample."*

[44] Maxell website on Oxygen Sensors / Lead-Free Oxygen Sensors: https://biz.maxell.com/en/tokki/oxygen_sensors.html (last accessed: 2nd September 2021)

[45] Angst+Pfister website on lead-free electrochemical oxygen sensor: https://sensorsandpower.angst-pfister.com/en/news/news/article/po2es-103p-lead-free-rohs-conform-long-life-expectancy-fully-co2-resistant-electrochemical-senso-1/ (last accessed: 2nd September 2021)

Besides this disadvantage, JBCE (2021b) stated: *"Due to the cause of the dark current described […], a local battery is formed in the electrode, which slows down the response by about 2 times. This is a disadvantage even outside the low concentration range."*

JBCE (2021b) provided a table listing the requirements for sensors in the measurement of dissolved oxygen compared to the specifications of examples of available lead-free sensors, which is reproduced in Table 6-12.

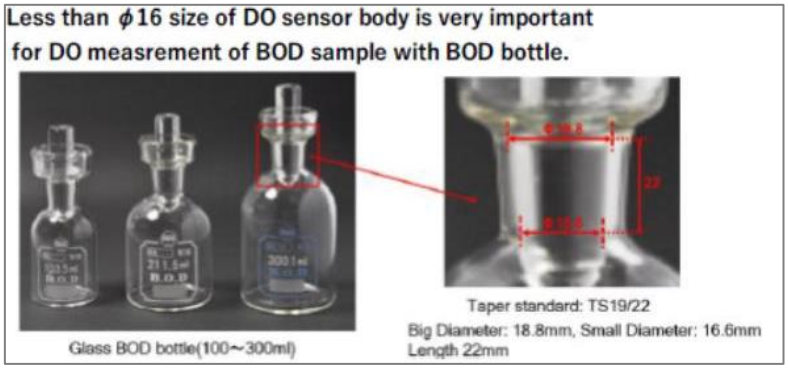
Table 6-12: Comparison table between the required specifications between and specification of lead-free sensors (Dissolved Oxygen sensor)

Company	ITG	Angst+Pfizer	MAXCELL	Sensorex	Requirements
Model	Type I	PO2ES-103P	KE-25LF	DO1200	of DO
Target sample	Gas	Gas	Gas	Water	Water
Size	Φ29×41 mm	Φ29×41 mm	Φ28×47.3 mm	Φ16.5×116mm	< Φ16.6
Measuremet range	(0.5 to 35 Vol.%)	0 to 100 Vol.%	0 to 30 Vol.%	Minimum 30 ppb to 20ppm	<5ppb to 20ppm
Operating temperature	5 to 45 ° C (0 to 50 ° C)	0 to 45 ° C	5 to 40° C	0 to 50° C	0 to 50° C
Response Time t90	(< 5 s)	< 10 s	< 15 s	<60 s	< 30 s

Source: JBCE (2021b)

For the required size of <16.6 mm, JBCE (2021b) provided a note, which is reproduced in Figure 6-7. It states that *"less than Ø16 size of DO sensor body is very important for DO measurement of BOD sample with BOD bottle"* JBCE (2021b).

Figure 6-7: Note on the size requirement for DO sensors



Source: JBCE (2021b)

The consultants further investigated the Sensorex DO1200 sensor listed in Table 6-12. It is a galvanic oxygen sensor with a zinc anode and silver cathode. It is described by a specification sheet dated to the year 2011 Sensorex (2011). According to the specification sheet, the sensor can measure a concentration range of 0-20 mg/L. JBCE (2021b) stated

the measurement range to be 30 ppb up to 20 ppm. While this appears to contradict previous statements by JBCE, where it was claimed that available lead-free oxygen sensors were not capable to measure oxygen concentrations in the ppb range, it does indeed not match JBCE's stated requirement of a measurement range below 5 ppb (Table 6-12). When asked whether JBCE would agree to apply 30 ppb as a threshold to distinguish between sensors that do and do not require this exemption, JBCE (2021d) stated to agree with this.

(b) Oxygen gas sensors

When asked about the suitability of ITG sensors to measure oxygen gas, JBCE (2021a) stated: *"As long as we confirmed, one of the specifications in ITG sensor cannot meet our required criteria, so we have never evaluated the sensors from ITG. However, we have evaluated the lead-free sensor from Maxell."* When asked to clarify which specification of the ITG sensor does not meet JBCE requirements, JBCE (2021b) stated: *"ITG sensor is mechanically compatible with our existing leaded sensor, but is not electrically compatible with our existing leaded sensor, instead Maxell sensor is both mechanically and electrically compatible"*. Despite being asked by the consultants, JBCE did not explain in which way the ITG sensor is electrically not compatible and does not match JBCE's requirements.

Regarding sensors from the other suppliers, JBCE (2021a) stated: *"We have ever evaluated the lead-free sensors from Maxell. However, we could not get our required performance."* JBCE (2021a) provided measurement data comparing a lead-free Maxell sensor to an leaded sensor as evidence of its lacking performance, however, this data was provided confidentially and can therefore not be reproduced in this report or used as a basis to form an opinion on the necessity to renew this exemption. JBCE (2021c) confirmed that a non-confidential version of the data could not be provided.

When asked to state reasons why lead-free sensors (other than ITG and Maxell) had not been tested, JBCE (2021b) stated: *"other suppliers' sensors are not compatible with our existing leaded sensor, Instead Maxell sensor is both mechanically and electrically compatible"*, providing the table reproduced in Table 6-13. JBCE (2021b) also added: *"even though we started to evaluate the lead-free sensor with mechanical / electronical compatibility, it takes for around 7 years to substitute."*

Table 6-13: Compatibility of sensors from different suppliers with JBCE existing sensor

	Mechanically compatibility	Electric circuit design compatibility
Maxell	Yes	Yes
Angst+Pfister	No	No
ITG	Yes	No

When asked to explain, which specifications are not met by available lead-free galvanic sensors that are met by leaded sensors, JBCE (2021a) stated that "*Even the lead-free*

sensor is commercially available, manufacturers need to ensure that they give accurate results, especially when measuring oxygen in the presence of other gases that might interfere with the sensor's behaviour to give incorrect results. There are about 60 kinds of interference gases that might occur, and the concentrations of these gases existing for each application is different and so their effect will be different."

When asked for which industrial applications ITG's lead-free sensors were available and proven in use, ITG (2021a) stated the following for a range of different applications:

- ***Portable emissions testing:*** *"In portable emission testing 50 % of the European devices already have galvanic lead-free sensors since 2010."*
- ***"Process technology for % oxygen measurements*** *is a very sophisticated market that already uses different technologies since many years. All requests to ITG to replace a galvanic sensor with lead could be successfully fulfilled by a lead-free sensor."*
- ***"Process technology for ppm oxygen measurements*** *is also a very differentiated and small market (< 5.000 devices in Europe) that already uses various technologies since many years. For the time being no galvanic lead free sensors are used, but it is possible to develop them within 2 years upon request from the market or by regulatory requirement."*

ITG (2021a) was requested to address the following points raised by (JBCE 2020a):

Statement JBCE: the influence of interference gas mainly affects the sensitivity, accuracy, and lifetime of the sensor

- *Response ITG (2021a): "No change from a lead sensor to a lead-free sensor was hindered by interference from other gases so far in various areas of application, also with complex gas mixtures (e. g. biogas measurement)."*

Statement JBCE: lead-free zinc-based oxygen sensors are not capable of measuring oxygen concentrations in the ppb range.

- *Response ITG (2021a): "Lead free sensors can be developed for the same measurement range as lead sensors. The market for ppm and ppb oxygen measurements is much smaller compared to the medical market. Thus, no manufacturer has yet taken the effort to adapt the technology. In principle this is feasible as well but might require a higher effort for the electronic adaptation."*

When asked whether a particular response time was required for oxygen gas measurements was required, JBCE (2021c) confirmed that a response time of <3 seconds was needed in some applications, such as for exhaust emission inspection for vehicles.

In conclusion, there are two issues that, according to JBCE, have not been solved when using lead-free sensors for oxygen gas measurements: validation against the vast number of influencing gases, low concentration measurements, and fast required response time. In the consultants' view, it is not necessary to test lead-free sensors against all possible influencing gases at once. Rather, an application-wise approach could be chosen, in which sensors are validated against subsets of influencing gases that can reasonably be expected to occur in a specific application (e.g. emissions testing or biogas measurements).

Elimination of lead

Both applicants provided descriptions for a number of oxygen measurement techniques together with drawbacks for each method that prevents the elimination of lead in relevant applications. The consultants carried out internet research to check statements made by the applicants and did not find contradicting information.

COCIR described potentiostatic sensors as an alternative to galvanic oxygen sensors and mentioned the Dräger Oxycell A sensor as a specific example that is already used in the market. However, it is not suitable for substitution in all applications as it requires an external power supply and is not suitable for MRI applications.

6.4.3. Environmental arguments and socioeconomic impacts

When asked about the treatment of waste oxygen sensors, given that they are used in a medical setting and may therefore potentially be infectious waste, COCIR (2020c) stated "*Some manufacturers operate a full take-back solution for WEEE and as such collect the used sensors. Some models of sensor operate on the inspiratory side of the breathing systems and therefore are not in contact with expiratory breathing air from the patient, however as air is filtered, contamination is very unlikely to occur and so they can be safely recycled. Customers are also asked to confirm proper disinfection of medical equipment prior to return so manufacturers are willing to take back and recycle.*"

When asked which materials are recycled from lead-based sensors, COCIR (2020c) stated that "*Lead is present in used sensors as a mixture of lead metal and lead oxide. This is treated with other electrical equipment waste for metals recovery, which includes the recovery of lead and platinum (and some also gold) contained within the sensors. The most commonly used recycling process for electrical equipment waste is smelting which is where the material is heated to a high temperature under reducing conditions when any lead oxide will be reduced to lead metal.*"

When requested to estimate the number and mass of waste electrical and electronic equipment that would arise if the exemption renewal request was not granted, COCIR (2021b) stated that *"there are at least 40.000 ventilators that would need to be discarded if the exemption for replacement sensors is not extended for 7 years. Ventilator weight is very variable (e.g. 7kg to >100kg), so an accurate total weight for all manufacturers products is not possible. One typical example ventilator is 25kg, but these are usually trolley mounted so total 59kg. 40,000 at 59 kg is 2,360 tonnes, but in reality, the total may be larger."*

ITG (2021a) stated that their lead-free sensors have a doubled or tripled lifetime and therefore don't have to be exchanged annually. Thus, they are much more sustainable than leaded sensors.

6.4.4. 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.*

Conclusions are drawn differentiating the application of oxygen sensors in the medical sector and in monitoring and control instruments, where measurement of gas and dissolved oxygen is further differentiated.

Oxygen measurements in the medical sector

With respect to the substitution of lead in galvanic oxygen sensors used in the medical sector, the main lines of argument and the consultants' views can be summarized as follows:

- Lead-free galvanic oxygen sensors for medical devices in scope of this exemption request have been introduced to the market as early as 2015 for some equipment (ventilators) and more recently for other equipment (anaesthesia machines, ECMO, CPAP) according to ITG. While ITG stated that the lead-free galvanic oxygen sensors are used and approved in practice in such medical devices, COCIR expressed concerns regarding their compatibility with existing medical equipment as well as their long-term reliability.
- In the consultants' view, mechanical and electrical compatibility is not a barrier that prevents the use of lead-free galvanic oxygen sensors. COCIR's line of argument is that relevant medical equipment requires current as output signal from sensors, whereas lead-free sensors only output voltage. ITG responded that 95 % of relevant medical equipment use sensors that output voltage. Examples of lead-free galvanic oxygen sensors identified by the consultants commonly output voltage. It appears to the consultants that indeed lead-free sensors may not always immediately be compatible with existing medical equipment and may therefore not necessarily be drop-in replacements. However, it seems that retrofitting exiting medical equipment with lead-free sensors is technically possible with certain sensor hardware and analyser software modifications. Further, in the consultants' understanding, this should not be an issue for new medical equipment designed with lead-free sensors in mind.
- Regarding the reliability of lead-free sensors, COCIR substantiated their concerns with test data from two sensors from two manufacturers, including ITG. The ITG sensor is shown to lack robustness with regard to the zero offset specification. However, test reports provided by ITG show that the zero offset specification is fulfilled. This situation in which test reports from both parties show contradicting results could not be resolved during the evaluation period.
- COCIR explained the situation that a member company will phase out medical equipment that requires lead-free sensors by the time its Medical Devices

Regulation certification expires on 25th May 2024. After this date, medical devices that require lead sensors will no longer be put on the market.

- While ITG stated not to see a reason to renew the exemption, as lead-free sensors are available for medical devices, they also stated to agree with the timeline suggested by COCIR, as not all manufacturers have switched to lead-free sensors yet. ITG estimated that 60 % of all ventilators in the EU will use lead-free sensors by the years 2022, and 50 % anaesthesia machines. Therefore, to the consultants, the substitution appears to be an ongoing process.

With respect to the elimination of lead in galvanic oxygen sensors used in the medical sector, COCIR described other measurement techniques, but all have disadvantages that prevents them from substituting galvanic lead sensors in all relevant applications. Potentiostatic oxygen sensors are already used in some applications but are not suitable as drop-in alternatives for existing equipment designed for galvanic oxygen sensors and are not suitable for all applications due to their technical drawbacks (require external power source, contain magnetic materials).

Considering the above points, the consultants conclude that in the medical sector, 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. For that same reason, the consultants can also follow COCIR's request to renew the exemption for replacement sensors, so that existing medical equipment only compatible with lead sensors may be used beyond this date.

Oxygen measurements with monitoring and control instruments

The use of oxygen sensors in monitoring and control instruments is a more diverse field with a wider range of requirements compared to medical applications: Some applications require the measurement of oxygen in gas and others measure dissolved oxygen in liquids; the concentration to be measured ranges from percentage down to ppb range; some applications measure discrete samples and others measure processes continuously, and some applications require particularly small sensors (e.g. BOD measurements). Fields of application include process control in industrial facilities, use in laboratories, quality control, environmental (pollution) analysis, and workplace control and security.

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.

With dissolved oxygen measurements, JBCE's main argument is that lead-free sensors cannot yet measure low concentrations in the ppb range. However, as the example of the Sensorex DO1200 shows, lead-free sensors do exist that are capable of measuring low concentrations down to 30 ppb. While this does not match JBCE's stated requirements of measurements below 5 ppb, JBCE did agree that sensors that are able to measure concentrations of 30 ppb and higher (but not below) can be excluded from the scope of this exemption.

When asked, JBCE confirmed that dissolved oxygen concentration measurements in the percentage range are not an issue with lead-free sensors. These can, therefore, be excluded from the scope of the exemption wording.

With measurements of oxygen in gases, the applicant mentioned two issues: their required response time of less than 3 seconds, and the effects of influencing gases on the measurements.

JBCE maintain that there are currently no substitutes for oxygen gas measurements, and that 7 years' time will be needed to fully qualify a lead-free alternative, once it becomes available. A lead-free sensor from the manufacturer Maxell was tested (by JBCE) but it was found that the performance did not match lead sensors in one essential parameter. As this information was only provided as a confidential document, the consultants cannot use this information to draw conclusions that would change the recommendation.

JBCE did not provide comprehensive testing results from several market-available lead-free oxygen sensors, but had only ever tested one lead-free sensor from one supplier. In the consultants' view, the applicant could have done more to explore lead-free alternatives and demonstrate their suitability or lack thereof. JBCE also did not specify the requirements in juxtaposition to the specifications of lead-anode and lead-free oxygen sensors in a structured list of applications, as had been requested by the consultants. Therefore, there is doubt regarding the comprehensiveness of the exploration of lead-free alternatives on the applicant's side.

Alternative measurement methods that do not require the use of lead have been described by JBCE, but each has drawbacks that lead to the conclusion that they cannot replace lead-anode galvanic oxygen sensors in every application. The consultants did not encounter information that contradict this assessment.

Conclusions summary

In conclusion, there indeed appear to be some remaining technical issues in the transition from lead to lead-free oxygen sensors: The electrical compatibility is not always given (current vs. voltage, required impedance on the analyser side) and the response time is not always fast enough to meet requirements. These aspects appear to be closer to being solved in the medical sector as opposed to monitoring and control instruments. This may in part be explained by the less varied range of applications in the medical field and the narrower range of oxygen concentrations to be measured (% oxygen in air breathed in and/or out by patients). Measurement and control instruments have a wider application range and more diverse requirements in comparison. For this reason, it may be advantageous to split the exemption into multiple entries to reflect the diverging requirements and states of substitutability.

Timeline

Concerning the medical sector, COCIR stated that it will take until the end of 2025 until all relevant medical equipment can be put on the market with lead-free oxygen sensors. ITG support that this exemption ends by the end of 2025. As the applicant (COCIR) and the supplier of lead-free sensors (ITG) agree on the timeline to substitute lead-anode sensors

with lead-free sensors until the end of 2025, the consultants propose following this timeline. COCIR further stated that replacement sensors meet the definition of EEE from RoHS Article 3(1) and 3(2), as they rely on electricity for their main function. COCIR requested the maximum validity for lead-based sensors as consumables to be used in medical equipment that hospitals and clinics already own and will continue to use in the foreseeable future. The consultants understand that granting this exemption would keep existing medical devices in use that may otherwise no longer be usable and become electrical waste prematurely. However, given the availability of lead-free sensors on the market, it may be reasonable to set the validity period to a time frame below the maximum of 7 years. From the provided information, the consultants understand that technically, the adaptation of lead-free sensors is likely possible for many existing medical devices.

Concerning monitoring and control instruments, JBCE requested to renew this exemption for the maximum validity period of 7 years. In measurements of oxygen gas, the rationale is that even if a suitable lead-free oxygen sensor became available, it would take 7 years to test it against the effects of influencing gases that may occur in various applications. ITG claimed that the transition of equipment that used lead-anode sensors to operate with lead-free sensors had never been hindered by effects of lead-free gases, including in cases with complex gases, such as biogas. Nevertheless, in the consultants' view, this does not necessarily mean that influencing gases in all possible applications have already been evaluated and found to be non-problematic, therefore more time may be needed to ensure the suitability of lead-free sensors. On the other hand, the consultants do not believe that a sensor needs to be tested against all 60+ influencing gases mentioned by JBCE at once before they can be used. Instead, sensors can be tested against those subsets of influencing gases that can reasonably be expected in a specific application (e.g. emissions testing or biogas measurements) and thereby be qualified gradually for individual applications. Therefore, in the consultants' view, 7 years may not be required for this procedure.

ITG stated that currently, sensors to measure dissolved oxygen in low (ppb) concentrations have not been developed yet as sensor suppliers have not focussed on this relatively small market, but that development would be possible within two year's time in principle.

JBCE confirmed not to need the exemption for handheld devices for the measurement of oxygen in gases, which can therefore be excluded from the scope of this exemption. However, JBCE stated that handheld devices for the measurement of dissolved oxygen in low concentrations still require lead.

6.5. Recommendation

The accessible information suggests that substitution and elimination of lead in anodes of electrochemical oxygen sensors are scientifically and technically not yet practicable in all applications. In the consultants' view, Art. 5(1)(a) would therefore allow granting an exemption and recommend to renew exemption IV-1(b) with the following wording:

	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.*

The definition of handheld device provided by JBCE is (wording slightly adapted by the consultants):

- A handheld device is a measuring instrument that is designed to be compact and lightweight as to be held with a single hand and is battery-operated and does not require a direct AC power for measurement.

The consultants recommend splitting the exemption into two parts to reflect the diverging state of substitutability in the medical sector and in monitoring and control instruments:

- In the medical sector, covered by exemption 1(b)(I), new equipment using oxygen sensors that require lead sensors to function will no longer be placed on the market after 26 May 2024. After this date, only replacement sensors with lead anodes will be required to allow hospitals and other users of the equipment to keep using it until the end of life of the equipment is reached. The consultants recommend the exemption expiry date to be set on 21 July 2025 to allow the continued use of existing medical equipment that requires leaded oxygen sensors as consumables.
- For monitoring and control instruments, covered by exemption 1(b)(ii), the exemption wording is specified to cover sensors designed for the measurement of (a) oxygen gas with a response time of <3 seconds and (b) sensors designed for the measurement of dissolved oxygen in concentrations below 30 ppb. In the consultants' view, the applicant could have done more to investigate available lead-free sensors. Therefore, and to align a possible future review of this exemption with exemption 1(a)(I), the consultants recommend to set the expiry date to 21 July 2025.
- For industrial monitoring and control instruments special requirements are necessary and thus it is proposed to keep the expiry date for IMCI with the original wording.

In case of an application to renew exemption 1(b)(ii) beyond the set expiry date, it is expected that the applicant(s) can provide test results in a non-confidential manner that show the performance of lead-anode sensors and lead-free sensors in all applications in which lead may still not be fully substitutable, including all relevant criteria (e.g. concentration range, response time, influencing gases) that are presented as arguments why leaded sensors are still not fully substitutable.

6.6. References

COCIR (2020a): Lead Free O2 Sensor Characterization. Full Nonconfidential. Document Number: ENG-XXXX; Revision Number: 01, zuletzt geprüft am 21.09.2021.

COCIR (2020b): Request for renewal of exemption 1b of RoHS Annex IV. COCIR, zuletzt geprüft am 07.09.2021.

COCIR (2020c): COCIR answer to Questionnaire 1 (Clarification). Exemption 1b of RoHS Annex IV. COCIR, zuletzt geprüft am 23.08.2021.

COCIR (2021a): COCIR answers to Questionnaire 2. Exemption 1b of RoHS Annex IV. COCIR, zuletzt geprüft am 30.08.2021.

COCIR (2021b): COCIR answer to Questionnaire 4. Exemption 1b of RoHS Annex IV. COCIR, zuletzt geprüft am 16.09.2021.

COCIR (2021c): COCIR answers to Questionnaire 3. Exemption 1b of RoHS Annex IV. COCIR, zuletzt geprüft am 09.08.2021.

COCIR (2021d): COCIR answer to Questionnaire 5. Exemption 1b of RoHS Annex IV. COCIR, zuletzt geprüft am 05.10.2021.

Directive 2002/95/EC: Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 1). RoHS 1. Fundstelle: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0095:EN:NOT, zuletzt geprüft am 04.12.2013.

Directive 2011/65/EU: 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 (recast). RoHS 2. Fundstelle: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065.

Draeger (2021): O2-Sensoren Verbrauchsmaterial und Zubehör. Draeger. Online verfügbar unter https://www.draeger.com/Products/Content/o2-sensors-pi-9049118-de-de.pdf, zuletzt geprüft am 17.09.2021.

Goodman (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report (amended). ERA Report 2006-0383. Unter Mitarbeit von Paul Goodman. ERA Technology Ltd. Online verfügbar unter http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf.

ITG (2020a): Response to consultation questionnaire for RoHS exemption 1(b) of RoHS Annex IV. Exemption 1b of RoHS Annex IV. IT Dr. Gambert GmbH.

ITG (2020b): MLF-16 Long Term drift. Verification Report. IT Dr. Gambert GmbH.

ITG (2021a): ITG answer to Questionnaire 1. Exemption 1b of RoHS Annex IV. IT Dr. Gambert GmbH, zuletzt geprüft am 21.08.2021.

ITG (2021b): ITG answers to Questionnaire 2. Exemption 1b of RoHS Annex IV. IT Dr. Gambert GmbH.

JBCE (2020a): Request for renewal of exemption 1b of RoHS Annex IV, zuletzt geprüft am 07.09.2021.

JBCE (2020b): JBCE answer to Questionnaire 1 (Clarification). Exemption 1b of RoHS Annex IV. JBCE, zuletzt geprüft am 07.09.2021.

JBCE (2020c): JBCE Responds to the public consultation for Exemption 1(b) of RoHS Annex IV. JBCE, zuletzt geprüft am 07.09.2021.

JBCE (2021a): JBCE answer to Questionnaire 2 - Non-confidential version. Exemption 1b of RoHS Annex IV, zuletzt geprüft am 30.08.2021.

JBCE (2021b): JBCE answer to Questionnaire 3. Exemption 1b of RoHS Annex IV. JBCE, zuletzt geprüft am 09.08.2021.

JBCE (2021c): JBCE answer to Questionnaire 4. Exemption 1b of RoHS Annex IV. JBCE, zuletzt geprüft am 21.09.2021.

JBCE (2021d): JBCE answers Questionnaire 5. Exemption 1b of RoHS Annex IV. JBCE.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

Sensorex (2011): DO1200 and DO1200TC Dissolved Oxygen Sensors. Product Specification Sheet. Sensorex. Online verfügbar unter https://sensorex.com/docs/specs/SpecsDO1200.pdf, zuletzt geprüft am 17.09.2021.

7. Exemption 1(c) of Annex IV: Pb, Cd, Hg in infrared detectors

The exact wording of the current exemption 1(c) is as follows:

"Lead, cadmium and mercury in infra-red light detectors"

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date was scheduled for 21 July 2023, and for IMCIs for 21 July 2024.

Declaration

In the sections preceding the "Critical review" (section 7.4), 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. Information directly taken from information provided by applicants, stakeholders or other sources is described in italics. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms

DCRS	Detectors containing RoHS-restricted substances
DLATGS	Deuterated lanthanum α alanine doped tri glycine sulphate, used in pyroelectric detectors
DWRS	detectors without RoHS-restricted substances
FTIR	Fourier transform infrared
IMCI	industrial monitoring and control instruments
IVD	in-vitro diagnostic medical devices
LC	Laser Components
LIRS	long-wavelength infrared spectrum (8 µm to 14 µm)
LiTaO, LiTaO3	lithium tantalate
MCT	mercury cadmium telluride
MIRS	medium wavelength infrared spectrum (3 µm to 8 µm)
NIRS	near infrared spectrum (0.78 µm to 3 µm)
PbS	lead sulphide
PbSe	lead selenide

PC	photoconductor/photoconductive
PE	Perkin Elmer
PIN	positive intrinsic negative, e.g. PIN diode
PPTF	Polish Technological Platform on Photonics
PV	photovoltaic
RoHS 1	Directive 2002/95/EC
RoHS 2, RoHS	Directive 2011/65/EU
S/N	signal to noise ratio
SBN	strontium barium niobates
TBE	T & B Electronics
TE	thermoelectrical cooling
TGS	glycine trisulfide, used in pyroelectric detectors
VLIRS	very long wave IR spectrum (14 µm to 30 µm)

Definitions of IR detector performance parameters

Detectivity	The inverse of the noise-equivalent power (NEP). The larger the detectivity of a photodetector, the more it is suitable for detecting weak signals which compete with the detector noise.[46]
NEP	Noise equivalent power, optical input required to obtain the same output signal strength like that resulting from detector noise47
Noise	Electrical output power of a detector in the absence of an IR input power
Responsivity	Ratio of output signal (e.g. a photocurrent and the strength of the optical input (as an optical power)[47]
Signal-to-noise ratio	Ratio of signal power to noise power in a detector[47]
Specific detectivity D*	Detectivity normalized to a unit detector area (1 m^2) and detection bandwidth (1 Hz) ; useful for comparing performance of different detector technologies[46], $D^* = \frac{\sqrt{A\Delta f}}{NEP}$ where A is the photosensitive area of the detector and Δf the bandwidth
Sensitivity	Often understood as ability to detect weak signals, measured as NEP and detectivity[47]

[46] Source: Sick, https://www.rp-photonics.com/detectivity.html

[47] RD Photonics Encyclopedia, https://www.rp-photonics.com/sensitivity.html

7.1. Background

Five applicants submitted requests for the renewal of exemption 1(c) of Annex IV for the maximum validity period of seven years, and eight stakeholders contributed to the online consultation.

7.1.1. History of the Exemption

Goodman (2006) recommended the COM to grant this exemption if cat. 8 and 9 were to be included into the scope of the RoHS Directive because at that time there were "*No substitutes which meet the combinations of all essential performance criteria*". The COM followed this recommendation and listed exemption 1(c) on Annex IV of RoHS Directive 2011/65/EU (2011) (RoHS 2) when it was officially published in 2011. The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 monitoring and control instruments (MCI) and other than industrial monitoring and control instruments (IMCI). Applications for renewal were submitted in time, and exemption 1(c) is to be reviewed to adapt it to scientific and technical progress.

7.1.2. Summary of renewal requests and stakeholder contributions

Overview of exemption renewal requests and stakeholder contributions

The below table gives an overview of the exemption renewal requests. All applicants request the renewal of exemption 1(c) for the maximum 7-year period for EEE of categories 8 and/or 9, but with slightly different wordings and scopes.

Table 7-1: Overview of exemption requests

Applicant	Proposed Wording	Substances and Applications
COCIR (2020)	*Lead in infra-red light detectors* for category 8 IVD and other than IVD	Lead selenide (PbSe) in capnographs
JBCE (2020a)	*Lead, cadmium and mercury in infrared detectors (current wording) for cat. 8 IVD and other than IVD, and cat. 9 MCI including IMCI*	Quantum type detectors: Mercury Cadmium Telluride (MCT), Lead Sulphide (PbS), Lead Selenide (PbSe) in a larger variety of EEE; PZT
LC (2020)	*Lead in infrared light detectors* for cat. 8 IVD and other than IVD, and cat. 9 IMCI and other MCI	PbS and PbSe in infrared detectors
PE (2020)	*Cadmium and mercury in infra-red detectors of Fourier transform infrared (FTIR) spectrometers and microscopes* for cat. 9 IMCI	MCT in FTIRs and microscopes
PPTF (2020)	*Cadmium and Mercury in infrared detectors for cat.8 other than IVD*	MCT in detectors for medical devices, specifically gas analysers and imaging devices for non-invasive diagnostics

Table 7-2 shows the stakeholders and their support for specific requests and exemption wordings.

Table 7-2: Overview of stakeholder contributions

Stakeholders	Supports/Views Expressed	Related Substances and Applications
Berghof (2020)	Supports the renewal as requested by LC and COCIR for 7 years	PbS infrared sensors as an essential component of microwave digestion systems
Drägerwerk (2020)	Supports the applications of COCIR and Laser Components	PbSe in detectors of medical mainstream capnographs
FFE (2020)	No specific support expressed, but FFE's use of IR sensors would be covered by COCIR's and LC's exemption requests	PbS in infra-red sensors of flame detectors
JBCE (2020c)	Supports its own exemption request	See above information related JBCE's application
Siemens (2020)	Supports wording in COCIR's and LC's exemption request («Lead in infra-red light detectors »	PbS in infrared light detectors
T&B Electronics (2020)	Support for all wordings	PbS and PbSe in detectors of spark detections systems
trinamiX (2020)	Use of PbS IR detectors, but supports renewal of current exemption wording as requested by JBCE and PE	PbS in near infrared detectors (NIRS) for analytics
voestalpine (2020)	No specific support expressed, but FFE's use of IR sensors would be covered by COCIR's and LC's exemption requests	PbSe in infrared detectors for hot box and hot wheel detection

Summaries of the exemption renewal requests

Sensors based on PbS and PbSe

According to COCIR (2020), *"PbSe infrared detectors are used in medical devices called capnometers, which are used to monitor the breathing of patients in EU hospitals and clinics. PbSe is the only detector material that meets all of the essential criteria and is able to detect small changes in breathing using a capnometer that can be indicative of health conditions as well as difficulties with breathing. All potential substitutes either do not adequately respond to changes in CO_2 concentrations in patients' exhaled breath, they respond too slowly, or the detectors require cooling. Cooling requires extra bulky equipment and would cause condensation of water from exhaled air onto the detector's surface. This will freeze and the ice crystals will block infrared light and so make the detector insensitive."*

LC (2020) explain that *"PbSe and PbS infrared detectors have unique characteristics that enable them to be used in a wide variety of applications. They are used in near infrared analysers used by very many diverse industries, medical devices for analysis of carbon dioxide in patients' breath and in spark detection systems. These detectors are used because of their high sensitivity in the near infrared range and can be used without cooling. Another advantage over thermal heat detectors is the very fast response times of the lead based detectors, which is essential in many applications."*

Sensors based on MCT

PE (2020) claim *"[…] that MCT [mercury cadmium telluride] is the only detector material currently available which is able to provide all of the following characteristics required for FTIR spectrometers and microscopes:*

- *Photoconductor with an electrical resistance that decreases as the level of incident infra-red light increases;*
- *High sensitivity to small infra-red light level changes producing a strong signal;*
- *Low dielectric constant, ensuring that the signal to noise ratio is maximised;*
- *Relatively low electrical resistance when not exposed to infra-red light;*
- *Low noise, otherwise averaging methods have to be used which increases measurement time by a factor of 4 for an improvement of the signal to noise ratio of two due to a square law relationship;*
- *Ability to detect over a wide range of IR regions therefore requiring both low and high carrier concentrations; and*
- *FTIR spectrometers for kinetics studies must have very fast response to changes in concentration of substances with typical requirements being the ability to measure spectra in times that are 1000 times shorter than the overall changes in concentration."*

PPTF (2020) state that "*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 medium wavelength infrared spectrum (MWIR, 3 to 8 µm) and especially the long wavelength IR (LWIR, 8 to 14 µm) 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 been yet any commercially available detectors matching MCT detectors in terms of detectivity.*"

Sensors based on PbS, PbSe, MCT and PZT

According to JBCE (2020a), *"Infrared (IR) analysis and measuring instruments provide a rapid, accurate analysis of materials to provide information on the chemical composition, surface properties and spatial distribution of substances. The technology is utilised by a wide variety of industry sectors, researchers and for educational purposes, examples of which are given in this exemption request. The choice of semiconductors intrinsically affects the infrared range detectable and usefulness of the signal produced. The current infrared detectors have features such as higher sensitivity and wider measurement wavelength ranges than their substitutes; as such substitutions are not capable to fulfil the requirements of analysis and measuring instruments."*

7.2. Technical description of the requested exemption

7.2.1. Amount of lead used under the exemption

JBCE (2020a) indicate the following contents of regulated substances per single IR detector:

- *MCT*
  - *Mercury 0.1 mg or less to 1 mg;*
  - *Cadmium: 0.01 mg or less to 50 mg,*
- *PbSe: Lead: 0.1 mg or less*
- *PbS: Lead: 0.1 mg or less*
- *PZT: Lead: 40 mg or less*

Based on the above, JBCE (2020a) indicate the following annual volumes of cadmium, lead and mercury used in applications in scope of the exemption in the EU:

- *Cadmium – 42.35 g in FTIR[48], and 0.2 g of the other analysis and measuring instruments entering into EU from JBCE member companies per year.*
- *Lead – 0.032 g in spectrophotometers[48], and 285 g of the other analysis and measuring instruments entering into EU from JBCE member companies per year.*
- *Mercury – 0.847 g in FTIR, and 0.005 g of the other analysis and measuring instruments entering into EU from JBCE member companies per year.*

Based on their 2018 sales, their estimated market share and contents of regulated substances in MCT detectors, PE (2020) estimate the annual volumes of cadmium and mercury entering the EU market as follows:

- *Cadmium: 1.00 g*
- *Mercury: 0.20 g*

It should be taken into account that the above figures refer to the JBCE members' products only which enter the EU/EEA.

LC (2020) estimate that one 2 x 2 mm detector chip will contain 38.4 µg of lead assuming these are 100 % dense single crystals. However, these materials are polycrystalline and so they estimate that they contain about 60 % of this figure, so 23 µg of lead. Although the total number of detectors produced by all manufacturers annually is unknown, LC (2020) estimate that this could be about 1 million of 2 x 2 mm equivalent size and one third of these are used in the EU. 1 million x 23 µg = 23 grams lead, so one third is 7.7 grams.

PPTF (2020) indicate the share of mercury and cadmium within a typical MCT infrared detector chip is around 0.7 % and 0.5 % of the chip weight respectively. They estimate the

[48] Estimate based on "Strategic Directions International, The 2019 Global Assessment Report: The Analytical and Life Science Instrumentation Industry, 2019"; source as referenced by JBCE 2020a.

yearly global production of MCT detectors for commercial application at around 10,000 pieces per year. The weight of a single pixel detector chip is around 0.005 g (PPTF (2020)), resulting in around 0.0235 mg of cadmium and 0.0314 mg of mercury per detector.

Therefore, the total global amount of regulated substances in MCT detectors are around 0.23 g of mercury and around 0.3 g. Out of this, only 1 % to 2 % are currently used for medical applications. Based on these conditions, PPTF (2020) estimate the overall amount of cadmium and mercury used under the exemption with 2.3 mg and 3 mg respectively.

PE (2020) indicate 0.2 g of mercury and 1 g of cadmium in MCT detectors based on their 2018 sales and market share.

Overall, it can be roughly assumed that the amounts of RoHS-restricted substances entering the EU/EEA market if the exemption was renewed would not exceed the following amounts:

- 100 g of cadmium per year;
- 1 kg of lead per year;
- 10 g of mercury per year.

7.2.2. Uses of infrared detectors – Overview

JBCE (2020a) present a non-exhaustive overview list of several application fields and devices in which infrared light detectors are used:

- *Use in laboratories:*
  The instruments such as spectrometers are placed in laboratories and utilized for research, quality control over processes such as feedstock quality, forensic science and others. Examples of spectrometer applications include the identification and characterisation of unknown materials, monitoring of automotive or smokestack emissions, kinetic studies and analysis of materials with low concentrations etc.
- *Use for analysis and measurement in the process / for instant and on-site analysis and measurement for workplace control and security*
  The instruments are utilized for controlling and monitoring working environment including factories, workplaces, and offices. They are installed and fixed to analyse and measure continuously during operation. Instant and on-site analysis and measurement is required for portable and mobile instruments, and are used in factories to warn workers of hazardous substances, etc. and may also be used outdoors. The instruments for security are utilized for monitoring leaks of flammable and toxic substances from industrial facilities.
- *Use for environment (pollution) analysis*
- *Use for material quality controls*
- *Use for clinical and testing instruments and systems:*
  The instruments are utilized for in vitro diagnostics of blood, urine and others, and for some in-vivo diagnostics.
- *Use for biotechnology:*
  The instruments are utilized for the fields of biotechnology and for applications such as pharmaceutical research

- *Use for the food industry:*
  The instruments are utilized for analysis of ingredients and hazard analysis including foods, beverages and others.

7.2.3. Properties and classification of IR-detectors

General information and overview

JBCE (2020a) describe infrared (IR) detectors as devices that receive infrared rays emitted from an object and convert them into electrical signals. By measuring light emission in the infrared region, it is possible to obtain infrared spectra to determine the temperature of the object or other aspects such as the composition which is determined by the wavenumber characteristics of absorption and reflection of a material.

IR electromagnetic waves cover a broad spectrum of wave lengths which are subdivided into sub-spectra which seemingly are not sharply demarcated since they slightly deviate depending on the consulted sources. Table 7-3 illustrates the situation based on the shortest and longest wavelengths demarcating the lower and upper limits of the IR spectrum indicated in various sources.

Table 7-3: Spectral ranges of the IR spectrum and detectors containing RoHS-regulated substances used for their detection

IR spectrum	Spectral range	RoHS-regulated substance used for detection
Near IR spectrum (NIRS)	0.78 µm to 3 µm	PbS, PbSe, PZT
Medium wavelength IR spectrum (MIRS)	3 µm to 8 µm	PbSe, MCT, PZT
Long wavelength IR spectrum (LIRS)	8 µm to 14 µm	MCT, PZT
Very long wavelength IR spectrum (VLIRS)	14 µm to 30 µm	MCT

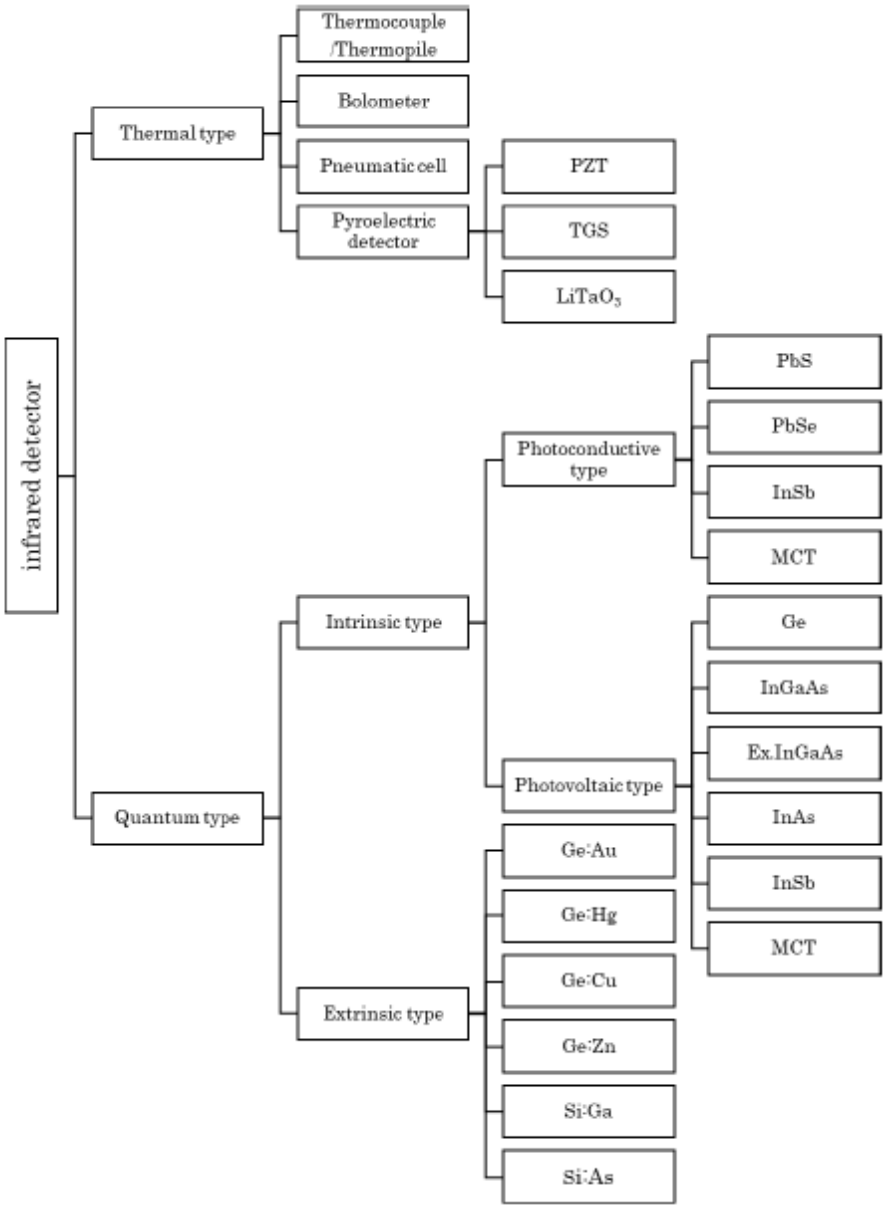
Sources: Zeiss (https://www.zeiss.de/spectroscopy/loesungen-und-anwendungen/measuring-principle/nahinfrarot-spektroskopie.html#die-wissenschaft), PE (2020), JBCE (2020a), JBCE (2021a)

Technically, IR detectors are differentiated into thermal and quantum type detectors according to JBCE (2020a). Thermal type detectors convert the temperature changes generated by absorbing the infrared rays radiated from objects into electric signals, to detect the intensity of the infrared rays radiated from the objects. Quantum type detectors measure the electron energy changes generated by the incident infrared rays – photons - as electrical signals, to detect the infrared intensity of the objects.

JBCE (2020a) further explain that quantum type detectors are classified into intrinsic type detectors and extrinsic type detectors. The extrinsic type detectors use the same detection method as the intrinsic type detectors, but detect infrared rays using changes in energy

differences generated by mixing impurities into the material. **Figure 7-1** *presents an overview of the various IR detector types and the related IR-sensitive substances or components.*

Figure 7-1: Classification of IR detectors and related substances



Source: Hamamatsu Photonics K.K. in JBCE (2020a)

Table 7-4 provides further insights into the properties of the various IR detector types and their IR-sensitive materials.

Table 7-4: Specific properties of materials used in infrared detectors

	Detector	Spectral response (μm) Typ.	Operating temperature (K) / (℃) Typ.	Detectivity D* (cm・$Hz^{1/2}$ /W) Typ.
Thermal Type	PZT	1-20 *1	300/27	3.2×10^{8}
	TGS	1-20 *1	300/27	1.1×10^{9} *4
	$LiTaO_3$	1-20 *1	300/27	2.0×10^{8} *5
	PbS	1-2.8	298/25	5.0×10^{10}
	PbS	1-3.2	263/-10	1.0×10^{11}
	PbSe	1-4.8	298/25	2.5×10^{9}
	PbSe	1-5.1	263/-10	5.0×10^{9}
	MCT (PC)*2	1-14	77/-196	4.0×10^{10}
Quantum Type	MCT (PC)*2	1-17	77/-196	1.3×10^{10}
	MCT (PC)*2	1-25	77/-196	1.0×10^{10}
	MCT (PV)*3	1-13.5	77/-196	3.0×10^{10}
	Type-II superlattice infrared detector	?-14.3	77/-196	1.6×10^{10}
	InAsSb	2-6	243/-30	5.0×10^{9}
	InAsSb	2-5.9	77/-196	8.0×10^{10}
	InAs	1-3.5	298/25	4.0×10^{9}
	InAs	1-3.5	263/-10	1.8×10^{10}
	InGaAs	0.7-1.7	300/27	5.0×10^{12}
	Ex InGaAs	1.2-2.55	253/-20	2.0×10^{11}

*1 Thermal types have little peaks of wave lengths. Window materials (filters) are chosen according to the wavelengths required.
*2 PC：Photoconductive detector
*3 PV：Photovoltaic detector
*4 not indicated by JBCE (2020b)

Source: Hamamatsu Photonics K.K.; YAMAKA Eiso, 1972, "Recent Development of Pyroelectric Infrared Detector; JBCE members; in JBCE (2020b)

Temperature dependence of IR detector properties and cooling

JBCE (2020a) state that the properties of IR detectors, such as wavelengths that can be detected and detecitivities, differ with the operating temperatures. While, depending on the detector types and on the samples/detection tasks, the analysis and measurement with room temperature may be possible without cooling, in other cases cooling is necessary by:

- *Using thermoelectric semiconductors (electronic cooling),*

- *Directly cooling the detector using liquid nitrogen (nitrogen cooling).*

According to LC (2020), some semiconductor sensors can be used only when they are cooled. This is because the semiconductors generate random electrical signals called "noise", and at ambient temperature this noise is sufficiently intense to prevent the detection and measurement of infrared radiation. JBCE (2020a) and LC (2020) explain the influence of the operating temperatures and consequences if cooling is needed:

Sensitivity

Generally, the sensitivity of the infrared detector increases as the operating temperature decreases. Therefore, with the same detector, the sensitivity of measurement and analysis increases from room temperature (300 K, 298 K), electronic cooling (263 K, 243 K), and nitrogen cooling (77 K).

Wavelength range

Even with the- same infrared detector, the wavelength range to which a detector is sensitive may increase with the operating temperatures. Therefore, the substances that can be measured and analysed are different depending on the operating temperature (c.f. Table 7-4 on page 168 and **Figure 7-2** *on page 171).*

Continuity of operation

As well as those operating at room temperature, the detectors with electronic cooling can be operated continuously because the required operating temperature can be realized if electricity is supplied. Nitrogen-cooled detectors require that the inside of the container be cooled with a certain amount of liquid nitrogen. Therefore, when the amount of liquid nitrogen decreases, the accuracy of measurement and analysis deteriorates. Thus, some instruments must be shut down to add liquid nitrogen.

Size, weight and safe use of equipment

Since the detector operating at room temperature does not require a special device, the equipment is smaller. Since the thermoelectric semiconductor is also very small, the size of the detector does not change significantly. Therefore, the size of the equipment is almost the same as that in the case where the detector operating at room temperature is mounted. Since a nitrogen-cooled detector needs to be cooled with filling the surroundings of the detection part with liquid nitrogen, the equipment is considerably larger than others. The operating temperature of 77 K requires cooling systems, such as dewar and cryocooler, and the protection from the low temperature for workplace safety. Analysis and measurement with nitrogen cooling requires additional space and engineering to protect the other components and workers from the low temperature. If nitrogen is vaporised, nitrogen gas causes asphyxiation. The manufacturers of the instruments strive to provide the safety information, such as, user manuals. Cryocooling also adds weight so may be impractical with handheld portable devices.

Additional electrical equipment and power consumption

Cooling requires additional electrical equipment and power consumption. The additional energy consumption will result in shorter time periods that battery powered equipment can be used. This can pose a safety risk to workers who rely on portable hazardous gas monitors and there is a safety risk if the battery cannot provide sufficient power for a full working day.

Condensation

Condensation on cold surfaces and ice or water droplets scatter infrared radiation so that it cannot be measured.

For the above reasons, JBCE (2020a) conclude, instrument manufacturers select infrared detectors according to the objects to be measured, the required specifications (wavelength range, accuracy, sensitivity, response speed, detector operating temperature), and the temperature of the environment in which the equipment is installed. Therefore, available detectors are limited.

PbS and PbSe detectors

LC (2020) describe the properties of PbS and PbSe infrared detectors that are essential in applications where they are used:

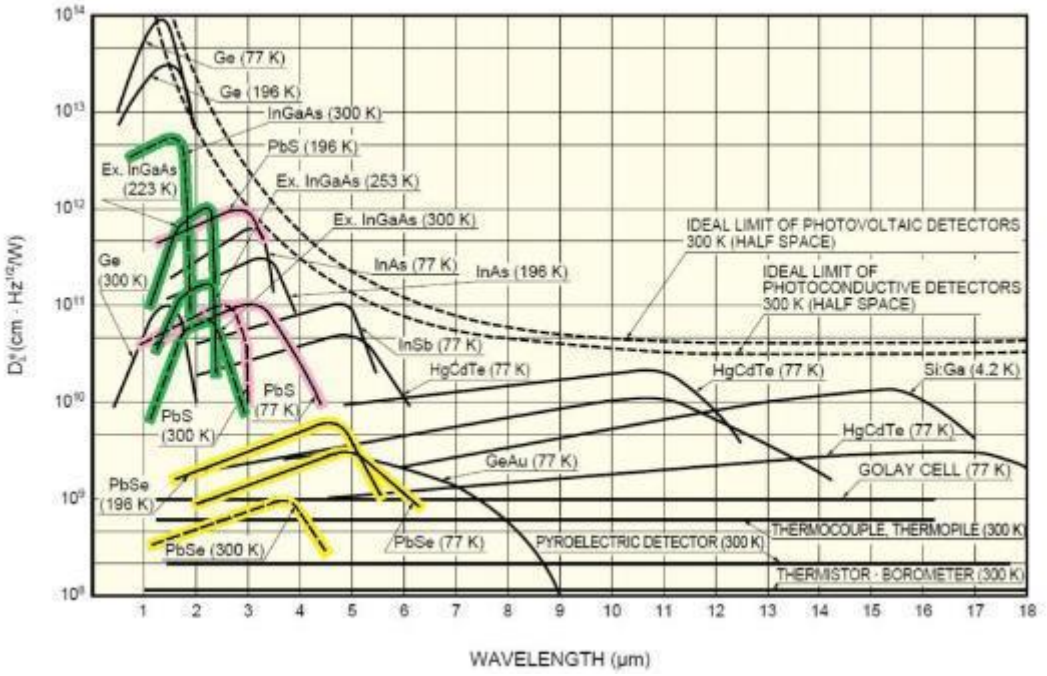
- *Sensitive in required wavelengths: PbS: From 1 to 3.0μm with a peak sensitivity at about 2.4 μm, PbSe: From 1 to 4.7 μm with a peak sensitivity at about 4.0 μm*
- *Photoconductor with a significant electrical resistance change when infrared intensity changes*
- *Functions at room temperature and does not require cooling*
- *Small size and lightweight detector circuits*
- *Fast response to changes in infrared radiation intensity*
- *High "detectivity" (this characterises performance, and is equal to the reciprocal of noise-equivalent power (NEP), normalized per square root of the sensor's area and frequency bandwidth). Higher detectivity values are equivalent to larger signal to noise ratios and superior sensitivity.*
- *High detectivity is especially important with spectrometers that analyse over a wide range of wavelength so that more than one type of detector is used. Each type of detector needs to have a similar high detectivity so that accuracy in each wavelength range is equivalent.*
- *Can be made in large size (up to 1 cm^2) required for measurements in inhomogeneous environments. For example, for remote temperature measurements and spark detectors*
- *Low power consumption in monitoring circuits when used in battery powered applications, such as portable hazardous gas monitors*
- *CO_2 sensor technology features two detectors with the following basic requirements:*
    - *Fast rise time and*
    - *High signal-to-noise ratio (S/N) and sensitive to around 4.3 μm.*

These requirements are fulfilled by using lead selenide (PbSe) photoresistors of 2 x 2 mm^2 sensitive area.

In **Figure 7-2***, JBCE (2020b) present more details about the detectivity of IR-sensitive substances and their wavelength-specific detectivity. The sensitive substances used in*

detectors for NIRS and MIRS detection below 8 μm are coloured. The figure also indicates the temperatures at which the IR-sensitive substances are operated.

Figure 7-2: Detectivity of IR-sensitive substances for different IR spectra



PbS: Pink PbSe: Yellow InGaAs: Green
Super low temperature: Solid line Room temperature: Dotted line
Source: JBCE (2020b)

JBCE (2020b) state that the detectors marked with colours of pink, yellow and green have higher detectivities and wider wavelength ranges with nitrogen cooling than that with electron cooling. PbS and PbSe cover a wide wavelength range at room temperature. Only MCT quantum type detectors in the above table can detect LIRS of 8 μm or more.

MCT detectors

PE (2020) explain that MCT consists of cadmium tellurides and mercury tellurides as a single phase non-stoichiometric semiconducting compound. Cadmium telluride (CdTe) is a semiconductor with a bandgap of approximately 1.5 electronvolts (eV) at room temperature. Mercury telluride (HgTe) is a semimetal, which means that its bandgap energy is zero. Combining these two substances into a single semiconducting material allows a tuneable bandgap between 0 and 1.5 eV which is dependent on the composition ratio of HgTe to CdTe. This results in infrared sensitivity within the 1 - 30 μm range, spanning the shortwave infrared to the very long wave infrared regions.

According to PE (2020), several properties of MCT qualify it as highly useful for IR detection:

- *Large optical coefficients that enable high quantum efficiency, i.e. how efficiently photons are converted to electrical signals, resulting in a strong signal with minimal noise;*
- *Strong optical absorption allows MCT detector structures to absorb a very high percentage of the signal while being relatively thin (around 10 – 20 μm). Minimizing the detector thickness helps to minimize the volume of material, which in turn*

minimises the generation of electrical noise and thermal excess carriers in the diffusion-limited operating mode, equating to minimal noise generation while a strong signal is produced;

- *MCT demonstrates near theoretical values of detectivity (the normalised signal-to-noise ratio) for medium wavelength IR to long wavelength IR spectral ranges, surpassing.*

Thermal detectors - PZT pyroelectric detectors

JBCE (2020a) explain that some ceramic materials provide particular properties, such as dielectric, piezoelectric, pyroelectric, ferroelectric, semiconductor, magnetic, for a wide use range including temperature. Ceramic materials which contain lead zirconate titanate have high pyroelectricity to temperature. Pyroelectric materials are electrically polarised and contain large electrical fields and thus generate a temporary voltage if they are heated or cooled. The change in temperature modifies the positions of the atoms within the crystal structure, which results in polarisation. If the pyroelectric material absorbs infrared light, the extent of the polarisation changes. The change of polarisation is utilised for infrared detection due to small changes in temperature. PZT-detectors can undertake measurement and analysis for a broad range of wavelengths. They also withstand thermal shocks which they might experience during their product lifetime, as well as operate at higher temperature ranges than other detectors and therefore does not require cooling.

7.2.4. Specific uses of infrared detectors – IR-detectors based on PbS and PbSe

LC (2020) explain that PbS and PbSe are infrared sensitive at different wavelengths as follows:

- *PbS from 1 to 3.0 µm with a peak sensitivity at about 2.4 µm (NIRS)*
- *PbSe from 1 to 4.7 µm with a peak sensitivity at about 4.0 µm (NIRS and short wave MIRS)*

LC (2020) classifies PbS and PbSe as photoconductors that change the electrical resistance when exposed to infrared radiation in the above wavelength ranges. Resistance decreases as the intensity of infrared radiation increases. PbS and PbSe are used as very thin layers inside small electronic components that are usually mounted onto printed circuit boards so that the entire detector module is very small and can be used at locations where there is very little space available. In some applications, it is used with an infrared source to analyse the composition of gases through which the infrared light passes and in other applications, infrared radiation from hot materials is detected and measured. LC (2020) mentions several examples for uses of PbS and PbSe IR detectors.

Spark Extinguishing Systems (LC (2020))

PbS and PbSe detectors are used in spark extinguishing systems where the detector is used to detect hot small particles (sparks), e.g. from cutting metal, that could cause a fire if they reach flammable materials. In some processes that emit sparks, these can, for example, be removed by ventilation in which the hot particles travel rapidly along fume extraction ducting. As soon as a spark is detected, it can be immediately extinguished e.g. with a water spray to prevent fires. The sensors must be very sensitive to low intensity infrared radiation as the particles can be very small and they must respond very quickly by

actuating the water spray to extinguish the spark before they can set alight flammable materials.

PbS and PbSe are essential for detection of all types of sparks and small hot particles in systems that are used in daylight or artificial light conditions, such as with open conveyors. Optical filters are used to remove visible light to allow the detection of very small hot particles. Spark detector systems for the detection of hot particles, which can occur, for example, during comminution processes use PbSe detectors which are sensitive to longer wavelengths than PbS, although PbS is more sensitive. PbS is sensitive to 1 – 3 µm IR whereas PbSe can detect IR of up to 4 µm.

Spark detectors must operate very rapidly as follows: The edge length of a PbS detector can typically be 6 mm. Sparks move typically at 30 m/s in air and so will be visible to a 6 mm length PbS detector for only 200 µs. If there is other material, e.g. dust, in the air flowing past the detector, the detection time can be even shorter. Therefore, the detector must detect and respond with an output signal in less than 200 µs.

NIRS chemical analysers: Food analysers (LC (2020), trinamiX (2020))

These PbS detectors are used in laboratories and in factories to analyse flour, grains, dairy products, etc. for moisture content and concentrations of protein, fat, gluten, lactose and other substances before and during processing to ensure that their composition is correct and is as labelled on product containers.

They need to be able to rapidly analyse the materials without complex sample preparation. Milk or flour powders for example are simply inserted into a compartment of the analysers) and analysed within one minute to avoid stopping the production process or producing material with an incorrect composition that has to be disposed of as waste. The materials to be analysed have characteristic IR spectra in the 0.4 to 2.5 m range. The analysers use a silicon detector for the 0.4 µm to 1.1 µm range and PbS for the 1.1 to 2.5 µm range.

The spectra of most of these materials are complex consisting of many absorption peaks at characteristic wavelengths for each type of molecular group such as carboxyl groups, hydroxyl groups, etc. For the resulting complex spectra of milk, flour and grains etc., special prediction algorithms have been developed that are used to determine the materials' constituents' concentrations with a high level of accuracy. These prediction models are based on the sensitivity range and the temperature response of the PbS sensor that is used, which, like all semiconductor detectors, is non-linear and is temperature dependent. If a different type of material is analysed, users can develop their own calibrations to provide accurate analysis.

Laboratory NIRS chemical analysers (LC (2020))

Commonly used laboratory instruments analyse substances and mixtures of substances by passing light through the material and measuring the proportion of light within the wavelength range that is absorbed. Most substances absorb light at specific wavelengths and so have characteristic spectra that can be used to identify these substances and/or measure their concentrations. Some laboratory analysers use special lamps, optics and detectors that allow analysis in the ultraviolet, visible and near infrared wavelength ranges, typically from 0.19 µm to 3.3 µm, where PbS is used for the near infrared range from 0.86 µm, 1.8 µm or 2.3 µm to 3.3 µnm, depending on which other types of detectors are also used. PbS is always needed however between 2.3 µm and 3.3 µm as no suitable alternatives exist. To achieve maximum sensitivity over the entire wavelength range, one spectrometer may use three different detectors:

- *A photomultiplier tube to detect UV and visible wavelengths from 0.19 µm to about 0.9 µm;*
- *InGaAs for part of near infrared range – up to 1.8 µm with standard types and up to 2.3 µm if the extended range (wideband) types are used; and*
- *PbS for the rest of the near infrared wavelengths up to 3.3 µm.*

Organic and inorganic substances have characteristic spectra in the near infrared range that depend on the characteristics of bonds in the molecules. Analysis in this wavelength range is used in pharmaceutical research, forensic science, failure investigations, chemical process development and in many other industries.

These analysers need to be very sensitive to detect substances at fairly low concentrations in mixtures and to analyse small quantities of substances. They are straightforward to use, very sensitive, accurate and do not require liquid nitrogen cooling (of detectors). It is also helpful to users that one instrument can analyse one small sample in the UV, visible and near infrared ranges as this allows the analysis of very small quantities that may be available, for example for forensic analysis, but insufficient is available for analysis by UV/visible and separately by infrared analysis.

Optics analysers (LC (2020))

Lead sulphide and lead selenide detectors are used in spectrometers used to measure the properties of optical components such as lenses and in particular for the spectroscopic analysis of optical coatings on lenses and lens assemblies during coating and etching processes. These materials need to be analysed in the wavelength ranges up to 3.5 µm (PbS) and 5.0 µm (PbSe) to ensure that they meet the required specification for quality and thickness. Optical components such as lenses that operate at infrared wavelengths use special coatings that must have the specified thickness and quality which can only be measured by using PbS and sometimes also PbSe detectors. Infrared optics are used in a very wide range of industries including:

- *automotive (collision avoidance systems etc.),*
- *aviation and space*
- *medical,*
- *military*

Application examples are

- *medical instrumentation*
- *volcanic ash detection*
- *mine safety*
- *flame detection*
- *food analysers*
- *environmental monitoring, ozone layer monitoring*

- *analysis and control of gaseous effluents from power stations*
- *analysis of vehicle exhaust gases*
- *detection instruments and safety systems on oil rigs*
- *security systems*
- *sensing instruments*
- *spectroscopes*
- *infrared cameras*
- *space applications*
- *blood alcohol meters (breathalysers)*

PbS detectors are critical in the production of high quality optical coatings. Most optical coatings used for any products in the near to far IR region, for wavelengths from 1.5 to 15 µm, will use PbS and PbSe detectors. The most important wavelength range that the PbS detector technology needs to operate in is the 1 µm to 2.4 µm region, because many of the materials used in the IR "film stacks" (these are multiple thin layers of coatings on the surface of glass or other materials) will be absorbing below 1.5 µm. PbS detectors are not needed for all of the components used in the above applications, but the coating spectrometers must be able to analyse a wide wavelength range including those where PbS and PbSe are especially suitable. Therefore, PbS detectors are needed in the manufacturing processes of all of the above listed applications.

Non-contact temperature measurement (LC (2020))

Infrared detectors can be used to measure temperatures of objects without physical contact by measurement of the intensity of infrared radiation emitted. As an object's temperature increases, the intensity of the emitted radiation in the range of infrared wavelengths increases. Many of the types of infrared detectors on the market can be used, unless temperature measurements must be made very quickly. Three examples are described below.

***Railway wheel temperature measurement** require very fast measurements, for example, using semiconductor sensors based on lead sulphide or selenide, depending on variables such as temperature being measured. They are built into "Hot Box Detectors" and "Hot Wheel Detectors" of trains. The sensors are built into a train's track and used to monitor the temperature of the bearing boxes, wheels and brakes of the passing rolling stock. Trains may pass over the sensors at over 200 km/h. Measurements need to be very fast so that only semiconductor types are suitable. When the temperatures of bearings, wheels or brakes indicate that these have overheated, alarms are immediately sent to the train operators and the trains can be stopped to prevent damage to the rolling stock or even derailment. Hot Box and Hot Wheels Detectors have drastically decreased the number of derailments occurring since they began to be introduced in the 1960s and as such have greatly increased the safety of train travel and transport.*

*Another example are **infrared temperature controls in microwave digestions**. Chemical analysis of inert materials, such as plastics, ceramics and alloys, can be carried out by first dissolving them in hot corrosive chemicals. The problem is preventing these chemicals from also dissolving the containment vessel in which the materials are dissolved. Ceramics, glass and quartz, for example are attacked by strong alkalines and acidic fluoride solutions. A*

widely used method is to place the materials and dissolution solution into a sealed fluoropolymer such as PTFE vessels which is heated internally by microwave heating. The microwave-heated pressure digestion vessel is sealed to prevent loss of substances as vapours, but it is essential that the temperature is controlled to prevent overheating which would increase the internal pressure to a level where the vessel would burst. Microwave heating is very rapid, so a fast non-contact temperature measurement method is needed and lead sulphide detectors are ideal. Temperature is determined by measurement of the infrared energy emitted from the inside of the vessel. Between 50 °C to 300 °C, the emitted radiation is at a maximum in NIRS detectable using lead sulphide detectors of about 3 µm. Conveniently, PTFE is transparent to infrared radiation of about 3 µm so that the temperature inside the vessel can be controlled externally by measurement of the infrared radiation passing through the vessel wall. Infrared radiation is however also emitted from the cooler external surface of the vessel which would interfere with the internal measurement, but this lower temperature radiation can be removed using a suitable optical filter.

Vessels are sealed and fitted with rupture discs that burst when a specified pressure is exceeded. A rapid temperature drop occurs when the disc bursts and when this happens or when a specified temperature is reached, the microwave's magnetron is switched off. Very rapid temperature measurement accuracy of +/- 1 °C is needed for this equipment.

PbSe infrared detectors are used to ***measure surface temperatures remotely during production processes****. Temperature control is essential to maintain quality and performance e.g. in the production of plastic thin films, metals, glass, food products, paper, textiles, etc., which may be moving so contact temperature measurement is not possible. Typically, it is necessary to measure temperatures between 100 °C and 200 °C, but higher temperatures may need to be measured in some applications. The wavelength of emitted infrared radiation from surfaces in this temperature range is about 3 – 5 µm, which coincides with the sensitive range of PbSe detectors. These instruments have an accuracy of 0.3 %. Hotter surfaces such as at 600 °C and hotter emit at shorter wavelengths and so different types of detectors are used. PbSe has an advantage over other types of detectors in this temperature range because it can measure surface temperatures that are behind flames or through infrared absorbing gases. The PbSe detector is located at the outer edge of the process and measures emitted radiation from the surface that has passed through the intervening gases and sometimes through a flame.*

The main difficulty of remote measurement of such surfaces is that the emitted radiation varies due to the emissivity of the surface. This variation can however be minimised by using the shortest wavelength detectors possible for the applicable temperature range. For 100 °C to ca. 300 °C, this is PbSe. Heat detectors such as pyroelectric and bolometer detectors detect all wavelengths (e.g. up to 14 µm) and so are as a result much less accurate.

Medical carbon dioxide analysers COCIR (2020), LC (2020))

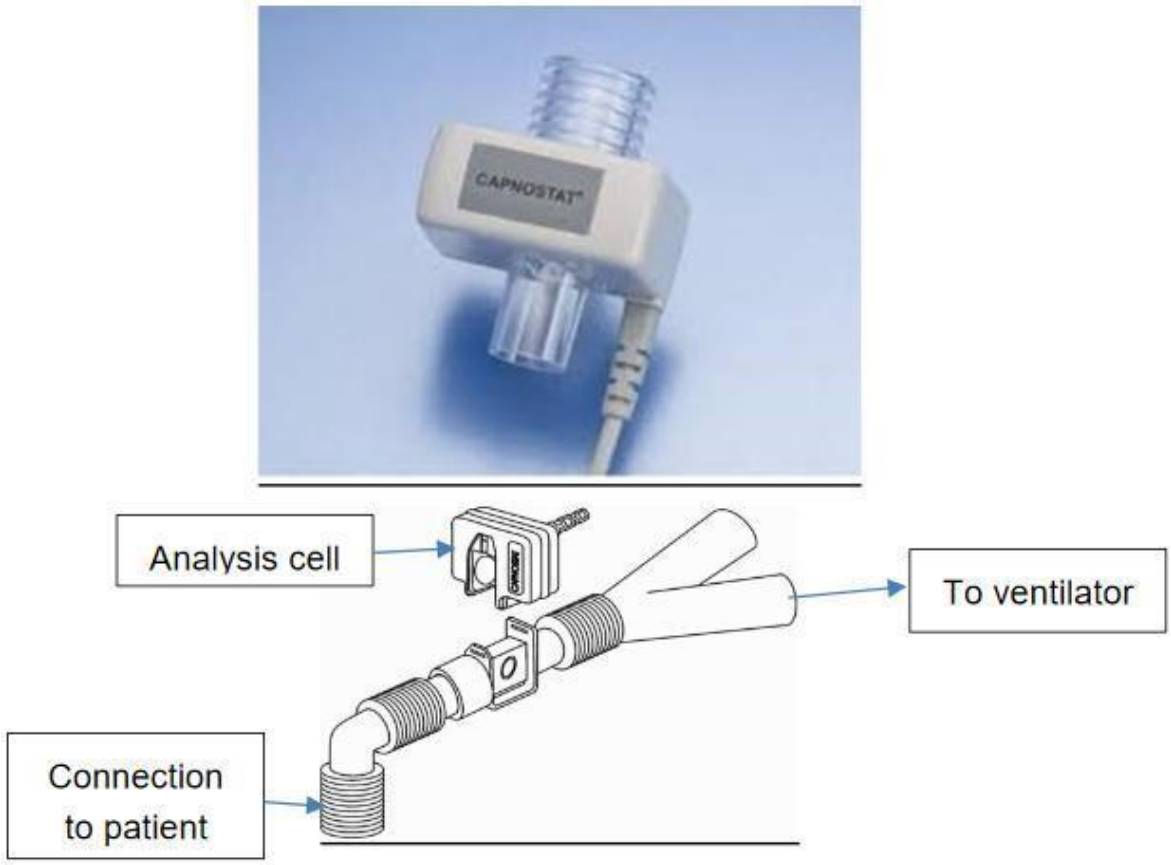
PbSe is sensitive to the wavelength range from 1 to 5.2 µm with a maximum responsivity at 4.0 µm. Carbon dioxide (CO_2) gas in air and in patient's exhaled breath has a strong infrared absorption peak at about 4.2 µm and so PbSe IR detectors are ideally suited to measure CO_2 concentrations in patients' inhaled air and exhaled breath (capnometers).

The PbSe detectors are installed in small electronic components, which are inserted into small-size electrical circuits, usually by mounting onto printed circuit boards. The two terminals of the PbSe light detector are connected to an AC power supply via a load resistor and the voltage across the resistor is measured to determine the intensity of infrared light. As these components are small and the measurement circuit is very simple needing few components, these types of infrared detector are ideally suited for small size analysis cells. The small CO_2 monitors are used to monitor patients with breathing difficulties, during operations and intubated patients to ensure that they are breathing correctly. Any sudden changes such as reduced or suddenly decreasing CO_2 concentrations in exhaled air can rapidly raise an alarm. It is important therefore that the PbSe sensor responds very rapidly to changes in CO_2 partial pressure. PbSe capnography sensors are used in intensive care units of hospitals and in emergency care, e.g. in ambulance cars or helicopters, paired with ventilators and monitors.

Infrared light is sent from a broadband (e.g. thermal) source through the sample gas to a detector, the spectrum being narrowed down by a bandpass filter. The higher the CO_2 concentration in the sampled air the less infrared light reaches the detector. A second detector and bandpass filter combination is used to correct for changes in the total light intensity present, e.g. due to dirt in the optical path or intensity fluctuations in the source by comparing the two signals.

COCIR (2020) differentiates mainstream and sidestream capnometers. In mainstream capnometers, inhaled air and exhaled breath pass directly through the measurement cell whereas in sidestream capnometers samples of air are taken to a separate analysis cell. Mainstream and sidestream versions have different advantages and disadvantages, but both use PbSe detectors.

Figure 7-3: Sidestream capnometer



Source: Philips in COCIR (2020)

The devices are rather small (6 cm x 3 cm x 2 cm), weigh approximately 40 g, feature a cable to the host system (ventilator or monitor) and are plugged onto the ventilator tubing near the patient's face. In order to be suitable for clinical use, all medical capnographs have to fulfil tight accuracy specifications in the relevant concentration range from 0 to 10 % (vol.) of CO_2. For outdoor use in emergency applications, additional requirements such as suitability within a broad temperature range from -20 °C to +50 °C plus robustness against shock and vibration (use in ambulance cars and helicopters) are essential. The performance of the mainstream capnograph is fine tuned to the host systems with respect to concentration accuracy, signal-to-noise ratio and rise time. For the clinician, it is important to see exactly how much CO_2 is present during inhalation and exhalation and how the shapes of concentration/time curves appear to deduce whether the ventilation parameters are set correctly. A short rise time results in meaningful clinical data even for patients with high breath rates or steep breathing patterns. Longer rise times tend to suppress data that otherwise can be useful to the clinician and so a fast response time is essential.

The use of mainstream capnographs is state of the art and essential for supporting clinicians using ventilators and patient monitors worldwide on patients in intensive care units and in acute care. PbSe detectors meet all requirements. If these sensors were not to be available, this would seriously deteriorate the quality of ventilation and consequently of the medical care given to patients with breathing impairments.

7.2.5. Specific uses of infrared detectors – IR-detectors based on MCT

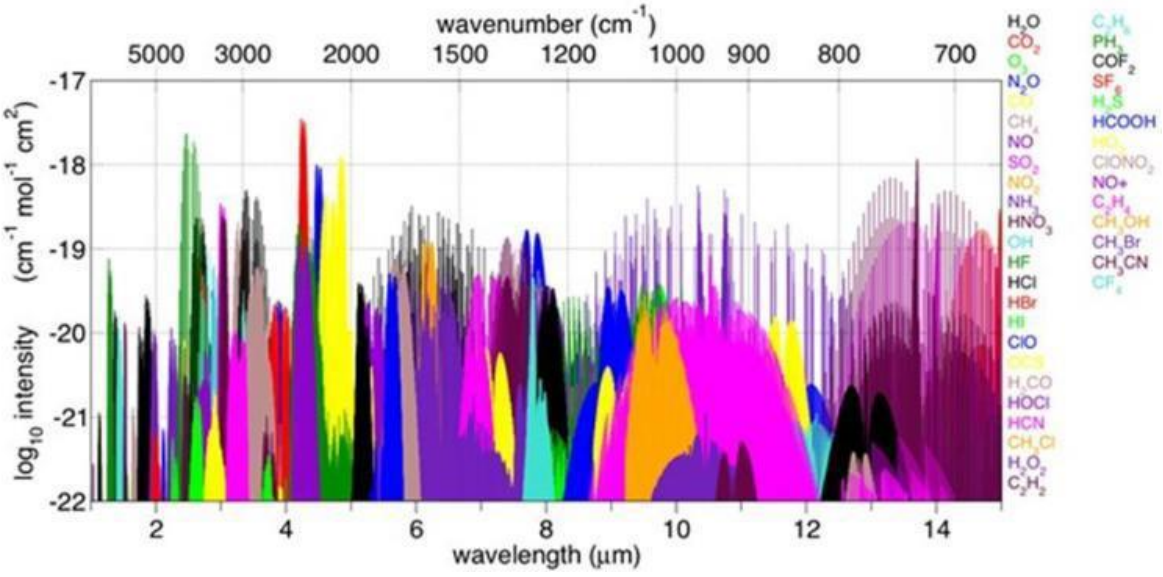
MIRS spectrometry – general information

PbS and PbSe are also used in spectrometers (c.f. previous chapter). PbS detects NIRS, while PbSe can be used to detect IR from 1 µm to maximum 5.1 µm wave lengths (c.f. Table 7-4 on page 168). Only MCT detectors can be used for longer wave lengths in the MIRS to LIRS according to JBCE (2020a).

PPTF (2020) say that IR spectroscopy is a very useful technique across the whole spectrum of infrared radiation. Nevertheless, MIRS gas sensing is especially important in the most popular industrial and medical applications. From an application point of view, the MIRS gas spectrometry has the following advantages over NIRS gas-measuring systems:

- *Many gases have significantly strong absorption features only in the MIRS.*
- *The fundamental absorptions of many gases are much stronger in the MIRS than the overtone bands in the NIRS (applies, e.g., to CO_2 and CH_4).*
- *Separation of the absorption "fingerprints" of different molecules is easier in the MIRS and LIRS.*

Figure 7-4: Infrared absorption bands of different gases in the MIRS



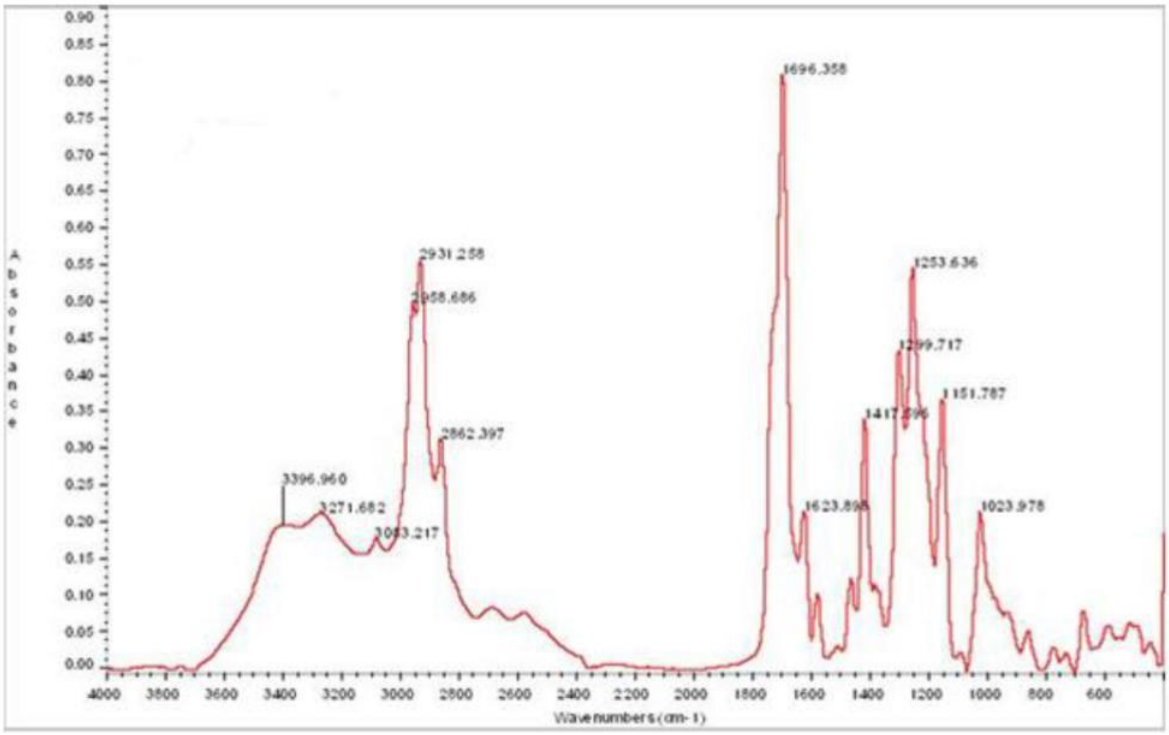
Source: PPTF (2020)

PE (2020) explain that MCT detectors in applications in scope of the RoHS Directive are widely used mainly in spectrometers and analysis equipment for manufacturing, forensics, pharmaceuticals, environmental testing, research and development. PPTF (2020) highlight the use for analyses of gases as a powerful clinical tool in medical diagnostics, due to its high specificity and sensitivity for disease detection and classification, allowing for low-cost, and rapid diagnostics. Photonic technologies permit non-invasive detection of diseases. Examination of the gas components in exhaled breath has become a valuable diagnostic tool which may reveal the status of the respiratory system. Additionally, trace breath components are markers for several diseases. Thus, breath analysis has become an important field of medical research. Laser spectroscopy is one of the promising analytical techniques to measure trace gas concentrations in exhaled breath to the "parts per billion" to "parts per thousands" range.

FTIR spectrometers using MCT detectors

PE (2020) explain that Fourier transformation infrared (FTIR) spectrometers work by passing modulated IR radiation through a sample. The MCT detector detects the passing IR radiation. Data can be acquired at rates up to 100 scans per second in commercial instruments. FTIR adds the absorption peaks of substances from multiple spectra and noise is cancelled out to increase sensitivity. The lower the substance concentration the larger the number of spectra required to reveal the spectrum of the substance from the background noise. The interferograms, which are plots of IR intensity versus time, are signal-averaged at intervals of less than 1 s and stored on the hard disk of the spectrometer's computer system. The data system then executes a Fourier transform of the interferograms, which are compared against a background spectrum interferogram to produce an IR spectrum of absorbance (or percentage transmittance) versus wave number or wavelength. Figure 7-5 demonstrates an example IR spectrum.

Figure 7-5: Example IR spectrum produced by an FTIR spectrometer



Source: PE (2020)

PE (2020) and PPTF (2020) mention a variety of example applications of FTIR spectrometers:

- *Identification and characterisation of unknown materials, used in forensic applications including drug identification and identification of counterfeit medications, as well as in research;*
- *Gain deeper understanding of product formulations, used in applications in the pharmaceutical industry as well as many others;*

- *Quality verification of incoming/outgoing materials allowing for greater control over processes such as feedstock manufacture or food production as well as facilitation of troubleshooting in manufacturing;*
- *Identification of contamination in or on a material, including oxidation, decomposition or uncured monomers in product safety studies. Example uses are for failure investigations or contamination in water or soil;*
- *Identification of additives after extraction from a polymer matrix;*
- *Analysis of thin films and coatings*
- *Monitoring of automotive or smoke stack emissions;*
- *Kinetics studies and for analysis of materials with low concentrations;*
- *Gaining deeper insights into the properties of novel and advanced materials;*
- *(Real-time) measurement of various (trace) substances, gases and fluids.*

7.2.6. Specific uses of infrared detectors – IR-detectors based on PZT

JBCE (2020a) explain IR gas/liquid analysers as an example for uses of thermal type IR detectors based on PZT. Gases absorb infrared radiation. If the value of infrared radiation before and after absorption are measured, concentration of gas/liquid can be determined. PZT-based pyroelectric detectors, one of the thermal type sensors are utilized for infrared gas/liquid analysers measuring concentration of gases/liquids with the absorption of infrared radiation, as the detectivity of thermal type sensors are stable and does not change very much because of wavelengths. The gas/liquid concentration is calculated by comparison with the result of several wavelengths; therefore, quantum type (semiconductor type, photodiode and others), which has variable detectivity dependent on wavelengths, is not suitable for infrared gas/liquids analysers for analysing and measuring concentration of gases/liquids by the absorption of infrared radiation.

7.3. Justification for the requested exemption

7.3.1. Substitution and elimination of lead in PbS and PbSe IR-detectors

JBCE (2020a) argue that alternatives to PbS photoconductive devices that satisfy the bandwidth and sensitivity at the same temperature conditions have not been found so far and refer to Table 7-4 on page 168 and Figure 7-2 on page 171. Indium arsenide (InAs) photovoltaic devices and indium gallium arsenide (InGaAs) PIN photodiodes have been proposed as candidates. InAs has the same wavelength range, with high infrared detection sensitivity only at low temperatures. It also has a high response speed. On the other hand, since the signal to noise ratio (S/N ratio), which is a measure of the useful signal produced, decreases at room temperature, this device cannot measure light accurately and cannot obtain the same sensitivity as PbS.

Although, JBCE (2020a) say cooling improves the sensitivity, large-scale equipment using liquid nitrogen is required to obtain the same sensitivity as the thermoelectrically cooled PbS. The additional equipment cannot be accommodated in all applications due to limitations on space, such as automatic facilities for continuous liquid nitrogen supply. Although cooling by liquid nitrogen is expected to improve the performance, there is also a concern about adverse effects on the optical system such as dew condensation, which would block infrared light due to the incorporation of a cooling device.

According to JBCE (2020a), InGaAs offers higher sensitivity and S/N ratio. However, it cannot provide the desired measurable wavelength range as PbS or PbSe due to limitations in the substances' inherent properties. In addition, there is InAsSb as an alternative to PbSe, which is sensitive to long wavelengths, but cannot provide the same signal-to-noise ratio as PbSe.

LC (2020) mention examples of trials with DWRS detectors as alternatives to PbS and PbSe detectors. Alternative types have been considered for ***spark detectors****, but all were found to be unsuitable. Cooling of semiconductor spark detectors is impractical as condensation will prevent them working, so most types of semiconductor detectors cannot be used. Also, they must operate very rapidly and therefore heat detectors (pyroelectric, bolometer and thermopile) cannot be used as they are too slow. InGaAs can be used without cooling and is a fast detector but has disadvantages compared with PbS and PbSe.*

- *InGaAs does not operate in the sensitive range of PbSe so it cannot be used when infrared light detection of >2.6 µm is needed.*
- *PbS is about 2.3 times more sensitive to infrared radiation than InGaAs and is sensitive over a wider wavelength range (than the more sensitive standard InGaAs with 1.7 µm cut-off).*
- *PbS detectors are available with larger surface areas than InGaAs which enables them to detect sparks at a larger range of angles to those sparks*

LC (2020) also put forward that ***Near infrared chemical analyser*** *manufacturers are carrying out research into alternative detector materials, but substitution with different semiconductor detectors is at present technically impractical.*

LC (2020) state that each type of infrared sensor has different characteristics and is used for different applications and uses. They present the **Table 7-5** *below comparing different types of sensors covering similar IR spectra like PbS- and PbSe-type IR detectors.*

Table 7-5: Comparison of PbS and PbSe type with other infrared sensors with sensitivity in the NIRS and MIRS

Detector	Type	Wavelength range (µm)	Peak wavelength (µm)	Typical detectivity (cm Hz½/W)	Response time	Operating temperature
PbS	Photoconductor	1 to 3.3	2.4	3.5 x 10^{10} (90Hz) 1.1 x 10^{11} (650 Hz)	Fast, 200µS	Ambient
PbSe	Photoconductor	1 to 4.7	4.0	6.0 x 10^{9} (90Hz) 1.8 x 10^{10} (1 kHz)	Very fast, time constant typically 4µS	Ambient
InGaAs	Photodiode (can be used as a photoconductor)	0.5 to ~2.55µm (several types exist with different ranges[3])	Standard range 1.55 / Extended range 2.25	From 4.8 x 10^{10} to ~10^{11} (1kHz for extended range type)	Fast	Can be used at ambient
InSbAs	Photodiode	1 to 11µm (but may be supplied with cut-off filters)	Depends on temperature	5.0 x 10^{9} (1.2 kHz)	Fast	Requires cooling
InSb	Can be used in both photovoltaic and photoconductive modes	Photovoltaic 1 to 5.5µm. / Photoconductor 1 to 6.7 µm	5.3 / 5.5	Photovoltaic = 1 x 10^{10} / Photoconductor at -10°C, 1 x 10^{9} (1.2kHz)[4]	Fast response	Cryogenic cooling needed
PtSi	Schottky barrier detector	Ultraviolet to far infrared. Detects in a wider range than PbS & PbSe	Not applicable	Ca. 1 x 10^{9} (at 80K[5])	Fairly fast, used for imaging	Needs cooling (to ≤0°C)
Pyroelectric	Pyroelectric	Responds to heat in all of heat spectrum	No peak	4 x 10^{8} (10 Hz)[6]	Slow response[7]	Ambient
DLATGS	Pyroelectric	Responds to heat in all of heat spectrum	No peak	2.7 x 10^{8} (1.3mm element size[8])	Slow response	Ambient
Thermopile	Generates a voltage from temperature change	Responds to heat in all of heat spectrum	No peak	10^{8} (1Hz), 10^{6} (at 1kHz[9])	Slow response	Ambient
Bolometer	Change electrical resistance with temperature	Responds to heat in all of heat spectrum	No peak	1 to 3 x 10^{8}	Fairly slow (typically 50mS[10])	Ambient

[3] Standard types have a range of up to 1.7µm, whereas extended range types are sensitive up to 2.55µm. However, the dark current values of extended range types is much larger (typically 20 times larger) so that they have an inferior detectivity.

[4] https://www.hamamatsu.com/resources/pdf/ssd/p6606_series_kird1026e.pdf

[5] http://photonics.intec.ugent.be/education/IVPV/res_handbook/v1ch23.pdf

[6] https://www.infratec.co.uk/downloads/en/sensor-division/detector_data_sheet/infratec-datasheet-lie-202-_.pdf

[7] For example, a thermal time constant of 150mS and an electrical time constant of 2 seconds, https://www.infratec.co.uk/downloads/en/sensor-division/detector_data_sheet/infratec-datasheet-lie-202-_.pdf

[8] https://fscimage.fishersci.com/images/D10942~.pdf

[9] https://www.ama-science.org/proceedings/getFile/ZGL0BN==

[10] http://www.xenics.com/en/faq/what-thermal-time-constant

Source: LC (2020)

FFE (2020) state that some manufacturers use pyro-electric infra-red sensors. Detectors of this type work by detecting the 4.3 µm light emitted from hot CO_2. This limits detection to carbon-based fires. Additionally, 4.3 µm light is blocked by window glass. This type of detector is not suitable for applications with a non-carbon fire risk or where the monitoring is performed from outside the area of risk, through a window (spray booths, engine test cells, etc.).

7.3.2. Substitution and elimination of lead in MCT IR-detectors

JBCE (2020a) report that there are no other materials with a similar performance like MCT. MCT cannot be replaced in uses that require high sensitivity and wide wavelength range. MCT is currently the only semiconductor detector which is sensitive to wavelengths between 6 µm and 20 µm. This region is particularly important for substance identification where the "fingerprint" region (8-15 µm) of samples is compared to a library of infrared spectra. According to JBCE (2021a), some producers offer MCT-based IR-detectors for the VLIRS with sensitivity up to 30 µm.

According to JBCE (2020a), to realize practical high sensitivity and high-speed time response in the mid-infrared band, other group II-VI compound semiconductors with a band gap corresponding to direct transition in the mid-infrared band have been proposed. As group II elements, Zn, Cd, Hg and Cn are known. Cn (copernicium) is a synthetic element and is not a realistic choice. Zn compounds such as ZnS and ZnSe are not applied as useful detectors as they are infrared transmitting materials. These materials are transparent to infrared radiation and are used to make windows and lenses that freely allow infrared to pass so they cannot be used as detectors.

JBCE (2020a) list type-II superlattice infrared detectors as detectors with sensitivity for IR up to 14 µm. These detectors have several disadvantages compared to MCT detectors. They need to be cooled with nitrogen which limits their uses. The sensitivity of the superlattice infrared detectors in the wavelength range up to 14 µm is about less than half that of MCT detectors in the same band. Finally, the optical design depends on the size of

the object size to be measured so that detector shall be optimized according to the size of the measurement target.

JBCE (2020a) mention InAsSb photovoltaic detectors as another potential alternative to MCT detectors, but their wavelength band is about 11 µm. InAsSb detectors have a high-speed response, but low sensitivity and noise in the lower limit of detectivity even with thermoelectric cooling. InAsSb would therefore require liquid nitrogen cooling. In some spectral measurements of the mid-infrared laser, weak signals like the spontaneous emission need to be measured clearly. InAsSb detectors need to be cooled down to 77 K (-196 degree C) by the dewar with the liquid nitrogen or by cryocooler in order to realize the essential detectivity. JBCE (2020a) say that nitrogen cooling is impossible for some applications due to the size of detector module including a dewar, and the structure is significantly different to conventional detectors so could not be used as replacements.

According to data provided by JBCE (2020b), thermal type detectors based on PZT, TGS and $LiTaO_3$ can detect IR in the same wavelength range like MCT, from 1 µm to 20 µm. PE (2020) explain that thermal detectors measure the power of incident electromagnetic radiation via the heating of a material with a temperature-dependent electrical resistance. There are also pyroelectric detectors which detect photons through the heat generated and the subsequent voltage generated in pyroelectric materials. A limitation of this technology is that infrared photons also cause a temperature rise, which in turn causes an electrical effect, masking desirable measurements and lowering the sensitivity. A thermal detector that is able to access the long wavelengths is typically 100 times less sensitive than MCT. To get equivalent performance to MCT a thermal detector would require 10,000 times the measurement time. Therefore, a one-minute measurement with MCT would take one week using thermal detectors. Consequentially any studies that are time critical, such as kinetic studies would not be remotely possible. Any other measurement would also be impractical due to the extreme time penalty experienced using this technology for long wavelength measurements. The stability of samples over such a long period will often be another limitation for heat detectors. PE (2020) provided the below table with more data about MCT and potential MCT substitutes.

Table 7-6: Potential alternative detector materials and properties

Type	Detector	Wavelength range and peak (µm)	Typical detectivity (cm Hz½/W)[18]	Responsivity	Suitability
Intrinsic II-VI	MCT	2 to 20 (various versions available)	10^{10} to 10^{11}	Time constant <1µsec	
Intrinsic IV-VI	PbSe	1 to 4.7 (4.0 peak)	10^{9} to 10^{10}	Time constant 4µsec	Due to the inclusion of lead would also be impacted by RoHS and therefore is not a suitable alternative. The wavelength range is smaller than MCT Poorer data quality due to a high thermal expansion coefficient.
	PbS	1 to 3.3 (2.4 peak)	10^{10} to 10^{11}		
Intrinsic III-V	InSb	Photovoltaic types 1 to 5.5 (5.3 peak) Photoconductor types 1 to 6.7 (5.5 peak)	10^{9} to 10^{10}		The wavelength range is smaller than MCT
	InAs	1 to 3.5 (peak 2.8)	10^{9}		
	InGaAs (2.6 micron cut-off)	0.5 to 2.6	Ca. 10^{11} [19]	Relatively fast	
	InGaAs (1.7 micron cut-off)	0.5 to 1.7	Ca. 10^{13} [16]		
	InSbAs	1 to up to 11	7 x 10^{7} [20]		Detectivity of 11µm cut-off detector is too low
Quantum wells	Type I	6 to 10 (peak around 8.9 dependent on type)	10^{10} to 10^{11} [21]		Poorer data quality due to high thermal generation
	(GaAs/AlGaAs, InGaAs/AlGaAs)				Due to complicated design and difficulty of manufacture, these are not commercially available The wavelength range is smaller than MCT
	Type II (InAs/InGaSb, InAs/InAsSb)	2 to 30 by changing the layer thicknesses	10^{8}		Due to complicated design and difficulty of manufacture, these are not commercially available Lower detectivity than MCT
Quantum dots	InAs/GaAs, InGaAs/InGaP, Ge/Si				Due to complicated design and growth it is not commercially available
Thermal	Pyroelectric	Responds to heat in all of heat spectrum	10^{8}	Much slower than MCT	Same wavelength as MCT range but much lower sensitivity/detectivity. Would require repetition of tests to a completely impractical level to reduce noise so that test time would rise exponentially as a consequence.
	Bolometer	Responds to heat in all of heat spectrum	10^{8}	Much slower than MCT, typically 50msec	

Source: PE (2020)

PE (2020) claim that recent (2019) developments such as Hamamatsu's InAs/GaSb alternative[49] to MCT offers wavelengths of up to 14.3 µm, which is lower than that of MCT (20 µm) and so is not a direct substitute for MCT. Additionally, the currently stated maximum detectivity of the Hamamatsu alternative is 1.6 x10^{10}, in comparison with the 16.6 µm detector of Perkin Elmer which is 4.5 x10^{10} and the commercially available alternative from Teledyne Judson detectors[50] of around 6 x10^{10}. As previously discussed due to the square law relationship between the detectivity and measurement time the implications of the differences in detectivity will result in measurement times which are orders of magnitude longer. Another issue is that the shape of the detectivity / wavelength curve of the Hamamatsu detector is very different to the shape of MCT detectors so that at higher wavelengths, the detectivity values of the Hamamatsu detector are much lower than those of MCT. Furthermore, the photosensitive area offered by the Hamamatsu alternative is 0.1 mm^2 in comparison with 0.15 mm x 0.15 mm offered by Perkin Elmer, resulting in a 50 % reduction in sensitivity.

[49] C.f. Hamamatsu, https://www.hamamatsu.com/resources/pdf/news/2019_08_27_en.pdf

[50] C.f. Teledyne Judson, http://www.teledynejudson.com/prods/Product %20Documents/mercadpc_08_254A.pdf

PE (2020) highlight that Hamamatsu currently only offer a slow increase of production that is expected to reach 1,000 units per year only after three years (i.e. by 2022). In addition to this, the technology currently offered by Hamamatsu would only be able to replace the single point detector and not the array detectors used in FTIR spectrometers and microscopes and also 2D imaging with the technology would not be possible.

For the above-mentioned reasons, the stakeholders request the renewal of exemption 1(c) for the use of cadmium and mercury with the wordings displayed in Table 7-1 on page 161.

7.3.3. Substitution and elimination of lead in PZT IR-detectors

JBCE (2020a) *mention thermopile detectors, lithium tantalite (LiTaO), strontium barium niobates (SBN) and TGS (glycine trisulfide) as potential alternative to PZT pyroelectric detectors.*

According to JBCE (2020a), thermopile detectors have equivalent sensitivity to PZT pyroelectric detectors. According to Hamamatsu (2021a), "Thermopile detectors are thermal detectors that utilize the Seebeck effect in which a thermal electromotive force is generated in proportion to the incident infrared light energy. Thermopile detectors themselves have no wavelength dependence. Sensitivity spectra are selected by attaching various window materials, and used for applications such as radiation thermometers, gas analysis, and flame detection." JBCE (2020a) claim that the disturbance noises such as temperature changes in surroundings, result in smaller signal to noise (S/N) ratio and lower accuracy of measurement results with thermopile detectors. The accuracy achieved using thermopiles is not enough for applications such as infrared gas analysers.

About lithium tantalite, JBCE (2020a) say that it is a highly stable single crystal material, however it has a sensitivity of only half of that of PZT and a reduced S/N ratio and therefore cannot replace PZT sensors. The improvement of sensitivity is currently being studied. SBN (strontium barium niobate) has 1.2 times the sensitivity of PZT, but stable measurement is not possible because the pyroelectric coefficient is reduced by thermal cycling, resulting in the decrease of detectivity of gas/liquid analysis. TGS (glycine trisulfide) has a high sensitivity but is deliquescent (so change in quality in air) and has a low Curie temperature of 69 °C in comparison with 287 °C of PZT. It is not suitable for infrared gas/liquid analysers because once the Curie temperature is exceeded, the detector will stop working. Exposure to infrared is likely to heat the detector and could exceed 69 °C. Other ferroelectric materials have been studied over the world. However, the stability and sensitivity of PZT has not been replaced by those other materials as they do not offer the same performance or properties.

JBCE (2020a) conclude that PZT has a high level of sensitivity for the wide wavelength range from NIRS to MIRS. It can be utilized for analysis of a wide variety of gases/liquids. No other sensors than PZT cannot be used for such a wide variety of gases/liquids.

7.3.4. Roadmap towards substitution or elimination XY

COCIR (2020) believe that a new type of sensor is needed that meets all of the essential criteria required for uses in medical capnometers. Semiconductor development is now relatively mature so that it seems unlikely that a new one will be discovered that could replace PbSe. If a detector were to be discovered, it would need to be thoroughly tested for performance under all conditions of use, tested for reliability, clinical trials carried out to monitor and assess its effect on a cross-section of patients' medical conditions before gaining approvals world-wide. This is likely to take eight to ten years.

JBCE (2020a) announce that the development of substitute detectors is on the way, but at present there are no substitutes with satisfactory characteristics. After the detector characteristics have been improved, the equipment manufacturer will conduct functional evaluations. Then the equipment manufacturer conducts a detailed performance and durability evaluation. At the same time, the system for procurement, manufacturing and service will be improved. So, it is estimated that it will take 4-7 years to develop the equipment after the properties of the substitute detector are improved. However, the equipment manufacturers sometimes change electronic circuits and mechanical designs in order to adopt substitute detectors, and it is not appropriate to describe the equipment manufacturer's schedule in general. In addition, a longer schedule is required if new cooling method is essential.

LC (2020) point out that research into infrared detectors has been carried out for many decades with many types being developed. Research will continue by looking for new materials and also into the possibility of alternative designs, but it is not envisaged that substitutes will be developed before the requested expiry dates and most likely this will take considerably longer. As fast response and high detectivity are both essential, only semiconductor detectors are suitable. There are a limited number of elements in the periodic table and only some combinations of these elements are semiconductors that are sensitive in the infrared range. Most, if not all combinations of elements have been considered, but this has shown that none can replace lead in PbS or PbSe where these are currently used and so the timeframe for substitution is likely to be very long and replacement may never be possible.

PPTF (2020) highlight that for many years, intensive efforts have been underway for several decades to replace HgCdTe. Theoretical analyses, literature studies and results obtained so far indicate the possibility of replacement of HgCdTe with the substitutes. Until now, the growth of complex heterostructures for the short, middle and long-wavelength detectors on GaAs substrates has been mastered. This allows the production of detectors monolithically integrated with immersion micro lenses, increasing sensitivity of the device by an order of magnitude. The most important results have been the development of uncooled and Peltier cooled devices.

Establishing substitutes to 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 centres 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 abovementioned 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. The applicant estimates that it would take another five to seven years to introduce new types of III-V detectors with detectivity and reliability levels of MCT.

PE (2020) point out that manufacturers have stopped using MCT in infrared spectrometers with lower performance requirements. For general-purpose analysis, pyroelectric detectors can be used. To substitute MCT, a new type of sensor is required that meets all of the essential criteria like MCT does. It is not possible to predict when one might be discovered as all known commercially available semiconductor detectors and other types of detectors have been evaluated and none of these meet all of the essential criteria. Semiconductor development is now relatively mature so that it seems unlikely that a new one will be discovered that could replace MCT in the near future. If a detector was to be discovered, although this seems unlikely based on current knowledge, then this would need to be thoroughly tested for performance under all conditions of use with consideration given to aspects such as reliability, stability and reproducibility of results. The alternative product would have to be commercially available, with the manufacture of the detectors in sufficient numbers to meet the demand for the alternative. The only promising recent development is the new single point detector from Hamamatsu. However, this is not yet available in sufficient numbers and has technical limitations – lower detectivity, smaller wavelength range and cannot yet be made as an array detector. The timescale needed for substitution of MCT detectors, once such a suitable detector becomes available, is likely to take three to five years.

7.3.5. Environmental arguments and socioeconomic impacts

COCIR (2020) are afraid that patients in EU hospitals and clinics would be seriously harmed if this exemption were not renewed. If breathing cannot be accurately monitored using capnometers, deaths and serious harm could occur. It is not known how many patients in the EU would be affected annually, but the number is likely to be of the order of thousands of people.

If the exemption is not renewed, JBCE (2020a) foresee that production costs of many types of manufacturing process would be adversely affected as quality control of substances would either not be available or would have to use a less sensitive detector. Consequentially other, less suitable control measures as part of the manufacture would have to be used.

- *Increase in fixed costs*
- *Increase in overhead*
- *Possible social impacts within the EU*
- *Possible social impacts external to the EU*

According to JBCE (2020a), there would be many other negative impacts if this exemption were not to be renewed. EU industry would become less competitive if infrared detectors were available outside of the EU but not in the EU. A large number of academic research is dependent upon the use of infrared detectors as an analysis tool for novel material developments as well as industries like pharmaceuticals. Without the exemption, there would be job losses as these roles and funding for research are transferred outside the EU.

LC (2020) as well forecast negative socioeconomic impacts if the exemption is not renewed. Many different industry sectors would be affected, e.g.:

- *Spark detectors: Fires in factories can cause damage to the infrastructure, deaths and injuries as well as emitting harmful fumes. Any measures to reduce the risk of fires is therefore beneficial.*
- *Near infrared analysis: Factories, research laboratories, universities and colleges use near infrared analysers. If these were no longer available in the EU, the socio-economic impact would be that EU researchers would be at a very significant disadvantage compared to their non-EU counterparts. EU statistics indicate that research and development account for over 2 % of gross domestic product in the EU and employs 1.2 % of the EU workers in 2016, equivalent to 2.7 million jobs. Many factories rely on near infrared analysers to maintain quality. Without these, quality would negatively affected. Large quantities of food products may need to be disposed of if they subsequently are discovered to not meet quality standards. This would be unacceptable as the costs would make EU manufacturers uncompetitive compared with non-EU manufacturers and as a result, there could be significant job losses.*
- *Optical components: There are many optical component manufacturers located in the EU, many of which are SMEs. Those that coat optical components would not be able to operate in the EU if this exemption were not renewed because they could not buy new analysers. About 5,000 companies operate in the photonics sector in the EU employing 300,000 people.*

PPTF (2020) put forward that there is no direct exposure of cadmium or mercury on users of control and monitoring equipment using infrared detectors. Both cadmium and mercury are bound by covalent bonds within the semiconductor material. Mercury cadmium telluride material is then itself hermetically sealed during packaging. It is highly unlikely that detector is handled, mechanically treated or otherwise modified by any user in such a way that cadmium or mercury could be released.

Also, exposure to cadmium or mercury from infrared detectors released to the environment as a consequence of end-of-life or recycling operations is highly unlikely due to very small amount of these substances introduced to the market annually in infrared detectors (less than 1 g annually).

PPTF (2020) further highlight that infrared spectroscopy is still a novel technique in medical diagnostics, although there is a variety of new R&D projects aimed at introduction of fast, accurate sensors allowing real-time measurement and monitoring of various biomarkers and diagnostics of many diseases. The European population ages increasingly: the number of people older than 65, relative to those in the working age, is assumed to increase by a factor of two by 2045. Since age is one major factor for an increased probability of becoming ill, a significant increase of corresponding illnesses like type 2 diabetes, many cancer subtypes like breast cancer in females and prostate cancer in males as well as lung cancer for both sexes, dementia and macular degeneration are concomitant effects. The future implementation of IR spectroscopic techniques extends to, and may redefine, numerous stages of clinical management from screening all the way through to treatment monitoring. There is a growing need for faster, more accurate, non-invasive diagnostics tools that will help diagnose various diseases at earlier phases or improve patient condition after medical

interventions at hospitals. Development of new medical applications will lessen the burden on the European healthcare system, which already consumes more than 10 % of the EU GDP, and with ageing population it will require substantially more spending. Elimination of MCT detectors will undoubtedly slow development of new diagnostics tools, as any substitute substance IR detectors are at least 3 times less sensitive than MCT.

PPTF (2020) forecast negative impacts on European Union economic growth without exemption 1(c). The European industry is already among the global leaders in the healthcare market, which is growing with double-digits. The total market volume of the segment in 2015 was € 33.8 billion. Photonics for Healthcare is assumed to reach around €50 billion worldwide by 2021. Accordingly, it is not only one of the largest markets among photonics, but also one of the more rapidly expanding sectors. With its rich innovation landscape formed by traditional companies, start-ups, universities and research institutions, Europe has a unique opportunity to secure a prominent role and lead the corresponding markets if the challenges are met accordingly in the next few years.

EU has currently leading position in the market of MCT detectors production for commercial (medical, monitoring and control instruments), with more than 50 % of the market share, which is also growing very fast (>10 % growth in recent years). Moreover, MCT detectors are critical components for many EU companies producing measurement and control equipment for many applications (industrial, medical, scientific, etc.). There is no accurate data on the global market for MCT detectors in commercial applications. It is estimated that its value is around 30-50 million EUR. However, the value of the market of measurement and control instruments using MCT detectors is at least 10x larger. Withdrawal of MCT detectors would undermine the position of EU companies in the global market, especially in comparison to companies from other regions, where using MCT detectors is not prohibited.

7.4. Critical review

7.4.1. REACH compliance – Relation to the REACH Regulation

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

Cadmium, lead and mercury are used in Infrared detectors in scope of exemption IV-1(c).

Cadmium

Cadmium is used in mercury cadmium telluride.

With regards to **Annex XIV of the REACH Regulation**, cadmium in general or in compounds is not mentioned in the list of substances that require an **authorisation** for use.

With regards to **Annex XVII of the REACH Regulation**, cadmium is mentioned in a few of the listed restrictions.

Paragraph 1 of entry 23[51] of Annex XVII refers to cadmium and several of its compounds. 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[52] 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.*

MCT is not an organic substance, cadmium is neither used as plating nor as brazing filler, and its use under the exemption is not related to jewellery. The above stipulations are therefore not applicable.

Due to their carcinogenicity, *entry 28[53] 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.*

Neither MCT nor any other compound is mentioned so that the restrictions related to entry 28 do not apply to MCT.

Entry 72[54] lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It refers among others to cadmium and its compounds as listed under entry 28, 29 and 30 (germ cell mutagenic substances) and restricts their use in clothing and textiles. The entries list several cadmium compounds, among others cadmium sulphide and cadmium nitrate.

Like or entry 28, this entry does not address MCT as it is applied in exemption 1(c).

To conclude, none of the entries currently listed under REACH would not apply to the case at hand. The Use of Cd in MCT IR detectors 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.

[51] C.f. ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e2518

[52] 'Cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface

[53] 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

[54] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

Mercury

Mercury is a constituent of mercury cadmium telluride IR detectors.

Annex XVII of the REACH Regulation contains several entries restricting the use of mercury and of mercury compounds. Entry 18 restricts[55] *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.*

MCT is not used for any of the above applications, and the restrictions are therefore not applicable.

Entry 18a[56] *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*[57]*, strain gauges to be used with plethysmographs*[58]*, tensiometers, thermometers and other non-electrical thermometric applications, mercury pycnometers and mercury metering devices for determination of the softening point.*

It cannot be excluded that MCT IR detectors may be contained in devices sold to the general public. MCT, however, does not contain metallic mercury, but is a solid compound containing the mercury. In the restricted professional use devices, thermometers are mentioned which in principle might be operated with IR detectors. These are, however, related to non-electric thermometers and refer to metallic mercury so that these restrictions do not apply to the uses of MCT at hand.

Entry 62[59] *lists several phenylmercury compounds*, which are, however, not related to MCT uses in IR detectors.

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 (October 2021) 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.

---

[55] ECHA, https://echa.europa.eu/documents/10162/5a7222b0-9d3a-4a90-9e55-258149e92b1a

[56] ECHA, https://echa.europa.eu/documents/10162/dbcaaec7-bd5b-4a7d-b164-23fa97950a86

[57] Device used to measure blood pressure.

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

[59] 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

Mercury: Relation to the Minamata Convention

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"*.

Exemption 1(c) was listed on RoHS Annex IV when it was published in 2011, and MCT IR detectors and the related monitoring and control instruments have been manufactured already before. The coherence with the Mercury Regulation is therefore established.

Lead

Lead is contained in IR detectors as lead sulphide and lead selenide as well as in lead zirconate titanate (PZT).

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by*" the REACH Regulation if the requested exemption would be granted/renewed.

REACH Annex XIV (2021)[60] lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- *Lead chromate (entry 10);*
- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

The applications in the scope of the exemption at hand do not use any of the above lead compounds.

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16[61] and entry 17[62] restrict the use of lead carbonates and lead sulphates in paints;*

[60] ECHA, https://echa.europa.eu/authorisation-list?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

[61] 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

[62] 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

- *Entry 19 refers to arsenic compounds but includes a few lead compounds[63] such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*

The above applications are not applicable to the use of lead in MCT, PbS or PbSe.

- *Entry 28[64] addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30[65] addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they 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 above restrictions are not applicable to the use of lead in MCT, PbS or PbSe. Further on, the substances are part of an article and thus are not placed on the market or used as substances, constituents of other substances or mixtures supplied to the general public.*
- *Entry 63[66] restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72[67] stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

PbS and PbSe are constituents of IR detectors. In the scope of the exemption at hand, PbS and PbSe are, however, not used in wristwatches or any other jewellery in the scope of entry 63, nor are conditions foreseeable where the IR detectors or the related equipment may be placed in the mouth by children. It cannot be excluded that IR detectors might be used in textiles, clothing or shoes in the scope of entry 72, e.g. in the context of medical monitoring of patients. In this case, the related applications would, however, be considered as EEE and as such are not in the scope of entry 72.

[63] 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

[64] 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

[65] 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

[66] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[67] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

No other entries, relevant for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status (October 2021) 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 the respective criteria of Art. 5(1)(a) apply.

7.4.2. Cooling and space requirements

If detectors are operated below ambient temperatures, they are cooled either thermoelectrically or with nitrogen or other liquids. Cooling with liquids requires the detector to be enclosed into a dewar, which considerably increases the required space for the detector in IR analytical tools so that it is evident that this kind of cooling limits the use of such detectors, in particularly if they are considered as a substitute for other detectors that can be operated at ambient temperature for the measurement task at hand.

The consultants investigated the space requirement for TE cooling. *LC (2021b) explain that in extreme cases cooling down to –90 °C is feasible with a TE4 (4 thermoelectrical cooling elements) and a vacuum package. A temperature difference of 80 °C to 90 °C against ambient temperature is rather common. The additional space requirement of a small detector with three stage TE coolers (TE3) increases for one order of magnitude - factor of three along one dimension – only for the detector and the TE coolers. Thermal insulation for the cold detector is generally required. Of course, the heat load for generating the temperature difference has to be deposited somewhere near the hot end of the TE cooler. If there is no suitable heat dump (thermal reservoir), this requires heat spreaders which need additional space for heat dissipation.*

Even though it has not become clear whether TE cooling requires less space than nitrogen cooling, the above shows that TE cooling also considerably increases the space requirements so that IR detectors operating at ambient temperatures would not easily be substitutable by TE cooled ones where the space is limited.

7.4.3. Review approach and overview of IR detector performance parameters

Goodman (2006) recommended this exemption to be granted because there were “No substitutes which meet the combinations of all essential performance criteria”, whereupon the COM adopted the exemption to Annex IV of Goodman (2006); (Directive 2011/65/EU) when it was published in 2011. The applicants stress Goodman’s argument as well.

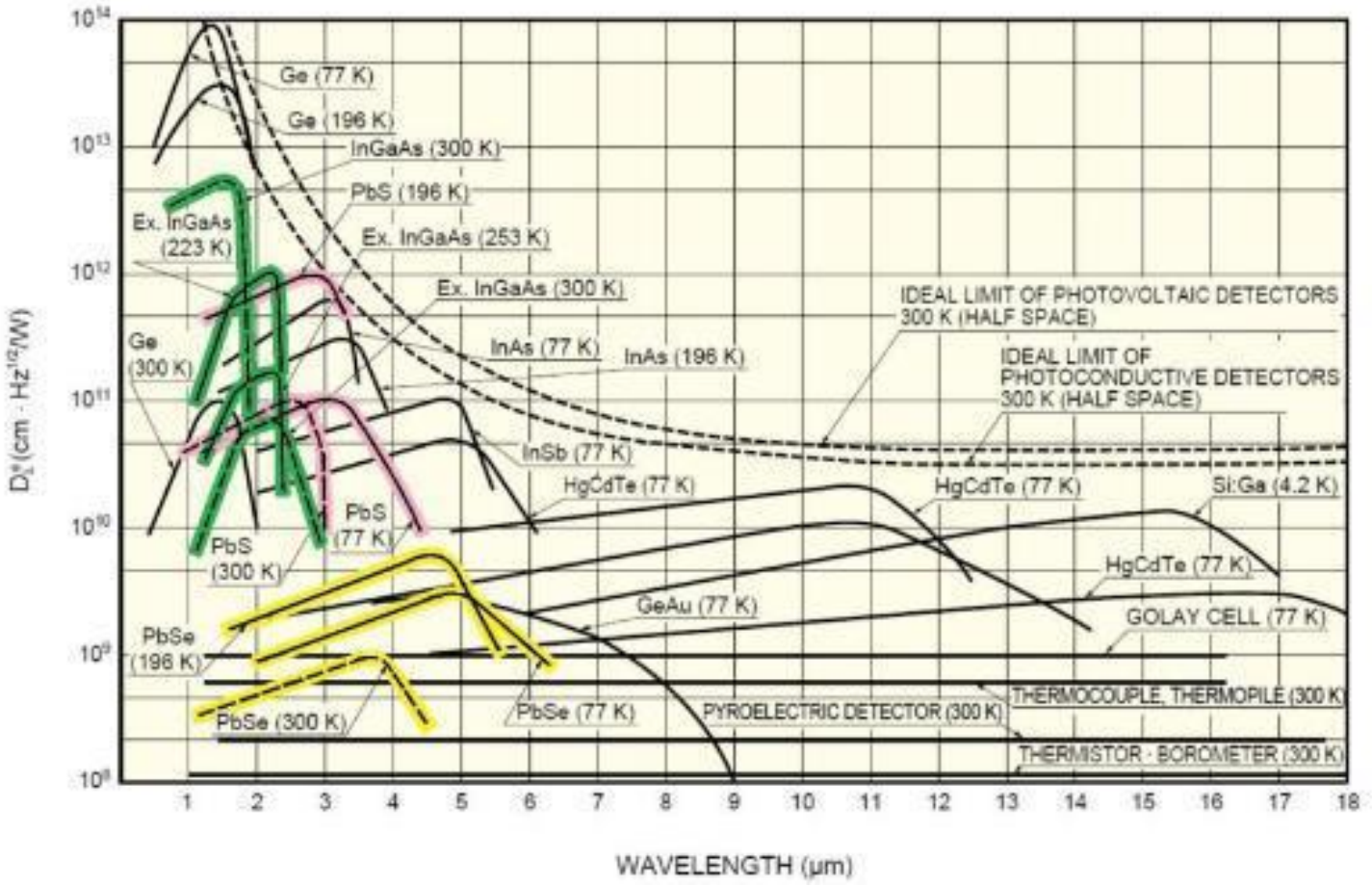
The detectors are used in a multitude of IR devices for various purposes and different requirements. The applications described in sections starting with chapter 7.2.4 on page 172 are examples and not exhaustive. An access via the applications to the substitution and elimination discussion was therefore not considered as promising. The consultants chose the following approach:

1) Clarify the properties of DCRS and DWRS to find out whether the current state of the art DCRS can replace state of the art DCRS with respect to:
    a) Detectable IR-spectrum
    Potential alternatives must cover the same or at least parts of the IR spectrum of the DCRS
    b) Detectivity
    The detectivity of DWRS must be comparable and at least be in the same order of magnitude like those of the DCRS
    c) Response time
    The response times must be comparable and at least be in the same order of magnitude like those of the DCRS
    d) Requirement for cooling
    Preferably uncooled detectors should replace uncooled DCRS due to the potential implications related to cooling[68]; thermoelectrically cooled detectors are preferred over nitrogen cooled ones since the cryogenic cooling additionally raises safety concerns and increases the volume of the device.
    e) Other relevant properties (comments)
2) Clarify whether DCRS can substitute DWRS with detectivity in equivalent or similar IR spectra and comparable response times

The below figure and table show the properties of various sensors to enable their comparisons in the subsequent sections. The figure is already displayed in the technical description part but is copied here since it complements the information in the table.

[68] For details see section „**Temperature dependence of IR detector properties and cooling**“

Figure 7-6: Detectivity of IR-sensitive substances for different IR spectra at different operating temperatures



PbS: Pink PbSe: Yellow InGaAs: Green
Super low temperature: Solid line Room temperature: Dotted line
Source: JBCE (2020b)

Table 7-7: Performance properties of IR detectors

Detector	Spectrum µm	Detectivity (cm $Hz^{0,5}$/W)	Response time (µs)	Operating temperature (°C)	Comment
PbS (PC)	1–2.8, peak 2.4	5 x 10^{10} 1 x 10^{11}	Fast (200)	Ambient	Smaller photosensitive area Increased photosensitive detector area (1 cm^2)
PbS (PC)	1-3.2	1 x 10^{11} 3 x 10^{11}	Fast (200)	-10 - 50	TE cooling
PbSe (PC)	1–4.8, peak 4.0	2.5 x 10^{9} 1x10^{10}	Very fast (4)	Ambient	Smaller photosensitive area Increased photosensitive detector area (1 cm^2)
PbSe (PC)	1–5.1	5 x 10^{9} 3 x 10^{10}		-10 -50	TE cooling
InGaAs (photodiode, useable as photoconductor from below -10 °C on)	0.7–1.7, peak 1.55	5 x 10^{12}	Fast	Ambient	
Extended InGaAs	1.2–2.55, peak 2.25	2.0 x 10^{11}	Fast	-20	TE cooling
InAs	1–3.5, peak 2.8	4 x 10^{9}	Extremely fast (< 1)	Ambient	

Detector	Spectrum µm	Detectivity (cm $Hz^{0,5}$/W)	Response time (µs)	Operating temperature (°C)	Comment
InAs	1–3.5, peak 2.8	1.8 x 10^{10}	Extremely fast (< 1)	-10	TE cooling
InAs	1–3.1, peak 3.0	1.0 x 10^{10}	Extremely fast (< 1)	-196	Nitrogen cooling, 500 K light temperature
InSb	1-5.5, peak 5.3	1 x 10^{10} (PV)	Fast	-196	Nitrogen cooling
InSb	1-6.7, peak 5.5	1 x 10^{9} (photocond.)	Fast		
InAsSb	2-6	5 x 10^{9}		-30	TE cooling
InAsSb	2 – 5.9	8 x 10^{10}		-196	Nitrogen cooling
MCT (PC)	1–14	4 x 10^{10}	Extremely fast (< 1)	-196	Nitrogen cooling
MCT (PC)	1-17	1.3 x 10^{10}		-196	Nitrogen cooling
MCT (PC)	1-25	1.0 x 10^{10}		-196	Nitrogen cooling
MCT (PV)	1-13.5	3 x 10^{10}		-196	Nitrogen cooling
MCT (PV)	2-12.5	10^{7} to 10^{8}	Extremely fast (< 1.5)	Ambient	
MCT (PV)	2-12.8	10^{8} to 10^{9}	Very fast (< 4)	-40	TE cooling
InAsSb	~2-11.0	10^{6} to 10^{7}	Extremely fast (~1.5)	Ambient	

Detector	Spectrum µm	Detectivity (cm $Hz^{0,5}$/W)	Response time (µs)	Operating temperature (°C)	Comment
InAsSb	2-10.2	10^6 to 10^8	Extremely fast (~1.5)	-30	TE cooling
InAsSb (photodiode)	1-11	7 x 10^7			Cooling required; detectivity decreases strongly with increasing operating temperature
Type II Superlattice	0.9 – 14 (peak 5.4)	~1.6 x 10^{10}	Extremely fast (< 1 µs)	-196	Nitrogen cooling; detector to be optimized according to measurement target. Detector available in 0.1 mm variations, limited use
PZT	1-20, no peak	3.2 x 10^8	Extremely slow (≥ 150,000)	Ambient	
$LiTaO_3$	1-20, no peak	2.0 x 10^8	Extremely slow (≥ 150,000)	Ambient	Sensitive to vibrations (microphony)
TGS	1-20, no peak	1.1 x 10^9	Very slow (10,000)	Ambient	Curie temperature of 49 °C too low for field applications
DLATGS	Responds to heat across IR spectrum, no peak	2.7 x 10^8 (1.3 mm element size)	Slow (1,000)	Ambient	Curie temperature of 62 °C too low for field applications
Thermopile	Responds to heat across IR spectrum, no peak	10^6, 10^8	Slow response	Ambient	

Detector	Spectrum µm	Detectivity (cm $Hz^{0,5}$/W)	Response time (µs)	Operating temperature (°C)	Comment
Bolometer	Responds to heat across IR spectrum, no peak	1-3 x 10^8	Very slow, typically 50,000	Ambient	
PtSi (Schottky barrier detector)	UV to entire IR spectrum	1 x 10^9	Fairly fast	≤ 0	
Type I Quantum wells	6-10, peak around	10^{10} - 10^{11}, depending on type			Poor data quality due to high thermal generation

Source: Hamamatsu, JBCE, Laser Components, Perkin Elmer, PPTF

7.4.4. Substitution and elimination of lead in PbS and PbSe detectors

According to JBCE (2020a), InAs photovoltaic detectors, InGaAs PIN photodiodes and InAsSb detectors have been proposed as potential alternatives for PbS and PbSe detectors, which can, however, not replace PbS and PbSe.

JBCE (2020a) claim that liquid nitrogen is required for InAs detectors to obtain the same sensitivity as the thermoelectrically cooled PbS, i.e. a detectivity of 10^{10} cm $Hz^{0.5}$/W. The additional equipment cannot be accommodated in all applications due to limitations on space, such as automatic facilities for continuous liquid nitrogen supply. There is also a concern about adverse effects on the optical system such as dew condensation, which would block infrared light.

The data in the above Table 7-7 confirm JBCE's statement concerning InAs as a substitute for PbS. The detectivity of InAs detectors is around one order of magnitude lower when comparing ambient temperature conditions for both detectors, and the same applies for the detectivity if the detectors are cooled thermoelectrically to -10 °C.

For PbSe, the differences are less evident. The detectivities of uncooled PbSe and InAs detectors are comparable, but the detectivity of PbSe with larger photosensitive areas is around one order of magnitude higher. The thermoelectrically cooled versions of both sensors show higher sensitivity for the InAs sensor at -10 °C. In all cases, PbSe covers a broader IR spectrum (from 1 µm to around 5 µm) than InAs (1 µm to max. 3.5 µm) and can therefore not be used in the range from 3.5 to around 5 µm. According to LC (2020), combinations of detectors are not feasible in some applications, which limits the possibilities to combine the InAs detector with other detectors to cover the same IR spectrum like with PbSe.

Concerning InGaAs, JBCE (2020a) state that it offers higher detectivity, but cannot provide the desired measurable wavelength range as PbS or PbSe, as can be seen in Table 7-7. The detectors have a small overlap only of 0.7 µm (uncooled) in in their detectable IR spectrum (NIRS) as shown in Table 7-7 so that InGaAs detectors are not appropriate to substitute or eliminate the use of lead in PbS and PbSe detectors.

With respect to InAsSb as an alternative to PbSe, *JBCE (2020a) state that it is sensitive to long wavelengths, but cannot provide the same signal-to-noise ratio as PbSe.* The InAsSb detector actually covers the spectrum between 1 – 6 µm similar to the combination of PbS and PbSe (up to around 5 µm). Compared to PbS, its detectivity is around one order of magnitude lower.

Compared to PbSe (ambient, smaller photosensitive area), the detectivity of InAsSb is around the double of the detectivity of PbSe, however with TE cooling to -30 °C. The detectivity of the PbSe detector with the larger photosensitive area on the contrary is twice as high as the one of this InAsSb detector. Taking into account that cooling limits the applicability of detectors, the detectivity advantage does not qualify the InAsSb detector as a general substitute for PbSe, but only for cases where sufficient space is available and the cooling does not cause other implications. *LC (2020) point out the example of CO_2 measurement in capnometers (renewal application of COCIR (2020), for which the detectivity of PbSe at 4.3 µm (peak of CO_2) is about 10 times better than the next best material, InAsSb (uncooled). The performance of InAsSb can be improved by cooling the*

detector but this causes condensation to form from patient's breath which interferes with the transmission of IR light resulting in poor accuracy.

Overall, InAsSb has high detectivity and fast response times, but seems to require cooling for most applications and thus cannot be considered a substitute for PbS and PbSe to a degree that would allow restricting the use of PbSe to cases where InAsSb cannot be used.

LC (2020) describe further criteria to be observed when selecting and using IR detectors for specific applications/devices. The range of wavelength to which the sensor is sensitive is important for applications where only certain wavelengths need to be detected. This is important, for example, in CO_2 monitors, gas analysers and moisture monitoring because these all rely on measurement of infrared intensity at specific characteristic wavelengths. Cut-off and band-pass filters can remove ranges of unwanted wavelengths but they cannot allow discrimination between gases or substances that have characteristic absorption wavelengths that are similar to each other. Also, for analysis of gases such as CO_2, the sensor must be sensitive in the main characteristic absorption range and the main absorption wavelength of CO_2 is 4.2 µm and so detectors like e.g. InGaAs are unsuitable. Each semiconductor type of detector is sensitive within a different range and the spectral response curve also depends on temperature, not only becoming overall more sensitive as temperature decreases, but the shape of the curve also changes with temperature.

The above example of the CO_2 measurement reflects some of the arguments which COCIR (2020) raise in their exemption request for the use of lead in CO_2 capnometers where the peak sensitivity of PbSe detectors at 4.0 µm under ambient temperature conditions for a reliable and quick detection of CO_2 with 4.2 µm absorption maximum is required. Cooling of alternative detectors or filters to achieve similar properties for alternative detectors is not feasible due to space limitations and potential dew generation on surfaces so that it can be followed that PbSe cannot be substituted at the time being.

Figure 7-2 on page 171 illustrates the detectivity of DCRS and DWRS over the entire IR spectrum at different operation temperatures. Defining criteria for the use of lead in PbS and PbSe detectors is thus a multiparameter problem with at least partially interacting parameters, e.g. detector size, detectivity at different operating temperatures, substance to be detected and the detector's detectivity at the peak absorption wavelengths, the environment in which the substance is to be detected, properties at ambient temperatures or requirement for TE or nitrogen cooling, space required or available for cooling, etc.

In synopsis of all the above facts and arguments, the consultants recommend renewing the exemption for PbS and PbSe. DWRS for the IR spectrum are available, but have different properties which qualify them for specific uses where these properties are required. The consultants could not identify DWRS with properties that would be sufficiently similar in their individual properties and the combination thereof which would allow replacing PbS and PbSe, and for the time being, such detectors are at the time being not foreseeable to become available in the next seven years.

7.4.5. Substitution and elimination of mercury and cadmium (MCT detectors)

Some detectors cover the broad IR spectrum of MCT ranging from NIRS to LIRS (1 to 14 µm) and even beyond into the VLIRS (close to 30 µm). Table 7-7 on page 199 shows that most of them are inferior in terms of detectivity and response time, and some have other disadvantages compared to MCT detectors.

PtSi Schottky detectors cover an even wider IR spectrum than MCT with a detectivity which at least comes close to some MCT detectors. *JBCE (2021c) say that they do not have any information or datasheet of PtSi Shottky detectors commercially available for IR-applications for spectral measurement, but there seem to be examples where they are used as image sensors, which is different from spectral measurement. LC (2021c) confirm this information and add that it seems that the development was stopped "at late 2010s" for IR detectors in the scope of this exemption request.* The PtSi detectors can thus not be considered as a substitute for MCT detectors.

The Type II Superlattice detector in principle offers similar performance over all the listed parameters.

Table 7-7 shows that only the Type II Superlattice detector in principle offers similar performance over all the listed parameters.

PE (2020) comment on Hamamatsu's[69] InAs/GaSb Type-II Superlattice infrared detector:

a) It needs to be cooled with nitrogen which limits its uses.

b) Only operates up to 14.3 µm and not up to 20 µm like MCT, and its sensitivity in this wavelength range is about less than half that of MCT detectors in the same band.

c) The optical design depends on the size of the object size to be measured so that the detector shall be optimized according to the size of the measurement target.

d) Maximum detectivity is 1.6 x10^{10}, in comparison with the 16.6 µm (MCT) detector of Perkin Elmer which is 4.5 x10^{10} and the commercially available (MCT) alternative from Teledyne Judson detectors[70] of around 6 x10^{10}, which due to the square law relationship between detectivity and measurement time results in measurement times which are orders of magnitude longer.

e) The shape of the detectivity/wavelength curve is very different to the shape of MCT detectors so that at higher wavelengths, the detectivity values of the Hamamatsu detector are much lower than those of MCT.

f) The photosensitive area offered by the Hamamatsu alternative is 0.1 mm^2 in comparison with 0.15 mm x 0.15 mm offered by Perkin Elmer MCT, resulting in a 50 % reduction in sensitivity.

[69] Hamamatsu claim that "By utilizing compound opto-semiconductor manufacturing technology developed in-house over many years, we are the first in the world to succeed in mass-producing a compound opto-semiconductor (Type-II superlattice infrared detector).", c.f. https://www.hamamatsu.com/eu/en/news/featured-products_technologies/2019/20190828000000.html)

[70] C.f. Teledyne Judson, http://www.teledynejudson.com/prods/Product %20Documents/mercadpc_08_254A.pdf

g) *The Hamamatsu detector would only be able to replace the single point detectors and not the array detectors used in FTIR spectrometers and microscopes, and also 2D imaging with the technology would not be possible.*

Asked about the intended uses of this type II superlattice detector and to react on the above objections against its use as a substitute for MCT detectors, *Hamamatsu (2021b) state that customers/manufacturers of equipment decide the intended uses of Type-II Superlattice IR-detectors, and that they have no comments on the above statements.*

The consultants also asked the detector manufacturer whether in their opinion this detector could replace MCT detectors or other DCRS*. Hamamatsu (2021b) replied that they cannot comment it because their customers/manufacturers of equipment should decide to replace.*

PE's argument that the superlattice detector needs nitrogen cooling which limits its use also applies to MCT detectors, but obviously they can also be operated at higher temperatures with TE cooling which requires less additional space and efforts. The detectivity decreases, however, for around one order of magnitude while the MCT detector seems to maintain its other favourable properties.

In the light of the above situation, the consultants must assume that the superlattice detector is not a substitute for MCT, unless manufacturer of IR measurement devices explicitly decide to use it for their applications due to its differing properties compared to MCT*. PPTF (2021) state that MCT detectors are used in the most demanding applications, but also state that there is no single group of most demanding applications. Customers often have requests regarding the detectivity being as high as possible, and/or that high speed response is also critical. Additionally, requested parameters often depend on customers' requirements, e.g. the noise equivalent temperature difference. Aiming for these parameters to be very low (allowing for precise temperature measurements) makes use of MCT detectors necessary.*

Some of the product examples like FTIR and FTIR microscopes, which PPTF (2021) mention for use with MCT detectors, are already described in chapter 7.2.5 "Specific uses of infrared detectors – IR-detectors based on MCT" on page 179 et sqq. *LC (2021a) point out that DLaTGS is already used in "bread and butter" FTIR instruments where performance can be compromised. DLaTGS suffers in speed and signal to noise ratio compared to the other mentioned materials.*

The above examples show that MCT is selected where its specific properties and combinations thereof are required, and that alternative DWRS may be used in other cases. The above discussion between PE and Hamamatsu suggests that DWRS cannot replace MCT in cases where its specific properties are required. All applicants' statements as to where DWRS can replace MCT or other DCRS coincide with the argument that each application has specific requirements according to which the IR measurement device manufacturer selects the detectors.

With respect to substitute or eliminate the use of mercury and cadmium in MCT detectors where scientifically and technically practicable, the question arises whether and how it can be avoided that MCT detectors are used in cases where cadmium and lead-free detectors would be appropriate as well. Following the approach in exemption IV-29 for the use of lead in micro-channel plates, this could be avoided by restricting the use of mercury and cadmium in IR detectors to detectors with certain properties and combinations thereof. These properties would have to reflect the border/limits of what can be achieved with cadmium- and mercury-free IR detectors in the relevant IR spectrum, and what can only be

achieved with cadmium- and mercury-containing IR detectors. The performance parameters would, among others, have to be

- the detectable spectrum, possibly with peaks where particularly high detectivity is required;
- the substances and their peak absorption wave lengths to be detected within a certain IR spectrum range;
- the detectivity, which among others depends on the operation temperature and the size of the photosensitive area;
- the response time, which is also interlinked with the operation temperature.

PPTF (2021) provide an example for the detectivity of MCT detectors depending on the IR spectrum to be monitored/detected, the detectivity related to specific wave lengths within this spectrum, and the operating temperature.

Table 7-8: Properties of MCT IR detectors at different absorption peaks and operating temperatures

Detector	Spectrum (µm)	Detectivity (cm $Hz^{0,5}$/W)	Response time (µs)	Operating temperature (°C)
MCT (PV)	2-12.5; peak 7.5 µm	> 2.0E+07 @ 8.0 µm >1.8E+07 @ 9.0 µm >1.5E+07 @ 10.0 µm >8.0E+06 @ 11.0 µm	< 1.5	ambient
MCT (PV immersed)	2-12.5; peak 8.2 µm	>2.0E+08 @ 8.0 µm >1.8E+08 @ 9.0 µm >1.5E+08 @ 10.0 µm >7.5E+07 @ 11.0 µm	< 1.5	ambient
MCT (PV)	2-12.8; peak 9.5 µm	~1.5E+09 @ 8.0µm ~1.5E+09 @ 9.0µm ~1.4E+09 @ 10.0µm ~7.5E+08 @ 11.0µm	< 4	-40

Source: PPTF (2021)

Adding to the above, MCT detectors can be used in other IR spectral ranges and at lower temperatures down to nitrogen cooled detectors operating at -196 °C, with largely different performance parameters as can be seen in Table 7-7 on page 198. The measurement tasks can as well be different, ranging from peak signals to be detected in an IR spectrum like above, or a task where multiple signals at different peaks have to be detected over a certain IR spectrum. Table 7-7 also shows that the performance of DWRS also depends on similar parameters like shown in the above table for MCT.

Overall, the approach to define performance criteria to exclude the use of mercury and cadmium in IR detectors for less demanding applications, where its high performance is not required, is not practicable.

7.4.6. Substitution and elimination of lead in PZT-based detectors

JBCE request the renewal of exemption 1(c) for PZT-based IR detectors. *JBCE (2020a) mention thermopile detectors, lithium tantalite (LiTaO), strontium barium niobates (SBN) and TGS (glycine trisulfide) as potential alternatives to PZT pyroelectric detectors and explain that none of them can replace PZT pyroelectric detectors for various reasons.*

LiTaO IR detectors are pyroelectric detectors like PZT. *JBCE (2020a) state that it is a highly stable single crystal material, however it has a sensitivity of only half of that of PZT and a reduced S/N ratio and therefore cannot replace PZT sensors. The improvement of sensitivity is currently being studied.*

The consultants compared the performance parameters of these two detectors in Table 7-7 on page 199 and found that the detectivity of LiTaO is almost the same like that of PZT, while the other listed properties are identical. LiTaO-based detectors are available on the market.[71]

Upon request, JBCE (2021b) declared that the above example LiTaO detector seems to have the required performance like PZT has. *Even though LiTaO looks like having the same performance in sensitivity and S/N ratio, the equipment manufacturer will have to conduct functional evaluations. For example, in the case of the carbon /sulphur analyser, which uses PZT based IR detector, the equipment manufacture has to verify the reliability, repeatability of the reading after installing the substitute detector. Especially as for the certified materials, it will be really crucial, if the analysers' reading value shifted after applying the substitute detector. There actually are many varieties of the certified materials that are specified in for example GB94/3993. Analytical equipment manufacturers have to evaluate and apply nearly 50 certified materials for the calibration curve in the analytical equipment.*

Some of analytical equipment have to be approved before these products can be sold in the EU. For example, environment emission analysis measurement systems have to be tested by EU notified bodies in accordance with the European Standards EN 15267. It normally takes two years to get approval. Therefore, it will take 4-6 years to develop the new equipment with the substitute detector.

JBCE confirm in their above statement that lead-free LiTaO detectors can replace PZT detectors, but that the devices in which they are applied need to be recalibrated and possibly require more changes to accommodate and adequately reflect differences between the two detectors in the evaluation and interpretation of measurement signals. Substitution and elimination of lead are thus scientifically and technically practicable, but the reliability of the substitute still needs to be ensured on the system level, i.e. its proper functioning in IR measurement devices so that they produce correct results.

JBCE (2021d) substantiate the remaining steps and the related timeline in the below Table 7-9.

[71] C.f. Laser Components, https://www.lasercomponents.com/de-en/product/one-channel-litao3-pyro-current-mode-and-voltage-mode/

Table 7-9: Roadmap for implementation of LiTaO detectors in IR measurement devices

	1st year				2nd				3rd				4th				5th				6th			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1.Initial feasiblity evaluation (detector performance)																								
Sensitivity, response time, accuracy, measurement range																								
Adjusting temperature compensation																								
Lifetime, shelf life evaluation																								
2.Evaluation of reliability, durability, transportation, evaluation by end users																								
3.Establishment of production lines and evaluation for production.																								
4 Specific approvals																								

Source: JBCE (2021d)

The consultants below wording and expiry of the renewed exemption 1(c):

	Exemption	Scope and dates of applicability
	Lead in PZT ceramics of infrared light detectors	*Expiry on 21 July 2027 for cat. 9 monitoring and control instruments incl. industrial monitoring and control instruments.*

JBCE (2021d) agreed to the above wording of the exemption, but asked to extend the expiry date to end of December 2027. Since the schedule JBCE present covers six years only, not 6.5 years, the consultants recommend a renewal for six years until 21 July 2027.

7.4.7. Environmental arguments and socioeconomic impacts

IR detectors are used in many different applications in research and development as well as in various branches of the economy. DWRS are crucial for most of these applications. The consultants follow that applicants' arguments that, should the exemption not be renewed, considerable risks and economic disadvantages would arise for the economies of the EU/EEA.

7.4.8. Conclusions

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

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;

- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

Five applicants request the renewal of exemption 1(c) for the maximum of seven years for different types of EEE in categories 8 and/or 9 and for individual applications of the IR detectors. The exemption requests are supported by seven stakeholders. The IR detectors covered by the scope of exemption 1(c) are based on lead sulphide (PbS), lead selenide (PbSe), mercury cadmium telluride (MCT), and lead zirconate titanate (PZT). They are used in different industries for manifold tasks.

Substitution of lead in PZT was found to be scientifically and technically practicable. $LiTaO_3$ based detectors can be used instead, but still need to be qualified in the devices in which they are applied to ensure their reliability. The exemption for the use of lead in PZT can expire in 2027 for cat. 8 IVD and cat. 9 IMCI. For all other devices of cat. 8 and 9, the exemption expires in July 2021 already in the absence of renewal requests.

The other detectors containing RoHS restricted substances (DCRS: MCT, PbS and PbSe) generally have high detectivity and short response times at ambient temperatures, and different peak sensitivities. All of these properties can be influenced/improved by decreasing the operation temperatures by thermoelectrical (TE) or liquid gas cooling (generally nitrogen), or with slight modifications of the detectors' material compositions.

Detectors without RoHS-restricted substances (DWRS) are available, and some of them perform similar or even better in individual parameters compared to MCT, PbS and PbSe. Like for the DWRS, TE or nitrogen cooling or modifications in their compositions/material structures change/improve these properties. The DWRS are used where their specific properties best match the IR-measurement task to be performed in specific applications/devices.

In the review of the exemption renewal requests, the consultants assessed the properties of DWRS with respect to their potential to substitute or eliminate the use of cadmium, lead and mercury in IR detectors. An approach focusing on their applications was not promising given the multitude of different uses of these detectors for a large number of analytical and monitoring tasks.

For the selection of a detector for the specific requirements of a specific task, individual properties and the combination thereof in the detector are crucial. The consultants compared the properties and combinations of DCRS and DWRS and could not identify DWRS which would offer a sufficiently similar performance profile to DCRS that would allow the substitution or elimination of cadmium, lead or mercury.

An additional approach could have been to define the properties of the individual DWRS and restrict the exemption scope to these properties. These properties are, however, not static and fixed for each of the detector types but depend on operating temperatures, exact detector material compositions/structures, etc. so that they cannot be used to define a clear and viable exemption scope.

In the synopsis of the above situation, a practicable scope restriction of exemption 1(c) only seems feasible if a DWRS can actually replace MCT detectors due to a similar performance across the relevant parameters. Both DCRS and DWRS are used where their specific properties are required or acceptable.

In the light of the above considerations, the consultants conclude that substitution or elimination of cadmium, lead and mercury are scientifically and technically not yet practicable to a degree that would allow the revocation or scope restriction of exemption 1(c). In the consultants' view, the renewal of the exemption can be justified by Art. 5(1)(a) since substitution or elimination of lead are scientifically and technically not yet practicable for the time being.

7.5. Recommendation

The available information suggests that substitution and elimination of cadmium, lead and mercury in IR detectors are scientifically and technically not yet feasible in MCT, PbS and PbSe sensors. Lead can be substituted in PZT detectors, but the reliability of the detectors in the IR measurement devices in which they are used still needs to be ensured. The renewal of exemption 1(c) can be justified by Art. 5(1)(a).

The below modified wording was agreed with the applicants:

	Exemption	Scope and dates of applicability
1(c)-I	*Cadmium and mercury in mercury cadmium telluride (MCT) of infrared light detectors*	*Expiry on* - *21 July 2028 for cat. 8 medical devices including in-vitro diagnostic medical devices, and for cat. 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*	*Expiry on* - *21 July 2028 for cat. 8 medical devices including in-vitro diagnostic medical devices, and for cat. 9 monitoring and control instruments incl. industrial monitoring and control instruments.*
1(c)-III	*Lead in PZT ceramics of infrared light detectors*	*Expiry on* - *21 July 2027 for cat. 8 medical devices including in-vitro diagnostic medical devices, and for cat. 9 monitoring and control instruments incl. industrial monitoring and control instruments*

PZT is a lead-containing ceramic which is also covered by exemption III-7(c)(I). To avoid the misuse of PZT ceramics in PZT detectors after July 2027, it is recommended to exclude the scope of exemption IV-1(c)(III) from the broader scope of exemption III-7(c)(I) or vice versa.

7.6. References

Berghof (2020): Contribution to the stakeholder consultation for exemption 1© of Annex IV. Online verfügbar unter https://www.rohs.biois.eu/Berghof.pdf.

COCIR (2020): Request for renewal of exemption 1c of RoHS Annex IV. Online verfügbar unter https://www.rohs.biois.eu/Ex_1c-IV_COCIR_Renewal-Request.pdf.

Directive 2011/65/EU: 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 (recast). RoHS 2. Fundstelle: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065.

Drägerwerk (2020): Contribution to the stakeholder consultation for exemption 1© of Annex IV. Online verfügbar unter https://www.rohs.biois.eu/Dragerwerk.pdf.

FFE (2020): Contribution to the stakeholder consultation for exemption 1© of Annex IV. Online verfügbar unter https://www.rohs.biois.eu/ffe.pdf.

Goodman (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report (amended). ERA Report 2006-0383. Unter Mitarbeit von Paul Goodman. ERA Technology Ltd. Online verfügbar unter https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf.

Hamamatsu (2021a): Thermopile detectors. Online verfügbar unter https://www.hamamatsu.com/resources/pdf/ssd/thermopile_kird9005e.pdf.

Hamamatsu (2021b): Answers to questionnaire 4 for RoHS exemption 1© of Annex IV, received via e-mail from Masakazu Kirihara, Hamamatsu, by Dr. Otmar Deubzer, Fraunhofer IZM.

JBCE (2020a): Request for renewal of exemption 1c of RoHS Annex IV. Online verfügbar unter https://www.rohs.biois.eu/Ex_1c-IV_JBCE_Renewal-Request.pdf.

JBCE (2020b): Answers to questionnaire 1 (clarification questionnaire) for RoHS exemption 1© of Annex IV. Online verfügbar unter https://www.rohs.biois.eu/Ex_1c-IV_JBCE_Questionnaire-1_Clarification.pdf.

JBCE (2020c): Contribution to the stakeholder consultation for exemption 1© of Annex IV. Online verfügbar unter https://www.rohs.biois.eu/JBCE_IV-1c.pdf.

JBCE (2021a): Answers to questionnaire 2 for RoHS exemption 1© of Annex IV, received via e-mail from Takuro Koide, JBCE, by Dr. Otmar Deubzer, Fraunhofer IZM, on 5 April 2021.

JBCE (2021b): Answers to questionnaire 4 for RoHS exemption 1© of Annex IV, received via e-mail from Takuro Koide, JBCE, by Dr. Otmar Deubzer, Fraunhofer IZM, on 17 May 2021.

JBCE (2021c): Answers to questionnaire 6 for RoHS exemption 1© of Annex IV, sent via e-mail by Takuro Koide, JBCE, to Dr. Otmar Deubzer, UNITAR.

JBCE (2021d): Answers to questionnaire 6 for RoHS exemption 1© of Annex IV, sent via e-mail by Takuro Koide, JBCE, to Dr. Otmar Deubzer, UNITAR.

LC (2020): Request for renewal of exemption 1c of RoHS Annex IV. Online verfügbar unter https://www.rohs.biois.eu/Ex_1c-IV_LC_Renewal-Request.pdf.

LC (2021a): Answers to questionnaire 2 for RoHS exemption 1© of Annex IV, received via e-mail from Sven Schreiber, Laser Components, by Dr. Otmar Deubzer, UNITAR.

LC (2021b): Answers to questionnaire 4 for RoHS exemption 1© of Annex IV, received via e-mail from Sven Schreiber, Laser Components, by Dr. Otmar Deubzer, UNITAR.

LC (2021c): Answers to questionnaire 4 for RoHS exemption 1© of Annex IV, received via e-mail from Sven Schreiber, Laser Components, by Dr. Otmar Deubzer, UNITAR.

PE (2020): Request for renewal of exemption 1c of RoHS Annex IV. Online verfügbar unter https://www.rohs.biois.eu/Ex_1c-IV_PE_Renewal-Request.pdf.

PPTF (2020): Request for renewal of exemption 1c of RoHS Annex IV. Online verfügbar unter https://www.rohs.biois.eu/Ex-1c-IV_PPTF_Renewal-Request.pdf.

PPTF (2021): Answers to questionnaire 2, sent via e-mail by Agnieszka Soduł, PPTF, to Dr. Otmar Deubzer, UNITAR.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

Siemens (2020): Contribution to the stakeholder consultation for exemption 1© of Annex IV. Online verfügbar unter https://www.rohs.biois.eu/Siemens.pdf.

T&B Electronics (2020): Contribution to the stakeholder consultation for exemption 1© of Annex IV. Online verfügbar unter https://www.rohs.biois.eu/TBelectronics.pdf.

trinamiX (2020): Contribution to the stakeholder consultation for exemption 1© of RoHS Annex IV. Online verfügbar unter https://www.rohs.biois.eu/trinamix.pdf.

voestalpine (2020): Contribution to the stakeholder consultation for exemption 1© of RoHS Annex IV. Online verfügbar unter Contribution to the stakeholder consultation for exemption 1© of Annex IV.

8. Exemption 2 of Annex IV: Lead Bearings in X-ray tubes

The current wording of the exemption is:

"Lead bearings in X-ray tubes"

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date was scheduled for 21 July 2023, and for IMCIs for 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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and definitions

CT	computer tomography
Pb	lead

8.1. Background

COCIR (2020a) submitted a request asking for the renewal of the above exemption for the maximum validity period of seven years in category 8 medical devices other than in-vitro diagnostic medical devices. COCIR (2020a) states that the exemption is also applied in EEE of category 9 such as X-ray inspection devices, does, however, not request the renewal of this exemption for this category of EEE. No other request was submitted for the renewal of this exemption for category 9 equipment.

8.1.1. Summary of the requested exemption

COCIR (2020a) claim *this exemption to be required for thin lead coatings on steel bearings used in rotating anode X-ray tubes. To avoid overheating of the focal track (portion of the anode where the electrons bombard) the target needs to rotate. The rotating anode is supported by a bearing, which has to be lubricated with vacuum compatible materials. Lead coated ball bearings are used due to their reliability and low noise. Low power X-ray tubes can use stationary targets (anodes) and some very high-power designs used in CT equipment with high power X-ray tubes use liquid metal bearings, but neither are technically suitable in the types of X-ray equipment that currently use lead coated bearings.*

8.1.2. History of the exemption

(Goodman 2006) made an assessment in 2006 as to potential substitution of lead bearings in X-ray tubes. At that time, substitute bearing materials did not appear to be available, but redesign of X-ray tubes to avoid the need for a bearing was described as an alternative approach to avoid the use of lead. (Goodman 2006) found at least one manufacturer who had developed a new design of X-ray tube which did not have lead bearings. This new type of tube can used in a limited range of new product designs whereas most X-ray equipment will continue to use tubes with lead bearings. These new designs have been patented so that competitors could not benefit from this invention and so could not utilise this approach to replace lead bearings.

(Goodman 2006) rated the use of lead in bearings of X-ray tubes to be an exemption which appeared to be justified for EEE of categories 8 and 9. The exemption was listed as exemption 2 of Annex IV in Directive 2011/65/EU when it was officially published in 2011. This exemption has now become due for the first review to adapt it to scientific and technical progress.

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

According to COCIR (2020a), the exemption is used in medical devices other than in-vitro diagnostic medical devices, namely in medical X-ray imaging equipment. A wide variety of X-ray equipment fitted with medical X-ray tubes is used, depending on the employed diagnosis or treatment procedure. They include computed tomography, fluoroscopy, mammography, angiography, etc. Dental X-ray use the lowest X-ray power whereas Computed Tomography (CT) scanners use high power. Some procedures require a brief burst of X-rays, such as to view a bone fracture, whereas some procedures require continuous imaging, such as during surgery.

COCIR (2020a) explain that X-ray tubes generate radiation that passes through patients in order to form an image on the detector. The X-rays are generated by accelerating an intense beam of electrons from a cathode to an anode. In the anode, the electrons are deaccelerated, and X-rays (by the Bremsstrahlung process) are generated. Typically, about 1 % of the energy is converted into X-rays by the Bremsstrahlung process, the majority (99 %) is converted to heat. The anode becomes very hot reaching temperatures that can lead to the destruction of the X-ray unit if the heat is not distributed over a larger surface area and the heat is subsequently removed from the unit. The X-rays are generated in a sealed vessel, which is under ultra-high vacuum with the electron emitting cathode and anode (target) rotating so that the heat generated by the electron beam does not melt or deform the anode material. In addition to this, COCIR (2020a) explain, the anode rotation prevents the electron beam from impinging at one location for too long and distributes the power equally in the circumference of the focal track.

COCIR (2020a) say that the rotating anode is supported by bearing units. The bearing unit cannot be lubricated by greases or polymers because these substances have too high vapour pressure so that gases are generated which would be ionised by the electrons causing arcing to occur which would disturb the electron beam. The generation of X-rays subsequently may cause arcing, which can destroy the X-ray tube and the high voltage generator. Due to the need to withstand a combination of high temperature and the required vacuum, the lubricant must have very low vapour pressure and must not outgas. All organic

materials outgas and have too high vapour pressure and so bearings with suitable lubricity have to be used.

COCIR (2020a) state that recently designed X-ray tubes use bearings with balls that are coated with solid lubrication in the form of a thin lead coating. Typically, these coatings have a thickness of 150 nm although the thickness is variable. Lead is used as the bearing material because it is inert in the X-ray tube vacuum, and it is not affected physically or chemically by the X-radiation. Lead is fairly soft and does not cold weld to other surfaces so that it slides against them, and the wear rate is very low giving a long lifetime. Lead has a sufficiently high melting point and low vapour pressure for use in all but the highest power X-ray tubes. Lead also does not cause corrosion or cause wear to the surfaces that it contacts and does not cause corrosion of the steel balls over which it is coated.

Further on, COCIR (2020a) explain, the bearing material should not become radioactive when exposed to X-radiation. Many metals can generate long-lived radioisotopes when exposed to high energy X-radiation, although this is not likely to be an issue with X-ray tube voltages. Any daughter products from lead have all relatively short half-lives which enables used X-ray tubes to be safely refurbished for reuse or disposed of at end of life without additional exposure of workers or the environment to rays from these radioisotopes. The bearings must also be very quiet as loud noises disturb patients, especially children. Sudden noise can cause involuntary movement by the patient that blurs X-ray images. Noise is also annoying to medical staff and can pose a hazard when X-ray imaging is used during surgical operations.

8.1.4. Amount of lead used under the exemption

According to COCIR (2020a), the content of lead in the bearing material (homogeneous material) is 99.9 % by weight. X-ray tubes contain lead in bearings in the range of few milligrams per device. COCIR (2020a) estimate around 25 g of lead to be placed on the market in devices sold in the EU for the application in the scope of the requested exemption. Further information on the background of this figure is not publicly available.

8.2. Justification for the requested exemption

COCIR (2020a) say that the choice of bearings depends on the types of X-ray devices:

- Low power or medium power for a very short period of time are unlikely to cause heat damage to the anode and so a fixed anode can be used.
- Medium or low power devices with the X-ray beam on for longer periods of time will cause heat damage to the anode, so a rotating anode must be used. Rotating anodes can use lead coated, silver coated or with gallium liquid metal bearings from which the lead bearings are the simplest design that uses least materials and energy consumption as well as having technical and other advantages.
- For some of the highest power applications, such as for some CT scanners, lead may be unsuitable because the bearings become sufficiently hot for the lead metal to vaporise inside the vacuum. This depends on other variables such as the time that the X-rays are generated. Silver has a higher boiling temperature than lead and so is less likely to vaporise, but silver coated bearings can be unacceptably noisy and also can be unreliable, as explained in the next section. Also, the highest power tubes may be

too hot for silver to be suitable without significant cooling. As an alternative, these devices use gallium alloys as liquid metal bearings.

8.2.1. Substitution of lead

Overview of potential substitutes

According to COCIR (2020a), several potential alternatives could be considered to be substitutes, but none meet all of the essential requirements of medical imaging X-ray tubes currently used. The choice of such alternative bearing materials is limited. Organic lubricants and polymers are unsuitable because they will emit volatiles which will cause arcing that destroys the X-ray tube when exposed to electron beam.

COCIR (2020a) states that most metals are too hard and so will cause excessive wear without oil-based lubricants resulting in short lifetimes, and the bearings could seize due to over-heating. Relatively soft metals may be more suitable but may cold weld to other oxide-free metal surfaces. The tubes are evacuated so as the wear surfaces on which the balls move are abraded, this creates an oxide-free surface because there is no oxygen inside the tubes. Many metals such as indium and gold cold weld to clean oxide-free metal surfaces causing excessive wear to the bearing or seizure. Some metals could react with the substrate such as tin which reacts with copper or steel at the temperatures at which X-ray tubes operate and so are unsuitable. Lead does not readily form intermetallic phases with other metals or cold weld to other metal surfaces such as steel and so is an ideal choice.

Silver-coated bearings

COCIR (2020a) put forward that some publications suggest silver to be used as the bearing material without lubricants. It does have the advantage of a higher melting temperature than lead and so the X-ray tube can operate at a higher temperature. Silver-coated steel ball bearings are available as X-ray tube bearings but are usually too noisy for medical imaging applications. Several publications state that silver bearings are much noisier, because it is harder than lead[72]. Excessive noise is an indication of wear and would indicate a shorter lifetime. However, the main problem with noisy bearings is that the sudden noise created when the tube is switched on will disturb patients who are required to keep very still while being imaged. Carrying out repeated exposures to obtain a clear image can be harmful to patients as repeated exposure to X-rays is known to increase the risk of getting cancer. Noisy bearings can thus prevent the system from being approved for use by an EU Notified Body under the Medical Devices Directive. Silver is therefore not being used in new designs of X-ray systems. Noise also disturbs medical staff, which can be a hazard to patients during operations or other treatments.

Silver could also react with the steel base metal when it becomes hot causing grain boundary cracking leading to premature bearing failure[73]. This will create additional waste due to inferior reliability, but also could harm patients when the X-ray imaging equipment is

[72] C.f. http://www.ams-medical.net/understanding-noise-in-x-ray-and-ct-tubes/; source as referenced by COCIR 2020a.

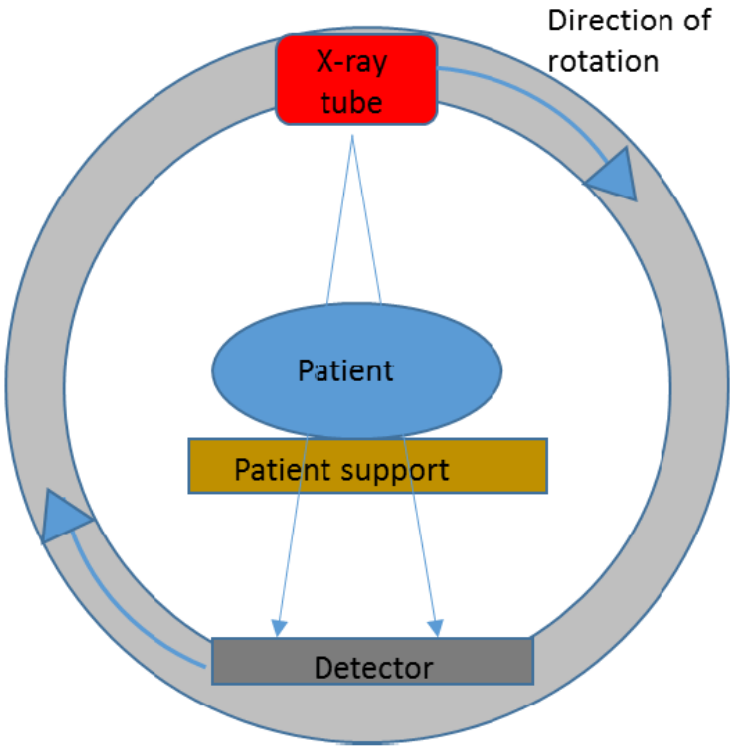
[73] C.f. 2 US Patent 6891928 B2, May 10, 2005, T. S. Martin et.al “Liquid metal gaskets in X-ray tubes“ and https://app.aws.org/wj/supplement/WJ_1984_12_s355.pdf.; source as referenced by COCIR 2020a.

unexpectedly no longer usable. X-ray tube manufacturers have not seen cracking of steel due to lead.

Use of liquid metal bearings

COCIR (2020a) point out that each manufacturer has its own proprietary designs of X-ray tubes including those with liquid metal bearings. They explain that several medical device manufacturers have patented X-ray sources which use liquid metal bearings. CT scanners on the EU market use X-ray tubes with rotating anodes either with lead coated steel bearings or with liquid metal bearings if other tube designs cannot achieve the required performance. The type of bearing used depends on how often the CT scanner will be used and other variables. Frequent start stop operation is less suitable for liquid metal bearings as the gallium alloy may need to be heated to melt it before the CT scanner can be used. Alloys that are liquid at room temperature are used by at least some manufacturers, but in cold climates, without heating these can freeze. In high power X-ray tubes such as for some types of CT, the rotating anode is supported by a sliding bearing with a liquid metal (gallium) as lubricant. The liquid lubricant has more restrictive temperature limits due to the corrosive nature of gallium than lead or silver coatings, which leads to a requirement for active cooling of the sliding bearing including cooling fluid, pumps and heat exchangers. This adds an enormous amount of apparatus to the system which results in a much more bulky and heavier X-ray system compared to solid lubricated ball bearing units.

Figure 8-1: Orientation of X-ray tube in CT scanner. Tube rotates around patient



Source: COCIR (2020a)

COCIR (2020a) states that some designs of liquid metal bearings use small bearing gaps providing sufficient capillary forces to keep the liquid metal in the bearing so that it can be used in more than one orientation. The highest power applications use gallium alloys as the liquid metal bearing. These types of X-ray tubes are much larger and heavier than tubes with fixed anode or with rotating anodes with lead bearing. The CT X-ray tubes rotate around

the patient and so are used in one orientation and rotate around one axis. This ensures that the liquid metal remains in the correct position although there are some designs of liquid bearing X-ray tubes that can be used in multiple orientations. COCIR (2020a) describe the significant disadvantages of liquid metal bearing tubes which is why they are applied only if solid metal bearings cannot be used:

3) *Larger equipment*

   Liquid metal X-ray tubes are on average larger and heavier than other types and can be at least an additional 20 kg plus the weight of the additional cooling equipment, although the size and weight vary considerably and depends on application. Also, some manufacturers have proprietary designs that affect the overall mass of the tube. Most X-ray imaging equipment, apart from CT, needs to be fairly small and compact because it has to be moved by hospital staff, either around the patient to focus on the required part of the body or moved around the hospital to different locations. Very large and heavy X-ray tubes would make the equipment difficult or impossible to move as required. An example of the difference in weight is[74]:

   - *Rotating anode tube example with lead bearings 25.6 kg*
   - *Rotating anode tube with liquid metal bearings 58 kg*

   Heavier X-ray tubes with both liquid metal and with lead coated steel bearings are used for some applications, some are over 90 kg.

4) *More lead required for shielding*

   X-ray tubes require internal shielding to protect hospital staff, patients and electrical equipment from radiation. Lead is usually used (RoHS exemption 5 of Annex IV) and there can be a much larger quantity of lead used in a liquid metal bearing X-ray tube than the types of tubes with lead bearings, although the amount of lead shielding used depends on tube design and application. Using the same two examples as above (note that <1 gram of lead is in the lead coated bearings of each tube):

   - *Rotating anode tube example with lead bearings: 5.4 kg of lead shielding*
   - *Rotating anode tube with liquid metal bearings: 8.3 kg of lead shielding*

5) *Higher power consumption because of higher friction and cooling*

   Typically, a drive power of about 1 kW is needed due to the use of liquid metal bearings, whereas ball bearings have nearly no friction. This increases the power consumed to accelerate the bearing and to maintain the operation frequency. This means higher effort in the power chain of such high power X-ray tubes (drive unit).

   COCIR (2020a) reports that one manufacturer measured the heat required to drive the liquid metal bearing at 700 W, another has quoted 1 kW. If the CT scanner is used for eight hours per day 365 days per year, this is an additional electricity consumption of 2 MWh per year per liquid metal X-ray tube. Hospitals have very limited budgets and will not want this additional cost unless this type of tube is essential for the medical procedures being used. In practice, X-ray

[74] C.f. https://www.philips.co.uk/healthcare/resources/recycling-passports/x-ray_tubes; source as referenced by COCIR 2020a.

tubes with liquid metal bearings need to be operating continuously which is why these tubes consume significantly more energy than tubes with lead bearings.

The friction generates heat which adds to the heat from X-ray generation and has to be removed. Active cooling of the bearing shaft leads to an enormous increase in apparatus required for operation due to additional cooling fluid, heat exchanger, pumps, etc.[75] *with the additional size and weight additions having a negative consequence on the operation of the equipment. Hospitals often have limited space so need the X-ray equipment to be a small as possible.*

6) *Use of molybdenum instead of steel*

The liquid metal contains gallium, which is highly corrosive at high temperatures. Therefore, the bearing has to be actively cooled to maintain temperatures below the temperature at which gallium attacks the metal (critical temperature T_{crit}). This critical temperature is much lower than the melting temperature of lead, which melts at ~ 300 °C. Gallium is aggressive to many metals including steel and so molybdenum has to be used to house the gallium alloy. The quantity and equivalent global warming potential of the molybdenum that is used is overall much larger than the steel that can be used in tubes with lead bearings.[76]

Table 8-1: Comparison of global warming impact

Type of bearing	Quantity of bearing housing metal	Global warming potential from production (kg CO_2-eq/kg)	Calculated global warming impact kg CO_2 eq per tube
Rotating anode tube example with lead bearings	600g Steel	1.5	0.9
Rotating anode tube with liquid metal bearings	1800g Molybdenum	5.7	10.26

Source: COCIR (2020a)

COCIR (2020a) calculated that the molybdenum in this example X-ray tube has an environmental impact from equivalent CO_2 emissions that is over 11 times larger than the steel in lead-bearing tubes. In addition, gallium has a much larger global warming potential (GWP) from its production than lead, and more gallium is used than lead for bearings:

- *Gallium production GWP: 205 kg CO2-eq/kg*
- *Lead production GWP: 1.3 kg CO2-eq/kg*

[75] Some of the largest types of X-ray tubes with lead coated steel bearings also need to be cooled but as there is no need for energy to overcome friction, these cooling units are typically smaller as less heat needs to be removed, although this depends on the application. COCIR 2020a.

[76] C.f. Life Cycle Assessment of Metals: A Scientific Synthesis, Philip Nuss, Matthew J. Eckelman http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0101298; source as referenced by COCIR 2020a.

COCIR (2020a) conclude that liquid metal bearing X-ray tubes cannot be used with most X-ray equipment because:

- *They are relatively heavy and bulky (including the cooling system) and so not suitable for mobile systems or systems that need to be used in confined spaces (very common in EU hospitals);*
- *They consume more energy to operate and require significant extra cooling equipment;*
- *Although lead bearings contain a very small amount of lead (< a few mg), the quantity of lead shielding needed for each tube is much more (many kg). The quantity of lead shielding required around the larger liquid metal tubes can be more than the total lead in the types of tubes with lead bearings due to the lead shielding plus lead in bearings); and*
- *The equivalent CO2 emissions for manufacture of the materials used in liquid metal X-ray tubes is far larger than those with lead bearings.*

8.2.2. Elimination of lead

Alternative designs of X-ray tubes: fixed anodes

COCIR (2020a) explain that the choice of medical X-ray tube design depends on a combination of X-ray output power and the time period for which the X-ray beam may need to be generated. Low or medium power for a very short period of time are unlikely to cause heat damages to the anode and so a fixed anode can be used. X-ray imaging equipment manufacturers will use fixed anodes if this is technically possible because these are simpler designs and lower costs.

COCIR (2020a) point out that medium or low power devices with the X-ray beam on for longer periods of time as well as some of the highest power X-ray devices such as some CT scanners require the use of rotating anodes with bearings since otherwise these use conditions will result in rapid damage to the anode.

8.2.3. Roadmap towards substitution or elimination of the restricted substance(s)

COCIR (2020a) state that most recent research has been to develop liquid metal bearings that are lead-free, although the reason why these have been developed was to achieve higher power output that is needed for CT scanners where lead bearings cannot be used. However, these cannot be used in other types of equipment as explained above.

COCIR (2020a) put forward that there are no alternative metals in the periodic table that have all of the essential properties that lead provides so that it is difficult to envisage that an alternative material will be discovered. Silver is the only potential alternative but because of the technical issues described above, usually cannot be used. Nevertheless, at least one manufacturer is planning to carry out further research with silver as a potential alternative although this will require the complete redesign of the X-ray systems in which they are used to ensure that the noise levels are at an acceptable level. This will be essential to obtain Notified Body approval although success is uncertain. Due to a lack of alternative bearing

materials, this exemption will be needed for many years in the future; at least another 20 years seems likely based on current knowledge.

8.2.4. Environmental arguments and socioeconomic impacts

COCIR (2020a) claim that liquid metal bearing tubes have a considerably larger environmental impacts than lead bearing X-ray tubes as illustrated in Table 8-1 and explained in the text on page 220. At end of life, most used X-ray tubes are returned to the manufacturer or their approved agents. Typically, the reusable parts of X-ray tube assemblies will be reused on average about three times before recycling of materials. However, ball bearings are not reusable and so are recycled.

As to the potential socioeconomic impacts in the case that the COM does not renew the exemption, COCIR (2020a) are afraid that EU hospitals would not be able to buy or replace the current range of imaging equipment or replacement X-ray tubes that they need to treat patients. If they are forced to use existing X-ray equipment for much longer than is normal, this older equipment will become increasingly unreliable as it ages so that it will more often be unusable. Therefore, there would be a gradual deterioration in overall health of EU citizens without this exemption as they more often cannot be treated. The EU estimates that there are about 600 million X-ray images taken each year in the EU although this includes dental X-rays which do not require rotating anodes. Assuming that about half of X-ray images require rotating anode X-ray tubes with ball bearings, then eventually, if rotating anode X-ray tubes cannot be sold in the EU up to 300 million EU citizens could not be examined by X-ray each year and their health would suffer, very significantly in most cases, as a result.

8.3. Critical review

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 criteria: 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.

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by* the REACH Regulation if the requested exemption would be granted/renewed.

REACH Annex XIV (2021) lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- *Lead chromate (entry 10);*

- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

A renewal of the requested exemption would not weaken the protection afforded by the listing of substances on the REACH Authorisation list (Annex XIV).

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16*[77] *and entry 17*[78] *restrict the use of lead carbonates and lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds*[79] *such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*
- *Entry 28*[80] *addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30*[81] *addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 63*[82] *restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72*[83] *stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

[77] 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

[78] 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

[79] 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

[80] 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

[81] 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

[82] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[83] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

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 cannot be considered 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.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status July 2021). Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

8.3.2. Scientific and technical practicability of substitution or elimination of lead

Substitution of lead by silver-coated bearings

COCIR (2020a) explain that silver-coated steel ball bearings are available as X-ray tube bearings but are usually too noisy for medical imaging applications. COCIR puts forward several reasons why in their point of view silver bearings are not used any more in new design X-rays:

- *The hard silver-coated balls cause excessive noise*
- *This noise indicates wear and would indicate a shorter lifetime.*
- *Sudden noise may disturb patients so that they move requiring repeated exposures to X-rays to obtain a clear image, and repeated exposure to X-rays is known to increase the risk of cancer.*
- *Noisy bearings can prevent the X-ray system from being approved by an EU Notified Body under the Medical Devices Directive.*
- *Noise disturbs medical staff, which can be a hazard to patients during operations or other treatments.*
- *Silver could also react with the steel base metal when it becomes hot causing grain boundary cracking leading to premature bearing failure. This will create additional waste due to inferior reliability, but also could harm patients when the X-ray imaging equipment is unexpectedly no longer usable. X-ray tube manufacturers have not seen cracking of steel due to lead.*

COCIR (2021a) is aware of a few medical uses of X-ray tubes that used silver coated bearings only in a few low rotation speed applications (~60Hz). In one discontinued application (no longer in use for new imaging equipment), higher temperatures were used by the manufacture to soften the silver coating, however the increased noise could not be overcome. The consumer accepted the higher noise generation for this singular application because at that time tubes with liquid metal bearings were not yet available. X-ray tubes with silver coated bearings are now sold only as replacement spare parts for this no longer produced type of X-ray system. Category 9 applications may still use silver bearings, but COCIR has no knowledge of category 9 X-ray equipment.

COCIR (2020a) mention a research initiative of a manufacturer to use silver coated bearings. COCIR (2021b) detail this initiative stating that manufacturers are carrying out research to replace lead as required by RoHS and this is one option that is being considered. It is not clear whether the problems associated with silver can be solved, so it is not possible to estimate accurate timescales. Currently, one manufacturer is investigating several failures observed during a development project into silver coatings. From the experiences of this project it can be determined that a substantial amount of development work is still to be undertaken.

The consultants can follow the applicant's arguments that at the time being silver bearings make substitution or elimination of lead scientifically and technically impracticable. The generation of sudden and high noise levels has adverse impacts that may affect diagnostic successes of X-raying patients. Additionally, the heat generated by X-raying may cause material deteriorations in the bearings that may reduce life time and reliability of the X-rays[84], and the harder silver surfaces compared to softer lead coatings increase the wear in the bearings. These problems may be solved in the future as the applicant points out some ongoing research projects which are not expected to produce results in time to place X-rays operating with coated silver bearings on the market within the next seven years.

Substitution of lead by ceramics

Ceramic bearings exhibit low friction, high durability and stability. They are used in many high quality and challenging applications ranging from ceramic highest quality hubs for bicycles to industrial hubs with high frequencies. X-ray tubes are operated with much lower frequencies, but such ceramic bearings should also be applicable in such conditions. COCIR was therefore asked whether ceramic bearings could be an option to enable substitution of lead in X-ray bearings.

COCIR (2020b) understand that there are two types of ceramic bearings used commercially. Pure ceramic bearings without lubricants are suitable only in low rotation speed applications whereas rotation speeds in X-ray tubes are very high (up to 9,700 rounds per minute = 162 Hz). At higher speeds hybrid bearings are sometimes used but require the use of lubricants. Lubricants cannot be added to bearings of X-ray tubes, because they must maintain a high vacuum for many years.

COCIR (2020b) continue that in X-ray tubes, heat dissipation is key as the Bremsstrahlung process converts the majority (99 %) of energy to heat which must be conducted away and a significant proportion of this is via the bearings, but ceramics in general show a low thermal conduction. The focal track on the anode becomes very hot reaching temperatures which can destroy the X-ray unit if the heat is not distributed over a larger surface area and subsequently removed from the unit, which is not feasible with ceramic bearings.

Further on, COCIR (2020b) says, the bearings also need to be electrically conductive for the X-ray tube to function correctly, with some manufacturers requiring up to 1 A current at

[84] https://app.aws.org/wj/supplement/WJ_1984_12_s355.pdf; source as referenced by the applicant

150 kV to be transferred with low resistance via the bearing to anode and cathode. All commercially available ceramic bearings are electrically and thermally insulating, so due to the intrinsic properties of ceramics, they cannot be used.

Yet another limitation of ceramic bearings is their poor resistance to shock loads as ceramics are relatively brittle materials in comparison with the coated steel bearings that are normally used. According to COCIR (2021b), such shocks can occur from unintentional impacts during transport and installation of X-ray tubes or during the service life of the equipment, e.g. if patients' beds accidentally impacting the X-ray machine.

COCIR (2020a) state that, because ceramics bearings can fail when impacted, they cannot be used as X-ray tube bearings. The consequence would be a so called "hard down situation", in which no further x-ray exposure and imaging as planned by the medical staff is possible in the clinical application (e.g. this could be with a catheter still inside the patient during a procedure).

The consultants can follow the applicant's above reasoning that ceramics are scientifically and technically impracticable to substitute lead bearings.

Substitution of lead by liquid metal bearings

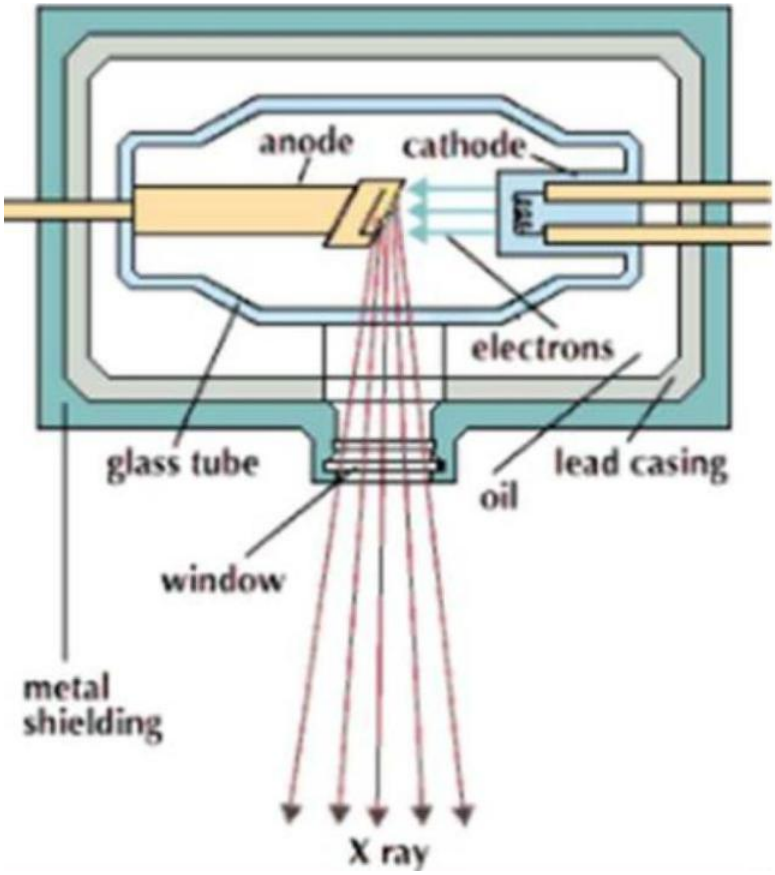
The applicant claims that X-ray tubes with liquid metal bearings require more lead for internal lead shielding (possible due to exemption IV-5) and provide the below comparison:

- Rotating anode tube example with lead bearings: 5.4 kg of lead shielding
- Rotating anode tube with liquid metal bearings: 8.3 kg of lead shielding

Liquid metal bearings are a lead-free solution and as such in principle could be an option to substitute or eliminate the use of lead. In the course of further exchange about the above additional lead shielding, COCIR (2021c) explain that these two examples of lead shielding are not based on an X-ray generating the same X- ray intensity because liquid metal bearings are only used for higher performance X-ray tubes. They included this example only to illustrate a typical difference in lead shielding quantity between these two types of X-ray tube bearings. The consultants therefore requested the applicant to explain the situation of additional lead shielding for the (fictive) case of two X-ray devices with the same X-ray performance.

COCIR (2021d) state that in a fictive example of identical X-rays the tube with liquid metal bearings in general would still require more lead shielding because liquid metal bearings are larger than lead bearings. To illustrate the situation, the applicant provides the below figure.

Figure 8-2: Outline of an X-ray tube

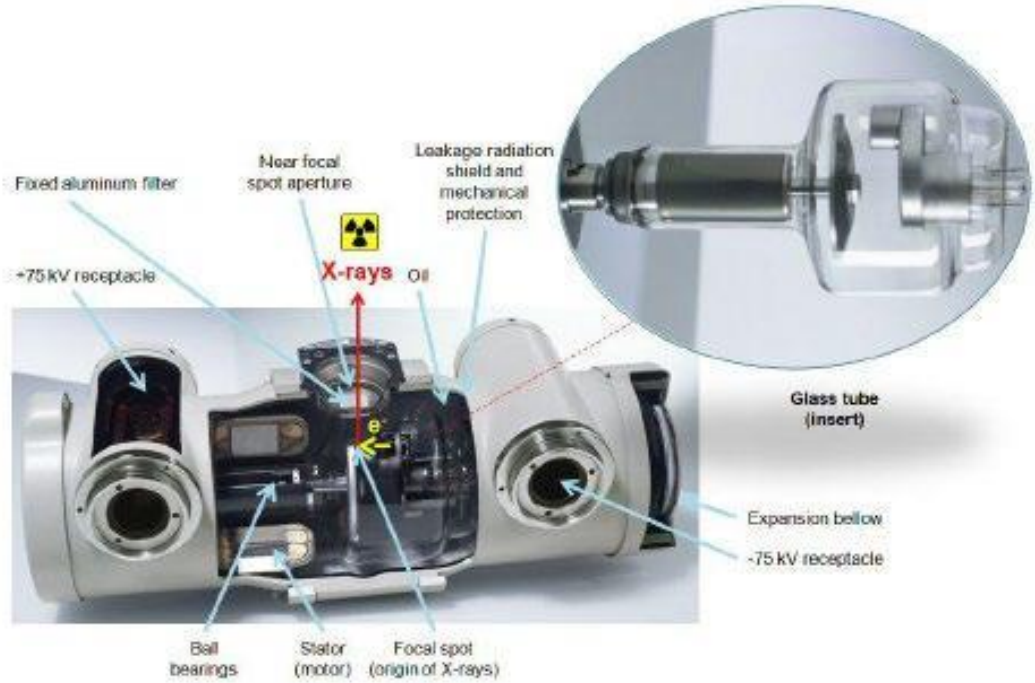


Source: COCIR (2021d)

The figure shows that the "X-ray tube" includes not only the glass tube but also the lead casing (= lead shielding) and the metal shielding. *What is not visible in the above figure is that the bearings for the rotation of the anode are located inside the X-ray tube as well according to COCIR (2021d).* This is illustrated in

Figure 8-2.

Figure 8-3: Conventional X-ray tube housing assembly with ball (lead) bearings



Source: COCIR (2021d)

This information substantiates the applicant's statement that if lead bearings were replaced by liquid metal bearings, the X-ray tube with the liquid metal bearings would generally be larger and therefore require more shielding than the X-ray tube equipped with the smaller lead bearings.

The effect can be assumed to be less drastic than in the above presented cases with around 54 % more lead in the shielding of the liquid metal X-ray tube. A higher performance X-ray with liquid metal bearings like assumed in that example requires an even bigger X-ray tube compared to a liquid metal X-ray tube with a performance level that would normally be constructed with lead bearings. Taking into account, however, that the total annual volume of lead placed on the EU market due to exemption 2 amounts to only 25 g, an even small amount of additional lead required for shielding would outweigh the lead substituted by the liquid metal bearings.

Considering liquid metal bearings as a substitute for lead bearings to avoid the use of lead could therefore overall considerably increase the use of lead provided the COM follows the consultants' recommendation to renew exemption IV-5 enabling the use of lead in X-ray bearings.

The applicant provided further arguments why liquid metal bearings may not be a substitute for lead bearings:

1) Larger, bulkier and heavier equipment due to more lead in the shielding and the active cooling

   Most X-ray imaging equipment, apart from CT, needs to be fairly small and compact because it has to be moved by hospital staff, either around the patient to focus on the required part of the body or moved around the hospital to different locations.

2) Higher power consumption because of higher friction and cooling

3) Use of molybdenum instead of steel to withstand the corrosive gallium at higher temperatures resulting in higher global warming potential (GWP). The use of gallium further increases the GWP versus the use of lead in the bearings. The use of more lead in the lead shielding would add to this effect as well.

Overall, the consultants follow the applicant's argumentation line that liquid metal bearings should not be considered as a substitute for lead bearings. Active cooling might not be required if lower performance X-rays were to be operated with liquid metal bearings, which would, however, not change the overall picture.

Other potential substitution or elimination possibilities

X-rays with fixed anodes do not require bearings and theoretically could be considered as a way to eliminate the use of lead. Practically, X-rays such as higher power and/or long time examination devices must be equipped with rotating anodes for technical reasons since the anode would otherwise be destroyed. The need of bearings complicates the X-ray device and increases the purchasing and operational cost as well as the space required in for the X-ray device in hospitals. The applicant's argument is therefore plausible that X-ray manufacturers will only design X-ray devices with rotating anode designs where these are technically indispensable. For this reason, the consultants abstained from lengthy discussions with the applicants about technical and use criteria that would exclude fixed anode X-rays from the exemption scope.

(Goodman 2006) indicated in his report that there was at least one manufacturer who had developed a new design of X-ray tube which did not have lead bearings. He stated that this new type of tube can used in a limited range of new product designs whereas most X-ray equipment will continue to use tubes with lead bearings. The applicant was asked to provide more details about this technology and its current status.

COCIR (2021b) answered that *"Given the timeframes since this information was first discovered and the fact that the design is patented, COCIR was unable to find further information on this technology."*

Neither the applicant nor any other stakeholder mentioned any current technology on the market that could eliminate the use of lead in lead bearings.

8.3.3. 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.*

COCIR request the renewal of exemption IV-2 for cat. 8 medical devices other than in-vitro diagnostic medical devices for the maximum validity period of seven years. The exemption – lead in bearings in X-ray tubes - is used in higher performance X-ray equipment which cannot be operated with fixed anodes and where the performance is not yet high enough to

require the use of liquid metal bearings. Silver bearings as a potential substitute may cause failures and are therefore not sufficiently reliable, and they are loud, which is not acceptable in this application. There is research to overcome these constraints, but it is not foreseeable that solutions are ready to be placed on the market within the next seven years for cat. 8 medical devices other than IVD.

Liquid metal bearings were discussed with the applicant as a potential substitute for lead bearings. If applied as substitutes, far more lead would, however, generally be required for the shielding of the then larger X-ray tubes than would be avoided in the lead bearings. Other disadvantages include the use of molybdenum instead of steel in the bearings, higher energy consumption for the operation of the rotating anode, and possibly additional cooling.

No technologies could be identified that would allow the elimination of lead for X-rays which require rotating anodes. In synopsis of all presented arguments and considerations, the consultants conclude that potential solutions to enable substitution or elimination of lead currently and in the foreseeable future are still scientifically and technically impracticable or are likely to outweigh the total environmental, health and consumer safety benefits thereof. Renewing the exemption in the consultants' point of view would therefore be justified in the light of Art. 5(1)(a). The ongoing research and development of silver bearings as a potential substitute is not expected to enable silver bearings in X-rays placed on the market in the next seven years. The status and progress of these projects should be assessed in case a next renewal of this exemption will be requested.

8.4. Recommendation

Based on the available information, the consultants recommend renewing the exemption. Substitution or elimination of lead are scientifically and technically still impracticable or their negative impacts are likely to outweigh their total environmental, health and consumer safety benefits. The applicants mention research into lead-free alternatives, but it is not foreseeable that this research results in lead-free solutions that could be placed on the market in the next seven years.

If the COM decides to follow the recommendation, the exemption should be renewed with the current wording and the below scope:

	Exemption	Scope and dates of applicability
2	*Lead bearings in X-ray tubes*	Expires on - 21 July 2024 for cat. 9 industrial monitoring and control instruments - 21 July 2028 for cat. 8 medical devices other than in-vitro diagnostic medical devices

COCIR (2020a): Application for renewal of exemption 2-IV. Online verfügbar unter http://www.rohs.biois.eu/Ex_2-IV_COCIR_Renewal-Request.pdf.

COCIR (2020b): Answers to questionnaire 1 (clarification questionnaire). Online verfügbar unter http://www.rohs.biois.eu/Ex_2-IV_COCIR_Questionnaire-1_Clarification.pdf.

COCIR (2021a): Answers to questionnaire 2 received from COCIR by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail.

COCIR (2021b): Answers to questionnaire 3 received from COCIR by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail.

COCIR (2021c): Answers to questionnaire 4 received by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail from Emily Tyrwhitt-Jones, RINA, on behalf of COCIR.

COCIR (2021d): Answers to questionnaire 5 received by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail from Emily Tyrwhitt-Jones, RINA, on behalf of COCIR.

Goodman (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report. ERA Report 2006-0383, July 2006, amended 19 Sep 2006. Unter Mitarbeit von Paul Goodman. Online verfügbar unter https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

9. Exemption 5 of Annex IV: Pb in shielding

The current wording of exemption 5 is as follows:

"Lead in shielding for ionising radiation"

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date was scheduled for 21 July 2023, and for IMCIs for 21 July 2024.

Declaration

In the sections preceding the "9.4 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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Information taken from applicants' documents is displayed in italics in all sections to enable its differentiation from the consultants' comments and arguments.

Acronyms and definition

JBCE	Japan Business Council in Europe
TMC	Test and Measurement Coalition
GWP	Global warming potential
IMCI	Industrial monitoring and control instruments
ITIA	International Tungsten Industry Association
IVD	In-vitro diagnostic medical devices
LCA	Life cycle assessment
Pb	Lead
CT	Computed tomography
PET	Positron emission tomography
SPECT	Single-photon emission computed tomography

9.1. Background

COCIR et al. (2020), i.e. COCIR, JBCE and TMC, submitted a request for the renewal of exemption 5 of Annex IV on 6 January 2020 with a slightly modified wording (modifications underlined) for the maximum validity period of seven years. The renewed exemption shall include cat. 8 medical devices other than in-vitro diagnostic medical devices (IVD) and cat. 9 monitoring and control instruments including industrial monitoring and control instruments (IMCI).

"Lead in shielding and in collimators used for ionising radiation"

No stakeholders contributed to the online consultation.

9.1.1. History of the Exemption

(Goodman 2006) recommended the Commission to grant this exemption if EEE of categories 8 and 9 will be added to the scope of the RoHS Directive. The exemption was listed on Annex IV of the Directive 2011/65/EU when it was officially published in 2011 including EEE of categories 8 and 9 into its scope. The application for renewal was submitted in time, and exemption IV-5 will be reviewed for the first time to adapt it to scientific and technical progress.

9.1.2. Summary of renewal requests and stakeholder contributions

According to COCIR et al. (2020), "Several types of medical imaging equipment utilise ionising radiation. It is essential that the safety of workers and patients is protected from stray radiation as well as to protect sensitive electrical circuits and so shielding is required as part of this equipment. Lead is usually the best material for radiation shielding and also for collimation of radiation. Lead has both significant technical advantages over other materials as well as having a significantly less negative overall health safety and environmental impact compared with alternative materials that might be considered. In some applications such as for anti-scatter grids, no suitable substitutes for lead exist. In applications where complex or intricate shapes are needed, this is currently possible only with lead. Many of the potential substitute metals (e.g. tantalum) are too brittle or are so expensive (e.g. gold) that hospitals could not afford to buy the medical device and there would be a significant risk that the expensive metal would be stolen."

No stakeholder contributions were submitted during the consultation.

9.2. Technical description of the requested exemption

9.2.1. Amount of lead used under the exemption

According to COCIR et al. (2020), the total amount of lead contained in category 9 devices sold in 2016 in the EU28 is estimated to be less than 20 tonnes.

The total amount of lead in shieldings in medical devices (category 8) is about 400 tonnes per year based on the following estimations:

X-ray imaging systems typically contain 10 – 16 kg of lead, with 14 kg being estimated as a typical amount. COCIR estimate that sales in 2016 in the EU28 countries were:

- *X-ray radiology digital non-mobile ca. 560 p.a.*
- *X-ray radiology digital mobile ca. 400 p.a.*
- *X-ray radiology analogue non-mobile ca. 86 p.a.*
- *X-ray radiology analogue mobile ca. 64 p.a.*
- *X-ray Mammography ca. 769 p.a.*

TOTAL number X-ray units 1,879 p.a.

Total amount of lead at an average of 14kg/unit: 26.3 tonnes p.a.

- *CT (25 kg lead per unit) ca. 1140 = 28.5 tonnes p.a.*
- *PET (100 kg lead per unit) ca.50 = 5 tonnes p.a.*
- *SPECT (ca. 300 kg lead per unit) ca.100 = 30 tonnes p.a.*

In addition, there is lead shielding in:

- *Replacement X-ray tubes estimated for all manufacturers at ca. 200 tonnes p.a.*
- *Estimated other uses ca. 100 tonnes p.a.*

9.2.2. Uses and function of lead in shieldings

The following paragraphs are provided by COCIR et al. (2020) in the exemption request:

Lead is used in various forms and shapes as follows:

- *Sheet, thicker sections and complex shapes are used as a barrier to X-rays;*
- *Machined and moulded parts of intricate shapes;*
- *Lead-bearing transparent glass*

Lead as ionising radiation shielding has the following uses:

- *Shielding – this is constructed from sheets of various thickness as well as complex shapes.*
- *Collimators – various types are used to either focus X-rays or to remove radiation that is not travelling in the correct direction to achieve a clear image. Fixed collimators are used at the windows of X-ray tubes for beam trimming and blade-types (made with stacks of thin sheets) are used as movable collimators are also used for beam trimming. Radiation can be scattered (e.g. by the patient and parts of the equipment) and this causes radiation to travel on many unintended directions which can lower quality images if not removed by a collimator (or an anti-scatter grid). The preferred design of lead collimators that are used with flat panel detectors have a hexagonal cell structure that resembles a bee's honeycomb. These are also known as anti-scatter grids.*
- *X-ray tubes – X-ray tubes are either made of high lead content glass or metals. Metal inserts are lined internally with lead sheet. All X-ray tubes contain a high vacuum and so must be perfectly sealed and this is fairly straightforward with glass.*

Glass is however relatively fragile and so larger heavier inserts are usually metal to prevent damage.

- *Viewing windows – These are essentially glass sheet that is used either as an integral part of a medical device or is used in a separate shielding screen between the radiation source and hospital staff. Patients who are being scanned or examined may be very ill and so must be continuously observed and this is easier and more reliable through a window than by viewing than via CCTV. Lead-based glass shielding used to protect hospital staff when they are observing the patient when being imaged and this is necessary where the position of the patient is critical, such as for mammography;*

The main types of medical device that utilise lead in radiation shielding are described below.

X-ray imaging equipment

Lead is used in various devices to improve X-ray images where lead is used for its radiation shielding properties, including:

- *Anti-scatter grids used to eliminate scattered radiation that would otherwise blur the image;*
- *As a layer of lead behind or in X-ray detectors to absorb X-rays;*
- *In glass of capillary plates used for X-ray collimation;*
- *Viewing windows, often used for mammography to ensure that the patient is in the correct position.*

Examples of X-ray imaging equipment that uses of radiation shielding include:

- *Computed Tomography (CT) which generates 3D images*
- *Radiography, used, for example for skeletal X-ray. Machines can be fixed or portable,*
- *Angiography, used for real-time viewing of the heart, blood flow, etc.*
- *Fluoroscopy, real time viewing of internal organs, usually using contrast agents*
- *Mammography.*

PET and SPECT

Lead shielding is also used in Positron Emission Tomography (PET) and single-photon emission computerized tomography (SPECT), which are 3-dimensional imaging techniques that detects β- and γ-radiation emitted from a variety of radio-isotopes that are given to patients to view specific parts of the body.

Both techniques use shielding to protect sensitive electronics and for collimators. Lead is used in the container that houses the PET and SPECT detector crystal and photomultiplier tubes to shield them from high energy photons. Another use of lead shielding in some products is around the edges of the PET detector module to prevent off-axis photons from the patient significantly from hitting the detector crystals which could cause misdiagnosis.

PET uses of lead to shield "out of field of view events" or "singles". Failure to shield these events will lead to increased noise in clinical scans as well as longer scans. There is also a risk of misdiagnosis if the image statistics are low.

In SPECT equipment, lead is used in collimators to significantly reduce the off-axis photons from reaching the scintillator crystal or digital detector (used to detect energetic photons from radioisotope sources in patients), which reduces scattered radiation and improves image quality (primarily contrast resolution). The optimal design of collimators is a hexagonal grid structure.

Radiotherapy

Higher energy radiation is used to destroy cancerous and benign tumours using a technique called radiotherapy. Various designs of equipment are used, but relatively thick layers of shielding are needed to protect hospital staff, the patient and electrical equipment. Collimators which also contain lead shaped to focus the radiation onto the tumour with as little radiation as possible reaching healthy tissue.

The material is required to have a high atomic number and high density to be effective. The thickness of shielding required depends on the energy of the radiation, the shielding material's atomic number, material density and the k-edge values of the shielding element or elements. The k-edge energy is that of the k-electrons of the element and x-ray absorption is more efficient when the energy of the ionising radiation is at and above the k-edge energy. At the energies used for medical imaging and for radiotherapy, the thickness of lead required as a barrier to ionising radiation will be less than that of metals which are less dense and have lower atomic number, such as steel.

Materials with lower atomic number or lower density would need to be thicker to achieve equivalent barrier performance to be effective as a barrier to ionising radiation and with many materials they would need to be considerably thicker. There is frequently very little space available for radiation shielding so that it is not technically feasible to use lower atomic number materials. Some forms of treatment require health workers (nurses, etc.) to have access to patients so shielding must not prevent this by reducing the space available. Thicker shielding would be severely restrictive if it had to be used and may also make it impossible to construct equipment with enough space for patients and access to them. The size of imaging equipment such as CT machines is dependent on the size of all the component parts that are required and these include radiation shielding to ensure that X-rays are focussed only where required and to shield hospital staff and the very sensitive X-ray detector and electrical circuitry.

9.3. Justification for the requested exemption

9.3.1. Substitution of lead

General requirements regarding the need for lead are described by the applicants:

- *Manufacturability is essential. Lead is easy to make into complex shapes by extrusion, deep drawing, rolling, brazing, etc., whereas materials such as tungsten and tungsten composites are much more difficult or impossible to fabricate into the required complex shapes.*

- *Some of the shielding used inside X-ray tubes is exposed to cooling oil. Metals are suitable, but polymer composites may absorb oil, swell and disintegrate so are unsuitable.*
- *It is essential that the shielding material is stable and does not degrade or disintegrate when exposed to ionising radiation.*
- *In some applications, high thermal conductivity is important to conduct heat away from warm electrical components*

Steel and concrete as a substitute for lead are excluded in most applications as they need to be much thicker due to the lower radiation number to achieve the same shielding effectiveness. Therefore, materials with high density and high atomic number are discussed in more detail (see Table 9-1), leaving tungsten as the only realistic option for discussion.

Table 9-1: Atomic number, density, and limitations of the heavier elements according to applicant COCIR et al. (2020)

Element	Atomic number	Density	Limitations
Uranium	92	19.05	Radioactive
Bismuth	83	9.8	Less dense so thicker material needed
Lead	82	11.3	Currently used
Thallium	81	11.8	Very toxic (as also is mercury atomic number 80)
Gold	79	19.3	Very expensive, likely to be stolen if used, making medical device un-usable and so harming patients
Platinum	78	21.1	Very expensive, likely to be stolen if used, making medical device un-usable and so harming patients, same with other platinum group metals.
Tungsten	74	19.3	Limited suitability as shielding, but see discussion below.
Tantalum	73	16.7	Has been evaluated but is difficult to fabricate and brittle so thin sheets are easily broken.
Hafnium	72	13.3	May be suitable, but less so than tungsten, difficult to fabricate and difficult to extract from minerals
Barium	56	3.51	Too reactive as a metal and gives inferior shielding glass due

Element	Atomic number	Density	Limitations
			to lower atomic number and density
Molybdenum	42	10.3	Similar density as lead but much lower atomic number so needs to be much thicker

According to JBCE (2021), "*The following are examples of technical constraints in which **tungsten** cannot be used as an alternative to lead for radiation shielding.*

- *It is difficult to obtain parts because the processing technology is not yet common.*
- *Since it is not as soft as lead, it cannot be applied to applications which it deforms into a free shape and closes the gap in the shield.*
- *It is not a substitute for lead-bearing transparent glass and acrylic which can pass visible light through.*
- *It becomes radioisotopes by high energy radiation.*
- *It cannot be welded to tungsten or to other metal frames."*

Metallic shielding

According to applicants COCIR et al. (2020):

- *Tungsten only partly usable because of more difficult manufacturability*
- *Drop-in replacement not possible due to more space (depends on specific tungsten material)*
- *Higher environmental impact according to LCA provided by COCIR [thinkstep (2018)]*
- *Higher price due to higher price of tungsten and more difficult manufacturability*

Collimators

Due to the small hexagonal hole size, such hexagonal-hole collimators cannot be made with materials other than lead according to COCIR et al. (2020). For pin-hole collimators, lead can be replaced by tungsten, which is already the case in many applications.

Transparent glass shielding and X-ray tubes

Lead-based glass is used as shielding and is used for constructing equipment such as some types of X-ray tubes and as windows to allow hospital staff to watch patients while they are being treated.

There are very few stable, tough and transparent glass materials that are efficient barriers to ionising radiation. Glass with a high lead content is easy to make and shape, it is not affected by water or humidity, so is stable and it has very good transparency. Most other

high atomic mass elements cannot be added to glass at high concentrations because they either will not form a stable, colourless, transparent material or they cause crystallisation which creates an opaque material. There are a few glass formulations that have been developed based on barium, which is sometimes used with lead. Barium has a lower atomic number and density than lead so the glass is less effective at shielding of radiation. Thicker windows would be needed, which would impair visibility.

9.3.2. Elimination of lead

No alternative technology is available which allows the elimination of lead.

9.3.3. Roadmap towards substitution or elimination lead

According to COCIR et al. (2020) and COCIR (2021c), a complete redesign of equipment to implement new shapes with tungsten instead of lead would need at least 8 years, if technically feasible.

According to COCIR et al. (2020), the following materials have been checked and deemed unsuitable as substitute:

- *"Tungsten – this can and is used for certain limited applications, however, it has technical disadvantages (…) which prevents its use in most medical devices. A significant reason for not using tungsten, however, is its substantially more negative overall environmental impact, as shown by the LCA.*
- *Tantalum – used as metal sheets, but these are very difficult to fabricate into shapes and are too easily broken so its use is impractical.*
- *Bismuth and barium compounds in polymer composites – these materials need to be considerably thicker to achieve equivalent shielding performance to lead and this makes their use impractical in applications where space for the patient and access by medical staff to the patient is limited (the situation with most medical devices). Testing has also found that these materials are too brittle and were easily damaged, such as from vibration or impact, making the equipment unusable*
- *Molybdenum has been assessed as a possible substitute, but us too hard and brittle to form into shapes with accurate dimensions and also needs to be much thicker than lead and a greater mass of material is needed, due to its much lower atomic number.*
- *There is some recent research with glass that contains both barium and bismuth, but as the atomic number and density of barium is much lower than lead and also the proportions of these heavy metals that can be added to the glass are much lower than can be achieved with lead in glass, this material has inferior shielding performance and so is usually unsuitable"*

According to COCIR et al. (2020), "*all high atomic number and high-density metals that give similar barrier properties to lead with the same or thinner sections have a very much larger overall negative health and environmental impact than lead. This situation is likely to change slowly in the future as energy generation switches from fossil fuels to renewable sources, but it is likely to be very many years before this makes a significant difference to the relative impacts of lead and other heavy metals.*"

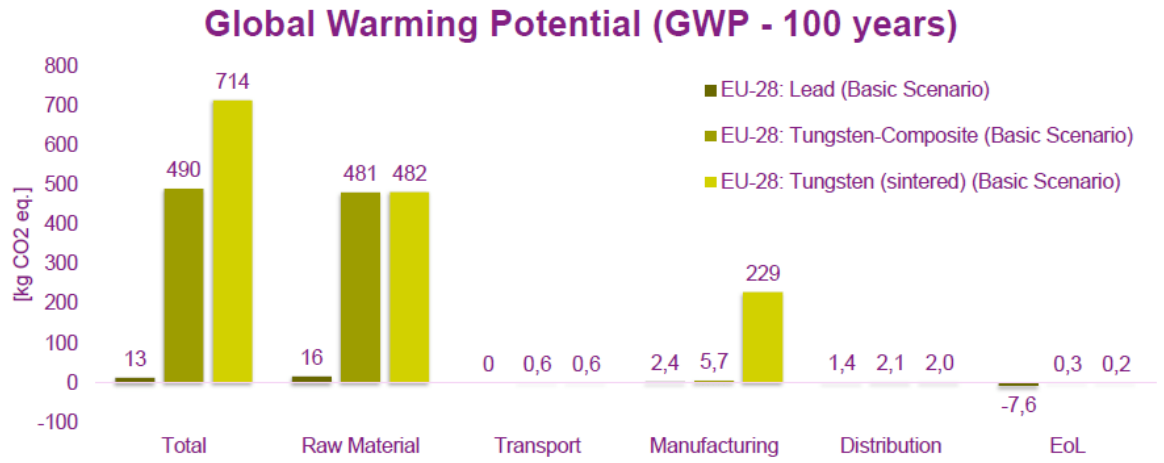
9.3.4. Environmental and socioeconomic impacts

Environmental arguments

The applicants provided a comparative LCA between **lead, sintered tungsten, and tungsten polymer** for radiation shielding (thinkstep (2018)). According to the baseline scenario (recycling of lead, landfill of tungsten at end-of-life), lead is preferable in all impact categories with much lower environmental impact. Scenarios with recycling options of tungsten polymer reduce the difference between lead and tungsten polymer.

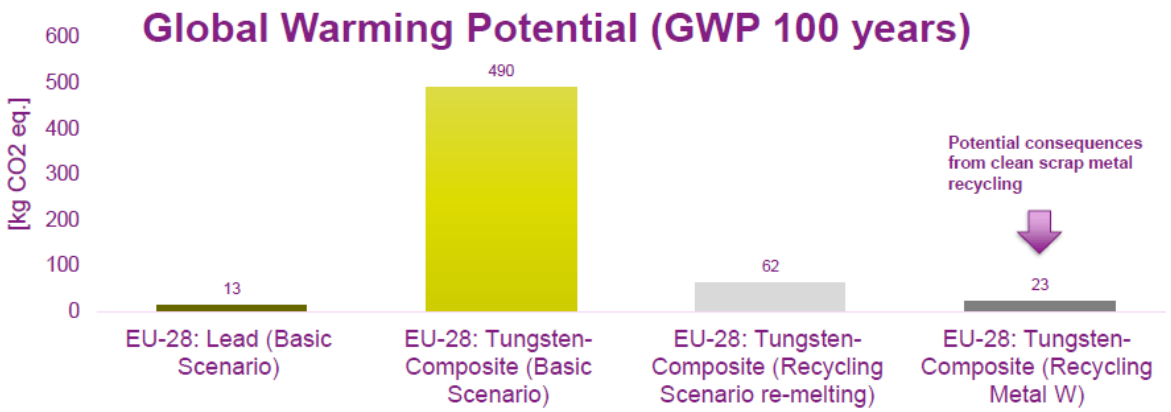
The differences in the result stem from raw material acquisition and for sintered tungsten also from the manufacturing phase (see Figure). Much of that can be reduced by assuming a material credit in the tungsten polymer recycling scenario (see Figure 9-2).

Figure 9-1: GWP for lead, tungsten polymer and sintered tungsten



Source: thinkstep (2018)

Figure 9-2: GWP for lead and tungsten composite with recycling of tungsten composite



Source: thinkstep (2018)

Socioeconomic impacts

According to COCIR et al. (2020), "*the material used should have a low overall environmental and health impact. Very expensive materials would prevent hospitals from being able to buy new medical devices and this would have a negative impact on the health of EU citizens.*"

"[I]f a high priced substitute was used; a) theft of the metal shielding would result in the equipment not being usable which would negatively affect patients (as they cannot be treated) and b) the higher cost (of tungsten, gold, etc.) would prevent hospitals from buying as much new equipment as at present, resulting in the average age of their equipment increasing. Older equipment can be less reliable and may have inferior diagnostic capability." COCIR et al. (2020)

"*All substitute materials have higher prices than lead. Metal price of tungsten is considerably higher than lead*[20] *and the price difference of collimators is even larger due to the higher cost of fabrication with tungsten than lead. There is also a possible increased cost due to increase in amount of waste if hard, brittle materials have to be used. Increased production costs would affect all medical equipment manufacturers equally and so the higher costs will be passed on to hospitals.*
The biggest impact is likely to be with collimators. Hospitals usually buy different types to optimise imaging for different isotopes used for PET and SPECT and for different medical procedures. A lead collimator typically costs $1500 where a similar tungsten collimator has been estimated to be $30,000. All EU hospitals have very limited budgets and this higher cost would mean that hospitals buy fewer types of collimator which could result in sub-optimal treatment." COCIR et al. (2020) This cost calculation is based on differences in the raw material price and estimated price differences in the manufacturing according to RINA (2021a).

"*As tungsten metal is often technically impractical and tungsten polymer composites need to be thicker (and have technical limitations), these cannot be used as drop-in replacements for lead. Therefore, if this exemption were not renewed, most types of imaging medical device could not be sold in the EU. New designs would be needed, although this may not be technically feasible without lead. If this exemption is not renewed, there would be no new medical devices suitable for X-ray imaging, PET, SPECT and diagnosis with these techniques available in the EU for many years, which would be very harmful to EU patients. If research can identify substitutes, this would take many years for redesign, prototype construction, testing, clinical trials and Notified Body approval, which typically takes at least 8 years.*" COCIR et al. (2020)

9.4. Critical review

9.4.1. REACH compliance – Relation to the REACH Regulation

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

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by*" the REACH Regulation if the requested exemption would be granted/renewed.

REACH Annex XIV (2021)[85] *lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:*

- *Lead chromate (entry 10);*
- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

The applications in the scope of the exemption at hand do not use any of the above lead compounds.

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16*[86] *and entry 17*[87] *restrict the use of lead carbonates and lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds*[88] *such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*
- *Entry 28*[89] *addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*

[85] ECHA, https://echa.europa.eu/authorisation-list?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

[86] 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

[87] 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

[88] 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

[89] 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

- *Entry 30*[90] *addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 63*[91] *restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72*[92] *stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

The exemption for lead used in shieldings 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, the use of lead in shieldings in the scope of the requested exemption 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.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status (October 2021) 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 the respective criteria of Art. 5(1)(a) apply.

9.4.2. Scientific and technical practicability of substitution or elimination of lead

Elimination of lead

Lead in shieldings could in principle be eliminated by using equipment which does not generate X-rays to achieve the same result as with X-rays, e.g. MRT scanners. The use of MRT scanners, however, at least in parts follow different indications so that they cannot replace X-ray imaging. In the absence of further technologies, the elimination of lead in shieldings is therefore currently scientifically and technically impracticable.

Scope clarification

COCIR et al. (2020) request to add collimators to the renewed exemption IV-5. The applicants were asked why collimators would need to be exempted now and not already in 2014. COCIR (2021a) explain that "*Collimators are an application of shielding. While not included in the wording in the original exemption that was part of RoHS 2 at the time of*

[90] 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

[91] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[92] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

publication, they were covered by the exemption anyway. This time we thought it would be better to name them explicitly in the exemption wording."

This justification is technically plausible as collimators can be understood as "shielding for ionising radiation" and the consultants recommend to add the collimators to the exemption to avoid uncertainties while it would not change the exemption scope. Pin-hole collimators can be produced and used with tungsten, but the applicants' environmental arguments should be considered in this context (c.f. section 9.4.3 on page 245).

Substitution of lead

According to the COCIR et al. (2020), "*Lead sheet is flexible so can be formed inside of X-ray tubes and other parts to perfectly conform to the inner surface including cable feed throughs. It can also be overlapped and formed to avoid seams and gaps*". This is not possible for very hard tungsten material, because it cannot be readily formed in the same way as lead.

Additionally, COCIR et al. (2020) claim that tungsten, except tungsten polymer, can only be manufactured in simple shapes. Complex shapes as needed for shieldings and collimators are not possible according to the argumentation. According to COCIR (2021a), melting and moulding of tungsten is not possible due to its high melting temperature and missing molding material.

However, this statement is rejected by the International Tungsten Industry Association (ITIA) in an email communication. According to (ITIA 2021), melting would not be the processing of choice but CNC milling and (partly) 3D printing of tungsten. The ITIA was contacted by the consultants during the critical review phase to obtain additional information on manufacturability of tungsten and recycling rates. According to ITIA (2021), tungsten alloys would be used for shieldings including collimators, which can be manufactured in different shapes by CNC milling or, comparably new, with 3D printing of tungsten according to (ITIA 2021). Offers[93] for tungsten shieldings including collimators could be found online, although it could not be clarified if all relevant shapes and applications are covered. The applicants of the exemption request could not substantiate their claim regarding "non-manufacturability" in face of these arguments.

The manufacturability of tungsten is therefore likely to be more expensive, but scientifically and technically practicable, and already applied in certain markets. It can be used for shieldings and collimators. COCIR et al. (2020) confirm this for pin-hole collimators, but state that hexagonal-hole collimators cannot be made with materials other than lead.

For transparent shieldings, there seem to be no alternative for lead. The only other material found in literature was barium, which was only applied for lower shielding effectiveness (Al-Hadeethi und Tijani 2019). Higher effectiveness would require much thicker shieldings, blocking transparency partly.

Overall, the reviewed information suggests that tungsten in principle can substitute lead in shieldings and collimators in the scope of exemption IV-5, but it cannot be excluded that there may be cases where lead is still required due to the complexity of shapes or for other technical reasons. Since the clarification of this situation would have required considerable

[93] https://www.wolfmet.com/applications/radiation-shielding-and-collimators/, https://www.plansee.com/en/products/components/radiation-generation-radiation-protection-and-beam-guidance/collimators-for-x-ray-detectors.html, https://www.dunlee.com/a-w/3d-metal-printing

efforts with uncertain prospects to be successful given the variety of shapes and applications, and because the applicants based their renewal request on environmental arguments, the consultants did not invest more time to detail the technical situation but focused on the review of the environmental arguments.

9.4.3. Environmental and socioeconomic arguments

Environmental arguments

COCIR presented results of an LCA provided by thinkstep (2018) in a slide deck. A full LCA report was not available. The comparative LCA for lead versus tungsten was reviewed by a third party RINA (2019), but by a single third party and not by a review panel, which is required by the respective ISO 14040 (section 7) /14044 (section 6). Therefore, the LCA is not considered fully compliant with ISO 14040/44 for its intended use in this exemption review process. Nevertheless, after consultation with the COM, the main findings are reviewed and taken into account:

The LCA results are dominated by very few data sets. The raw material acquisition phase causes the main environmental impact for tungsten polymer and sintered tungsten. This is based on one single data set for sintered tungsten according to the process plan in the provided slide deck called “tungsten metal powder (expert judgement)”. The data set itself was not part of the third party review.

The environmental impact values of the data set itself is not accessible for the consultants. A back-calculation shows about 28 kg CO_2e/kg (CO_2 equivalents) for tungsten metal powder. Other sources state much lower values, such as 2.8 kg CO_2e/kg tungsten by probas (2012) and 12 kg CO_2e/kg tungsten by Nuss et al. (2014) as also cited by the applicants at other parts of the exemption request.

The baseline LCA considers 100 % recycling of lead versus 100 % landfill for tungsten at end-of-life. According to COCIR et al. (2020), “*It is very common for X-ray imaging equipment, PET and SPECT to be returned to manufacturers by users. These are refurbished for reuse if possible otherwise parts are removed for reuse. Damaged and unusable parts are recycled. Therefore, most equipment is collected within a closed loop system*.”

According to COCIR et al. (2020), “*Many parts are refurbished including X-ray tubes, detectors, circuitry, etc*.” (about 200 tonnes), non-refurbished parts are recycled (about 300 tonnes) COCIR et al. (2020). This situation might be similar for tungsten shieldings. Reuse and refurbishment might even be more extensive, as tungsten is extremely hard and might show less mechanical wear.

COCIR et al. (2020) put forward that “[…] *the International Tungsten Industry Association estimate that 35 to 40 % of tungsten metal scrap is recycled. The true impacts are therefore somewhere between those of basic and best scenarios for tungsten metal, but the basic scenario for tungsten composites is more realistic. The International Lead Association estimate that 55 % of lead is recycled globally, however, close to 100 % of lead shielding from medical devices will be recycled due to its positive value*.”

In that context, the consultants do not follow the assumption that tungsten (alloy) would <u>not</u> be recycled 100 % from medical equipment like it happens for lead. Due to the higher price of tungsten, reuse and recycling of the respective parts may be even more attractive than for lead. The price for the raw material differs between 30,000 $ per tonne for tungsten and

2,477 $ per tonne for lead according to Metalary as stated in COCIR et al. (2020). Additional raw material cost for using tungsten thus increase for about 385 $ for X-ray imaging equipment (~14 kg per device) and 8,257 $ for SPECT (~300 kg per device). According to (ITIA 2021), recycling of tungsten is standard. The 35-40 % recycling rate quoted by the applicants refer to the worldwide average, not to the recycling of a specific device in a (nearly) closed loop system which the applicants assume for the medical devices. Therefore, the recycling scenario seems the more realistic comparison than the landfill scenario for tungsten.

Additionally, due to missing data, two different approaches were applied for lead and tungsten: "*lead Model is based on net scrap approach i.e. the required secondary input for the Lead production is fed with post-consumer scrap (less credit) (state of the art)*" thinkstep (2018). Thinkstep states in the slide deck "*An application of the net scrap approach to Tungsten might have a positive impact on the results*" thinkstep (2018). How that would impact the absolute values if data were available for both materials is not clear.

Looking at the materials which thinkstep (2018) compare in the provided LCA, ITIA states that the material used for comparison would not be the material of choice for shieldings. Tungsten polymer would degrade fast under radiation as also stated by COCIR et al. (2020). According to ITIA, **tungsten heavy alloy** would be used for shielding (ITIA 2021). It is not completely clear how this would affect the results. COCIR (2021b) states the following:

"*In terms of processing, the LCA considers for Tungsten (sintered) the manufacturing process of Grinding and Sintering based on Continuous Burning Ceramic process, resulting in a 2 % loss as a best case. Tungsten heavy alloys manufactured by powder metallurgical process and CNC milling is not likely to be dissimilar to this. It is worthwhile noting that even if the alternative processing resulted in a lower loss, this has been considered for tungsten composites which considered < 1 % loss, which still demonstrated a higher overall health, safety and environmental impact. We also believe that as tungsten heavy alloys are typically 95 – 97 % tungsten, the LCA will still be applicable.*

Our LCA did consider a scenario where tungsten metal is recycled (but as sintered powder and as composite). […] "in the case of Tungsten (sintered) the difference would be higher (GWP of Tungsten sintered approx. 252kg CO2eq.)". The LCA concludes that the energy for recycling tungsten composites would be similar to lead, if this were technically feasible - which it is not. The GWP for lead at 13 kg CO_2eq is much lower than of sintered tungsten that is recycled at 252kg CO_2eq. This large difference is likely to be due to the very hard nature of tungsten metal and its alloys which requires the consumption of considerable energy to grind these materials and also energy for sintering shapes at high temperature (typically at >1000°C)." According to RINA (2021b), the direction of impacts would be similar for the other impact categories as well. However, they were not calculated in the initial LCA.

In summary, it is very likely that the environmental impacts are higher for tungsten shieldings than for lead shieldings. The main difference thereby is caused by the manufacturing part, which is more energy intensive for tungsten. Differences between impacts of raw material acquisition of lead and tungsten are reduced with high recycling rates. Direct reuse of shieldings would reduce impacts of both materials even further.

Socioeconomic impacts

According to COCIR et al. (2020), *"[a] lead collimator typically costs $1500 where a similar tungsten collimator has been estimated to be $30,000"*. If tungsten was used instead of lead

the price difference for raw materials would result in additional costs of about 385 $ for X-ray imaging equipment (~14 kg per device) and 8,257 $ for SPECT (~300 kg per device).

Price differences due to more energy-intensive and more difficult manufacturing are likely but could not be quantified by the reviewers. The strong price difference for one collimator of 28,500 $ as well as the price increases for X-ray and SPECT devices could neither be verified nor dismissed. Higher raw material value would enhance the likelihood of recycling with higher revenues but would only materialize several years after the purchase of the devices. The consultants do not have access to any studies as to the price sensitivity of hospitals and other customers when purchasing such types of already very expensive equipment.

Overall, the consultants can therefore not exclude that the adverse impacts pointed out by the applicants (c.f. section 9.4.3 on page 245) might materialize if this exemption is not granted.

9.4.4. 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 applicants explained that there are severe technical constraints with the substitution of lead by tungsten, but they base their exemption request on environmental grounds rather than the scientific and technical impracticability of substitution.

The available information actually suggests that for transparent shieldings, lead-free alternatives have severe drawbacks. It can be concluded that substitution or elimination of lead in this type of shieldings is scientifically and technically impracticable.

For other applications, tungsten definitely has drawbacks regarding more difficult manufacturability and higher price, but substitution of lead in principle is scientifically and technically practicable. There are companies on the market offering shielding solutions without lead including for collimators. Whether tungsten can replace lead in all intransparent lead shieldings in the scope of the exemption was not be determined since the applicants based their exemption request on environmental arguments.

They claim that the environmental impact of tungsten used in shieldings is significantly higher than for lead. The LCA to support the claims does not fulfil the requirements of ISO 14040/44 but, after consultation with the COM, was nevertheless reviewed and taken into account. Several assumptions made in the LCA (use of specific substitutes, recycling quotes of substitute) were challenged by ITIA as stakeholder during the critical review phase. In conclusion, the overall environmental impact of lead in shieldings and collimators in the scope of exemption 5 is lower than for tungsten, but with much smaller differences between the materials than presented in the provided LCA.

Finally, the applicants point out higher costs of medical equipment for hospitals, leading to a lower number of products as broken equipment will not be replaced and no additional equipment purchased. Based on this, a less and older equipment would be available for the health care. The consultants could not verify the cost differences and thus cannot exclude those adverse impacts for health of patients could actually materialize if this exemption was not granted.

9.5. Recommendation

In the consultants' view, the available information shows that the substitution of lead in radiation transparent shieldings in the scope of exemption 5 is currently still scientifically and technically impracticable. Tungsten can substitute lead in other shieldings in the scope of exemption 5 even though it cannot be excluded that lead might still be required for specific shielding shapes and applications including collimators.

The provided information shows that lead causes less environmental impact than tungsten in shieldings and collimators. These negative environmental impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits of substitution.

Despite the at least partially technically practicable substitution of lead by tungsten, it is recommended to renew the exemption based on environmental arguments for five years with the below modified wording as proposed by the applicants:

	Exemption	Scope and dates of applicability
5	*Lead in shielding and in collimators used for ionising radiation*	Expires on - 21 July 2023 for cat. 8 in-vitro diagnostic medical devices - 21 July 2026 for category 8 medical devices other than in-vitro diagnostic medical devices, and for category 9 monitoring and control instruments including industrial monitoring and control instruments

The collimators were added to the exemption wording as a clarification of the scope. The exemption scope is thus neither extended nor restricted, and a transition period from the current to the renewed exemption is thus not required.

The time period for the exemption is limited to five years due to the limited reliability of the provided life cycle assessment. It was concluded that at the moment the benefits outweigh the negative impacts using lead. However, some doubts are left. It is recommended to renew the life cycle assessment if a future exemption request should be based on environmental arguments. Thereby the LCA should address the aspects, which were considered critical:

- review process through interested parties including a review of the life cycle inventory data
- comparison with specific material alternative used for radiation shielding and collimators (e.g. tungsten heavy alloy)

- realistic and comparable assumptions regarding end-of-life treatment.

9.6. References

Al-Hadeethi, Y.; Tijani, S. A. (2019): The use of lead-free transparent 50BaO-(50-x)borosilicate-xBi2O3 glass system as radiation shields in nuclear medicine. In: *Journal of Alloys and Compounds* 803, S. 625–630. DOI: 10.1016/j.jallcom.2019.06.259.

COCIR (2021a): Answer to Questionnaire 2, received from Riccardo Corridori, COCIR, via e-mail by Marina Proske, Fraunhofer IZM.

COCIR (2021b): Answer to Questionnaire 3, received from Riccardo Corridori, COCIR, via e-mail by Marina Proske, Fraunhofer IZM.

COCIR (2021c): Answer to Questionnaire 5, received from Riccardo Corridori, COCIR, via e-mail by Marina Proske, Fraunhofer IZM.

COCIR et al. (2020): Exemption Renewal Form – Exemption 5, Annex IV. Unter Mitarbeit von COCIR, JBCE, TMC. Online verfügbar unter https://rohs.biois.eu/Ex_5-IV_COCIR-JBCE-TMC_Renewal-Request.pdf.

Directive 2011/65/EU: 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 (recast). RoHS 2. Fundstelle: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065.

Goodman, Paul (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report July 2006, amended 19 Sep 2006. ERA Report 2006-0383. Unter Mitarbeit von Paul Goodman, ERA Technology Ltd. ERA Technology Ltd. Online verfügbar unter https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf.

ITIA (2021): Email correspondence with Burghard Zeiler, ITIA: Recycling of tungsten composite?, 01.03.2021. Email an Marina Proske.

JBCE (2021): Answer to Questionnaire 5, received from Takuro Koide, JBCE, via e-mail by Marina Proske, Fraunhofer IZM.

Metalary: Tungsten Price. Online verfügbar unter https://www.metalary.com/tungsten-price/.

Nuss et al. (2014): Life cycle assessment of metals: a scientific synthesis. In: *PloS one* 9 (7), e101298. DOI: 10.1371/journal.pone.0101298.

probas (2012): Umweltprofil Wolfram. Hg. v. Umweltbundesamt. Online verfügbar unter https://www.probas.umweltbundesamt.de/php/prozessdetails.php?id={A4A89322-AC81-4FA2-BB1C-5EE0B77E9180}.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

RINA (2019): RoHS exemption 5 Annex IV - Assessment of comparative cycle assessment for lead and tungsten. Report No. 2019-0870. Online verfügbar unter https://rohs.biois.eu/Ex_5-IV_LCA_REG0364001_COCIR.pdf.

RINA (2021a): Answer to Questionnaire 6, received from Emily Tyrwhitt Jones, RINA, via e-mail by Marina Proske, Fraunhofer IZM.

RINA (2021b): Answer to Questions by email, received from Emily Tyrwhitt Jones, RINA, via e-mail by Marina Proske, Fraunhofer IZM.

thinkstep (2018): Comparative life cycle assessment; LCA study commissioned by COCIR. RoHS Exemption for Lead - Project Delivery. Unter Mitarbeit von Constating Herrmann Marta Bonell, Timo Brechenmacher, thinkstep. Online verfügbar unter https://rohs.biois.eu/Ex_5-IV_LCA_REG0364001_COCIR_Presentation.pdf.

10. Exemption 11 of Annex IV: Lead in alloys in MRI

The current wording of the exemption is:

"Lead in alloys as a superconductor and thermal conductor in MRI"

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date was scheduled for 21 July 2023, and for IMCIs for 21 July 2024.

Declaration

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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Information taken from applicants' documents is displayed in italics in all sections to enable its differentiation from the consultants' comments and arguments.

Acronyms and definitions

A	Ampere
Bi	Bismuth
EEE	Electrical and electronic equipment
Hc	Critical magnetic field strength; magnetic field strength above which a superconductor develops electrical resistance and is no longer superconductive
In	Indium
IVD	In-vitro diagnostic medical devices
Jc	Critical current density; current density above which a superconductor develops electrical resistance and is no longer superconductive
MRI	Magnetic resonance imaging
NMR	Nuclear magnetic resonance
Nb	Niobium
Pb	Lead
Sb	Antimony

Sn	Tin
Tc	Critical temperature; temperature above which a superconductor develops electrical resistance and is no longer superconductive
Ti	Titanium

10.1. Background and Technical Information

COCIR (2020a) requested the renewal of the above exemption on 2 January 2020 for the maximum validity period of seven years with a slightly modified wording:

Lead and its alloys as a superconductor and thermal conductor in MRI

The proposed modified wording explicitly exempts the use of lead additionally to lead in alloys, while the current wording only refers to lead alloys. The applicant requests the renewal for cat. 8 medical devices others than IVD.

10.1.1. Summary of the exemption request

COCIR (2020a) summarize their exemption request as follows:

"Lead and its alloys are used to make superconducting and thermal bonds to superconducting electromagnet coils of medical Magnetic Resonance Imaging (MRI) scanners. Superconducting materials must be used to achieve the very powerful magnetic fields needed to obtain clear MRI images. The bonding material that contains lead must be a superconductor as otherwise, the large current used to generate the powerful magnetic field would cause enough heat to raise the electromagnet coil's temperature above the superconducting critical temperature; rapid heating would occur and the MRI would not function. Very few metals suitable for making bonds are superconductors at the temperature required for the magnet coils to be a superconductor and only lead and certain of its alloys meet all of the essential requirements which include an ability to be formed into a reliable bond.

This exemption needs to be renewed for the foreseeable future to allow new MRI to be sold in the EU as no substitute materials or designs exist with proven reliability for decades at low temperatures.

MRI manufacturers have assumed that exemption 11 is the applicable exemption for superconducting and thermal bonds made with lead or lead alloys in MRI. However, lead as a thermal conductor (used in cryocoolers, cold heads, i.e. cryorefrigeration components) has been assumed to be covered by exemption 29, so does not also need to be included in exemption 11. COCIR has learned that some manufacturers, especially NMR manufacturers, rely on exemption 12 for lead in superconducting bonds to superconducting electromagnet coils used in both MRI and NMR. Only one of these exemptions would appear to be needed to cover superconducting and thermal bonds as described in this renewal request."

10.1.2. History of the exemption

Goodman (2006) recommended this exemption to be granted in case EEE of category 8 (medical devices) would be integrated into the scope of the RoHS Directive. The exemption was listed as exemption 11 of Annex IV in the (Directive 2011/65/EU) and is now reviewed

for the first time to adapt it to scientific and technical progress after the submission of COCIR's request for the renewal of this exemption.

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

According to COCIR (2020a), "[…] *the exemption is used in MRI medical devices including MRI/CT and MRI/PET. MRI scanners are used to obtain three-dimensional images of soft tissue and organs in human patients. MRI applies a very powerful circular electromagnet into which patients are placed to expose them to a very powerful magnetic field. "Radio Frequency (RF) send and receive coils" are located around the patient and inside the magnetic field and these transmit RF signals which excite magnetised protons in soft tissue and organs of the patient and the protons then emit characteristic signals that are received and measured by these coils and this is used to generate the image."*

COCIR (2020a) explain that "[…] *the circular electromagnet has to be very powerful to obtain detailed images since image quality improves as the field strength increases. Modern MRI devices therefore use magnets of 0.3 Tesla (T) to 7 T and higher, depending on the type of diagnostic techniques that are used and image quality required, although 1.5 and 3 Tesla magnets are the most commonly used clinical types."*

According to COCIR (2020a)*, "[…] the only way that high power MRI electromagnets can be made is to use superconductors for the electromagnet coil. The magnetic field strength is proportional to current and number of turns of superconducting wire so the powerful magnetic field is achieved by passing a high current, typically of 400 A to 800 A (Ampere) for 1.5 and 3 T MRI scanner, through many kilometres of superconducting wire. At ambient temperature, all metals have a small electrical resistance so that passing this very large current will cause heating of the wire and its connecting bonds raising their temperature significantly and potentially this heat could destroy insulating materials or even melt the metal. MRI magnets overcome this issue of resistance heating by using superconducting coils that have zero electrical resistance at very low temperatures so that the passage of high current generates no heat."*

It is important, COCIR (2020a) state, "[…] *that the bonding material is a superconductor as well because passage of 800 A through a material with even a small electrical resistance will cause at least enough heat to warm the superconducting coil to above the critical superconductor temperature so that it is no longer a superconductor. The increased temperature would also boil away the liquid helium which would be lost. It is currently not possible to achieve the high magnetic field strength (> 0.4 T) required in an MRI device with an electromagnet coil at ambient temperature or without superconducting materials at very low temperature. This has been the state of the art now for several decades.'*

COCIR (2020a) describe that "[…] *superconductors used for large reliable MRI magnets are niobium (Nb) alloys, usually niobium-titanium (NbTi), although niobium-tin (NbSn) can also be used. NbTi wire is fairly brittle, especially at low temperatures, so it needs to be supported by embedding it into copper which acts as a physical support. Nb alloys are superconductors only at temperatures below 9.4 K. They are either immersed in liquid helium which has a boiling temperature of 4.2 K or they are in good thermal communication through thermally conducting bonds with a cooling system that operates at ~4.2 K. Modern MRI designs are very efficient. There is no steady loss of helium so long as power and water cooling are provided for the cyrorefrigeration system while the MRI is in normal use and*

only small amounts are vented during maintenance. Some helium can be lost if a fault occurs or if the magnet needs to be switched off in an emergency. This is important because the global helium supply is very limited, global shortages have occurred and MRI cannot be used without it."

The superconducting coil, COCIR (2020a) explain, "[…] [*has to be electrically connected to the power supply to be energised. The bonding material that is used must not generate heat due to resistance heating when the current is passed, because this would raise the temperature of the bonding material and the connected superconductor coil so that the coil is no longer superconducting. Heating of the bonding material is avoided by using bonding materials that are also superconductors at 4.2 K so that no heat is generated at the bonds to the superconducting coil. Previously, an alloy containing lead and cadmium was used (Woods alloy), but cadmium-free alloys can now be used and lead metal and lead-bismuth alloy have been found to be the most suitable superconductors for bonding. Each MRI manufacturer has own proprietary designs so there is variation in the bonding materials that are most suitable and used. "*

COCIR (2020a) demand that the material used to make bonds to MRI coils must have all of the following properties which the currently used Pb and PbBi alloys can provide:

- *Superconductor at temperature of MRI coil (at 4.2 K) and ideally at temperatures higher than 4.2K*
- *Must remain a superconductor when passing the required current to MRI coil. All superconductors cease to be superconducting when passing currents above their critical current density value of the material, so they should have a relatively high critical current.*
- *Must remain a superconductor when exposed to intense magnetic field from the MRI coil. All superconductors cease to be superconducting when exposed to intense magnetic fields above their critical field strength values, so high critical field strength values are required.*
- *Must be suitable for making electrical connections between MRI coil and external power supply. This requires:*
- *A fairly low melting point (< 400 °C)*
- *No interaction with niobium alloy superconductor alloys*
- *Have some ductility, including at liquid helium temperature. After bonds are made, these are cooled from ambient to -270 °C. As the thermal expansion coefficients of Cu/NbTi and solder will be different, this mismatch induces a significant strain which would cause de-bonding if the solder is not ductile.*
- *Resistance to vibration from MRI*
- *The material must not create intermetallic phases that are not superconductors at the boundary between copper, NbTi and the bonding material*
- *The bond material must be stable in all of its temperature use range*

10.1.4. Amount of lead used under the exemption

COCIR (2020a) declare both lead-bismuth solder alloys as well as lead metal solders to be used with lead contents from around 40 % to 99.9 %. The amount of lead used per MRI under the exemption varies depending on manufacturer and MRI design. With an average of 1 kg lead per MRI device and around 900 of such devices sold in the EU, the approximate annual volume of lead used under the exemption amounts to around 1,000 kg in the EU.

10.2. Applicant's justification for the requested exemption

10.2.1. Substitution of lead

COCIR (2020a) present metallic elements other than lead and their alloys that are superconductors and add that many non-metallic superconducting materials have been developed. Bonding with metals is more likely to be technically possible than using non-metal conductors, so metallic bonds are considered first. When bonding with lead, the lead melts and flows over the copper/Nb-Ti magnet coil material to make an electrical connection between the lead and NbTi alloy. Lead is a good choice because it does not form intermetallic phases with copper or react with the Nb-Ti. Intermetallic phases, such as tin/copper, would form if tin alloys were used. These are usually not superconductors. The other important properties of the metal used for bonding are:

- *Critical temperature (Tc) above which superconductivity is lost*
- *Critical field (Hc) above which superconductivity is lost*
- *Critical current, (Cc) above which superconductivity is lost.*

Table 10-1 displays the characteristics of lead and other metals that are superconductors at atmospheric pressure and may be considered for bonding due to their fairly low melting temperatures.

Table 10-1: Comparison of metallic superconductors

Metal	Tc (K)	Hc (mT)	Other limitations	Critical current
Lead – Bismuth (60 % lead)	8.4	1 770 at 4.2K		2 x 10^8 A/m^2 at 0.1 T, 1.3 x 10^8 A/m^2 at 0.2 T
Lead	7.19	80.34	Lower Hc than PbBi but fairly high Tc so is suitable in some MRI designs. Hc is higher with addition of Bi, Sb, In, etc.	
Tin	3.72	30.55	Reacts with copper to form SnCu intermetallic compounds. Disintegrates at low temperature due to “tin pest”. Tc is too low	
Tin – Indium (Sn50 %In50 %)	6.5	640 but can drop to < 100 after aging	Most promising substitute, but has a lower Hc than PbBi alloy and also has a lower critical current.	
Other tin alloys	2.3 to 4.8	40	Tc and Hc too low	
Indium	3.41	28.15	Tc too low as below boiling temperature of He.	
Gallium	1.08	5.93	Tc too low as below boiling temperature of He.	
Cadmium	0.52	2.8	Toxic, RoHS restricted. Some alloys with cadmium have higher Tc, but Hc is lower than lead alloys	
Zinc	0.86	5.4	Tc too low as below boiling temperature of He.	
Niobium (for comparison)	9.25	173	Too high melting temperature, much higher than copper.	
$Sn_{33}In_{50}Bi_{15}$	6.9	180		< 10^7 A/m^2 at 0.1 T, zero at 0.2 T

Source: COCIR (2020a), COCIR (2021a)

COCIR (2020a) add that some metals, such as elemental barium and bismuth are superconductors only at high pressure (or as alloys) and so these elements would be technically impractical. Also, their Tc values are mostly below 4 K, which is the boiling point of liquid helium and the temperature at which it is retained in MRI scanners.

COCIR (2020a) explain that the magnetic field of MRI reaches many Tesla at the location of the patient. MRIs have to be designed in a way that the bonds to the coil are in zones of

lower field strength below the bonding materials' critical field value, but high Hc values are essential. This is technically possible for lead and for lead-bismuth in commercial MRI as these have higher Hc and Tc values than other lower melting temperature metals as shown in the table above.

COCIR (2020a) state that there are no other metals in the periodic table that have relatively low melting temperature well below that of copper and have Tc values sufficiently higher than 4 K so that they behave as superconductors when passing a large current and in the magnetic field. COCIR (2020a) conclude that lead and its alloys are therefore the only technically suitable option.

COCIR (2020a) and COCIR (2021a) report research carried out with ternary alloys. Sn-In with the addition of third elements have been shown to increase the critical field and critical current values but to values that are much lower than that lead-bismuth alloy. BiSnIn and SnInSb alloys have been shown to be superior to SnIn, but are very inferior to lead-bismuth and so are unsuitable.

10.2.2. Elimination of lead

COCIR (2020a) put forward that research into several alternative bonding methods has been carried out, but with only limited success.

Cold pressing

According to COCIR (2020a), research[94] has been carried out on a laboratory scale only: Low resistivity bonds have been achieved by joining NbTi wires by cold pressing, but these are inconsistent and the bonding method is difficult to carry out and requires very hazardous chemicals such as hydrofluoric acid. This type of bonding between two NbTi wires requires that the copper encapsulation is first removed and then that the metal surface is oxide free. Copper can conveniently be dissolved using nitric acid but this leaves an inert coating of niobium oxide as well as residual copper on the superconductor wires that prevent bonding. Alternative methods of removal of copper all leave some oxide coating and residual copper. Removal of oxide has been investigated using hydrofluoric acid based etchants which appears to be effective at oxide removal (but less so for copper) but longer-term testing of bonds shows that results are very variable and superconductivity properties deteriorate. Research at Oxford University showed that oxide and copper at the bond boundary prevent effective bonding.[95]

Spot welding (COCIR (2020a))

Spot welding[95,96] of pairs of niobium alloy wires has been shown to form reasonable metallic bonds. This method causes the metal to melt, disrupts the oxide coating and forms a bond.

[94] Review article: Persistent Current Joints between Technological Superconductors, G. Brittles, et.al., Superconductor Science and Technology, Volume 28, Number 9, 2015; Source as referenced by COCIR 2020a.

[95] Superconducting Joints for Magnet Applications, Susie Speller, downloaded from https://www.stfc.ac.uk/files/superconducting-joints-for-magnet-applications/; source as referenced by COCIR 2020a.

[96] Superconducting Joints for Magnet Applications, Susie Speller, downloaded from https://www.stfc.ac.uk/files/superconducting-joints-for-magnet-applications/ Review article: Persistent Current Joints between Technological Superconductors, G. Brittles, et.al., Superconductor Science and Technology, Volume 28, Number 9, 2015; Source as referenced by COCIR 2020a.

However, testing of spot welded NbTi wires shows that these have poor (low) critical current values. Techniques to improve the critical current have been investigated and progress is being made so that this may form the basis of a suitable bonding method in the future. However, at present it is technically impractical with commercial MRI electromagnets.

Composite solders (COCIR (2020a))

Bonding using a mixture of lead-free BiInSn solder with a dispersion of strands of NbTi superconductor have been evaluated[97]. This gave superior performance to the BiInSn solder alloy alone, but was very inferior to PbBi alloy solder.

Non-metallic superconductors (COCIR (2020a))

Non-metallic superconductors which are essentially ceramics cannot be used for bonding for several reasons. The main reason being because they have too high melting points or decompose without melting. The first so-called “high temperature” superconductor to be developed (yttrium barium copper oxide) melts at over 1000°C so is impractical as a bonding material to copper which melts at 1085°C. To date, bonding of copper NbTi coils to non-metal superconductors as a means of making connections to MRI magnets has not been possible.

Many of the high temperature superconductors are mixed oxides. When heated to very high temperature to bond to copper or other metals, chemical reactions are likely to occur that would change the copper content and the oxygen stoichiometry so that the superconducting properties change or are destroyed.[98] Academic research into bonding to high temperature superconductors is being carried out, but the use of high temperature superconductor bonding to NbTi is not yet technically feasible.[99]

Other bonding methods (COCIR (2020a))

Other bonding methods used for electrical circuits like electrically conducting adhesives are not suitable for use at 4 K as they will become too brittle. The conductor materials used (copper, silver and gold are most common) are not superconductors so would generate heat that destroys the superconducting properties of the magnet coil.

Roadmap towards substitution or elimination of lead (COCIR (2020a))

Alternative electromagnet designs and materials

One potential future way to avoid lead may be to change the electromagnet materials so that it does not need to operate at liquid helium temperatures. Research into the use of so-called high temperature superconductors (these can operate in liquid nitrogen, i.e. below around 77 K (−196 °C)) is being carried out but has not yet been successfully used in commercial MRI. Even if high temperature superconducting electromagnet coils could be

[97] Lead-Free Persistent Mode Joints Between NbTi Wires, T J Davies, M Bristow, T Mousavi, A Thomas, M Lakrimi, C R M Grovenor and S C Speller, dowloaded from https://www.stfc.ac.uk/files/superconducting-joints-for-magnet-applications; source as referenced by COCIR 2020a.

[98] Review article: Persistent Current Joints between Technological Superconductors, G. Brittles, et.al., Superconductor Science and Technology, Volume 28, Number 9, 2015; source as referenced by COCIR 2020a.

[99] https://data.oecd.org/healthcare/magnetic-resonance-imaging-mri-exams.htm; source as referenced by COCIR 2020a.

made large enough for MRI and be reliable, an electrical connection would still be needed and the preferred material for this with proven reliability is lead. High temperature superconductors are being researched for use in powerful electromagnets for NMR and MRI but it seems likely that these will be used at liquid helium temperatures to maximise critical field strength and so lead or lead alloys would be the only suitable bonding material.

Several companies now sell tape with superconductor coatings including BASF who supply tape with yttrium-barium-copper oxide (YBCO) superconductor coating and Fujikura whose tape has a coating of GdBa2Cu3Ox. SEI sell lead-doped BSCCO wire which is used in superconducting electromagnets[8]. YBCO is not ideally suited for powerful electromagnets because it has a low critical current[9] although it has been evaluated as a possible superconducting power cable. Fujikura claim that GdBa2Cu3Ox is suitable for high power electromagnets and based on research carried out at CERN[10], very high magnetic fields may be possible eventually in the future (although this may be at liquid helium temperatures).

Bonding to superconductors

As with current MRI, one technical problem is how to make electrical connections to a high temperature superconducting magnet coil. As high currents will need to be passed to achieve powerful magnetic fields, these connections must have very low electrical resistivity. There are no metals that are superconducting at liquid nitrogen temperatures and so the design must rely on very low electrical resistance to avoid excessive heat generation and suitable materials and designs are still the subject of on-going research. High temperature superconductor MRI are however likely to be used at liquid helium temperatures as this would allow much higher magnetic field strengths to be used than at liquid nitrogen temperatures, which will improve image quality. At this temperature, only superconducting lead-based bonds are suitable.

Siemens and Mitsubishi have developed demonstration electromagnets for MRI, although these are relatively small with coils being suitable for small animals such as a mouse only. Scaling up will entail very significant challenges. MRI experience severe vibration in use whereas ceramics are usually brittle materials and so long-term reliability will be a concern.

It could be many years before commercial high temperature superconductor-based MRI with proven reliability and with Medical Device Regulation approval from EU Notified Bodies can be used in the EU. However, bonding material to the superconductor coils will be required and the same lead and lead alloy bonding methods used for NbTi coils are likely to be needed.

10.2.3. Environmental arguments and socioeconomic impacts (COCIR (2020a))

There would be a significant negative impact on the health of EU citizens if this exemption is not renewed. Without this exemption, EU hospitals would not be able to buy new MRI equipment that they need to treat patients. Old equipment becomes increasingly unreliable as it ages so that it will often not be usable. Also, modern designs can provide superior diagnostic capability compared to older models. Therefore, there would be a gradual deterioration in overall health of EU citizens without this exemption, although it is not possible to quantify this.

The OECD estimates that about 14 million MRI scans are carried out in the EU annually. Without this exemption, this number will gradually decline as MRI become too old but cannot be replaced. This would result in a growing number of EU patients not being able to be diagnosed using the most suitable technique, which is often MRI. Use of alternatives (if possible) can result in much later diagnosis or misdiagnosis, both resulting in serious health implications and higher healthcare costs. Quantification of the number of patients in the EU affected is difficult but could reach several millions within five years as most MRI have a lifetime of seven to ten 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.

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV as an element. The fact that lead is a candidate substance therefore at the time being does not weaken the "*environmental and health protection afforded by*" the REACH Regulation.

REACH Annex XIV (2021) lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- *Lead chromate (entry 10);*
- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

The above substances are not relevant in the context of the exemption at hand. A renewal of the requested exemption would not weaken the protection afforded by the listing of substances on the REACH Authorisation list (Annex XIV).

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16[100] and entry 17[101] restrict the use of lead carbonates and lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds[102] such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*
- *Entry 28[103] addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30[104] addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 63[105] restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72[106] stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

The use of lead alloys 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 in alloys 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.

---

[100] 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

[101] 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

[102] 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

[103] 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

[104] 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

[105] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[106] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status July 2021). Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

10.3.2. Scientific and technical practicability of substitution or elimination of lead

Clarification of scope of the renewed exemption 11 as requested

COCIR (2020a) request the renewal of the exemption with a slightly different wording, i.e. "*Lead and its alloys as a superconductor and thermal conductor in MRI*", while the current exemption reads "*Lead in alloys as a superconductor…"*. The current wording restricts the use of lead to alloys in superconductors, whereas the new wording would include the use of pure lead.[107]

COCIR (2020b) explain that when they submitted the exemption IV-11 renewal request, they had been informed that one MRI manufacturer used lead metal whereas all others use lead alloys such as lead-bismuth. A more recent investigation showed that meanwhile all MRI manufacturers use lead alloys and none use pure lead metal any more.

Shift of NMR devices from exemption IV-12 to exemption IV-11

In the last review of exemption IV-12 by Gensch et al. (2020a), the applicant and COCIR had agreed to exclude MRI and NMR devices from the scope[108] of exemption IV-12 and transfer them to exemption IV-11 so that superconductive bonds containing lead are regulated for these two technically almost identical types of devices in the same exemption.

Removal of the thermal conductivity criterion from exemption 11

The current and the proposed renewed exemption wording includes the superconductivity and the thermal conductivity as two functions of lead alloys in MRI and NMR. In the course of the review, the consultants tried to shed light on the thermal conductivity requirements of lead alloy bonds in MRI devices. COCIR (2021b) finally stated that lead alloys acting as thermal conductors can be removed from exemption 11 since they believe thermal bonds to be covered by exemption IV-26 (c.f footnote[109]) Due to the technical similarity of MRI and NMR devices, this statement is applicable to NMRs as well. This conclusion is supported

107 In the consultants' understanding the term "lead" in exemption wordings includes both lead and lead alloys or lead compounds whereas "lead in alloys" restricts the use of lead to alloys excluding the use of pure lead.

108 Exemption 12 of Annex IV: Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors. Expires on 30 June 2021

109 Exemption IV-26: Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions:(a) solders on printed circuit boards;(b) termination coatings of electrical and electronic components and coatings of printed circuit boards;(c) solders for connecting wires and cables;(d) solders connecting transducers and sensors.
Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C.

by the fact that the current exemption 12 of Annex IV, which currently still covers NMR devices, does not include the thermal conductivity property in its exemption scope either.

Overlaps of exemption IV-11 with other exemptions

The scopes of exemptions IV-26 and IV-27 at least partially overlap[110] with the scopes of the new exemption 11. Superconducting bonds in MRI and NMR are durably exposed to very low temperatures below -20 °C (current and proposed renewed ex. 26, c.f. Gensch et al. (2020b)) and can be located within 1 m of the magnet's isocentre (ex. 27, only MRI equipment in scope). It was therefore agreed with the applicant to exclude the scope of exemption IV-11 from the scope of exemption 26 and to recommend the same for the next review[111] of exemption 27 so that only exemption 11 covers superconducting bonds in MRI and NMR.

In their renewal request, COCIR (2020a) mention that for MRI "[…] *lead as a thermal conductor (used in cryocoolers, cold heads, i.e. cryorefrigeration components) has been assumed to be covered by exemption 29 […]".* Since the thermal conductivity aspect is no longer included into the scope of the renewed exemption 11, this potential overlap between these two exemptions would no longer exist if the COM adopted the wording recommended for the renewed exemption IV-11. Further on, in the course of the review of exemption IV-29, the superconductivity aspect was removed from the scope of the recommended renewed exemption 29, and its scope was restricted to cryo-cooled cold probe heads, which are irrelevant for MRI scanners as well as for NMR devices. If the COM follows the recommendation to renew exemptions 11 and 29 with the proposed wordings and scopes, any overlaps between them can be excluded for MRI scanners and for NMR devices.

While expired in July 2021 for cat. 8 medical devices other than in-vitro diagnostic medical devices, i.e. including MRI scanners, the current exemption 29 remains valid until 2024 for cat. 9 industrial monitoring and control instruments, which includes NMR devices. This exemption comprises lead in superconducting as well as thermally conducting bonds. As mentioned above, COCIR had considered thermal bonds in MRI to be covered by exemption 29 in the past, which would have been applicable to NMR devices as well due to the technical similarities. Since thermal conductivity has been erased from the scope of exemption 11, there are no scope overlaps for NMR equipment between the renewed exemption 11 and the current exemption 29.

Wording of the renewed exemption IV-11

The consultants agreed with COCIR (2021c) to exclude the scope of the renewed exemption 11 from the scopes of exemptions 26 and 27 and to renew exemption 11 with the following wording if in case the COM agrees that its renewal would be justifiable by Art. 5(1)(a):

"Lead in alloys as a superconductor in MRI and NMR"

110 Exemption IV-27: Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors,which are used in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere

111 Exemption 27 is not part of this review.

Substitution of lead

The applicants discuss various lead-free superconducting materials as potential substitutes for the currently applied PbBi alloys in their exemption renewal request. Besides reliability and manufacturability aspects, the critical temperature Tc, the critical current Cc and the critical field strength Hc of lead-free superconductors restrict the choices of substitutes. These parameters should be as high as possible, but at least comparable to the currently used PbBi solders for uses with the current low temperature superconducting coils manufactured from materials NbTi and sometimes also NiSn. The applicants claim that for the time being, none of the lead-free materials listed in Table 10-1 on page 256 can substitute lead-free alloys.

Comparing the values for the three critical parameters in the table substantiates the applicant's statement. Adding to this, there are manufacturing challenges when bonding to NbTi superconductors mainly due to the very inert nature of niobium oxide that readily forms on the surface of niobium alloys. According to COCIR (2021b), these effects were researched mainly with NbTi superconductors that are the commercially most commonly used material, but are likely to be the same with NbSn superconductors because they also contain Nb. The available information suggests that substitution of lead is scientifically and technically not practicable now and in the foreseeable future. This conclusion coincides with the previous review of exemption IV-12 by Gensch et al. (2020a) where the situation was assessed for NMR devices, which are based on very similar superconducting technology like MRIs.

Elimination of lead by spot welding and cold pressing

Spot welding

COCIR (2020a) describe spot welding as a technique with potential to eliminate the use of lead in the future, and report approaches to overcome the still low critical current of the welded bonds, c.f. section "Spot welding (COCIR (2020a))" on page 257. Upon request to detail these approaches and to indicate a timeline for the further research, COCIR (2020b) explain that spot welding has been investigated as a possible alternative bonding method for niobium alloy superconducting wires in a copper support matrix. To date, the researchers found that thin layers of oxides and residual copper form at the bond interface creating electrical resistance. In this bonding method, copper first has to be dissolved in acid then the exposed niobium alloy must be de-oxidised using hydrofluoric acid (to dissolve niobium oxide) before welding can be carried out. Unfortunately, exposed niobium metal alloy re-oxidises as soon as the hydrofluoric acid is washed off and the surface dried and this oxide remains in the spot-welded bonds creating electrical resistance. Niobium oxide is exceptionally inert and is resistant to most chemicals. Niobium metal oxidises immediately when exposed to even low concentrations of oxygen. The Oxford University[112] has investigated other substitutes but all gave bonds with electrical resistance.

COCIR (2020a) close pointing out that many potential alternatives to lead and its alloys have been investigated with none being suitable for MRI superconductor bonding and so it

[112] C.f. https://stfc.ukri.org/files/superconducting-joints-for-magnet-applications/

is difficult to predict when a more suitable substitute will be discovered. They refer to their roadmap for the further steps and timelines, c.f. section 0 on page 258.

A closer look at the provided information showed that the researchers referenced in the Oxford University study[113] did not use hydrofluoric acid to spot weld the contacts, but HNO_3 to remove the Cu-matrix. The use of the hazardous hydrofluoric acid thus may not be required. Since the researchers conclude that spot-welding forms good metallurgical joints but ruins the carefully engineered microstructure of NbTi wire by local melting, the consultants did not follow up on these potential contradictions, but follow COCIR's argument that further research is still required and solutions are not foreseeable within the next seven years.

Cold pressing

According to COCIR (2020a) described in section "Cold pressing" on page 257, laboratory research[114] with cold pressing produced low resistivity bonds. The bonds are, however, inconsistent, the bonding method is difficult and implies the use of the very hazardous hydrofluoric acid. COCIR (2020a) reference research at Oxford University[115] which they interpret to show that oxide and copper at the bond boundary prevent effective bonding.

A closer look at the above-cited Oxford University study confirms COCIR's statement that the researchers found oxide layers and residual copper at the interface between NbTi filaments so that no metallurgical bonding was achieved, but they had etched the copper matrix away with HNO_3, no hydrofluoric acid was used.

The same study also reports, however, that the bonding problem was solved by a standard tinning method to prevent the oxidation of the NbTi filaments. As a result, the researchers rate cold-pressing technologies as promising.

Upon request, COCIR (2021a) commented that "*The paper's author clearly states that this option is not yet a commercially viable solution and more research is needed. This is one of the planned avenues of investigation which will be explored in the coming years.*".

Research after 2015

Further investigations showed that the referenced Oxford study was published[116] in 2015 already. Besides academic partners, Siemens was involved into this research.

COCIR was asked which steps have been undertaken since 2015 to either bring spot welding and cold pressing bonding technologies or possibly other approaches from

[113] Susie SpellerGreg Brittles, Tayebeh Mousavi, Canan Aksoy, Chris GrovenorCentre for Applied SuperconductivityUniversity of Oxford: Superconducting Joints for Magnet Applications, retrieved from https://stfc.ukri.org/files/superconducting-joints-for-magnet-applications/

[114] Review article: Persistent Current Joints between Technological Superconductors, G. Brittles, et.al., Superconductor Science and Technology, Volume 28, Number 9, 2015; Source as referenced by COCIR 2020a.

[115] Superconducting Joints for Magnet Applications, Susie Speller, downloaded from https://www.stfc.ac.uk/files/superconducting-joints-for-magnet-applications/; source as referenced by COCIR 2020a.

[116] C.f. webpage of the Science & Technology Facilities Council, https://stfc.ukri.org/search-results/?keywords=speller&page=1&perPage=10&sortBy=_score&sortDirection=desc&selectedYear=2015&

laboratory research scale closer to practice, or to exclude that they can eliminate the use of lead.

COCIR (2021b) reference latest research of Speller's group in Oxford[117] who concludes that $B_{c,2}$ (the upper critical field) of BiInSn solder joints may be too low for a 'drop-in' replacement for commercial MRI magnets, it has potential for use in small magnet systems. COCIR (2021b) also report current research exploring the impacts of microstructure, such as 'The study in the atmospheric oxidation of NbTi superconductor'[118], and 'The effect of the size of NbTi filaments on interfacial reactions and the properties of InSn-based superconducting solder joints'[119]. The latter of which concludes that the property of bulk solder is regarded the limiting factor and not any interfacial reactions. Such developments of understanding are crucial to understanding of potential ways forward, however it shows that the commercialisation of such technologies is still some time off.

Further research work has been commissioned to investigate, according to COCIR (2021b), at a scientific level, the physical boundary between superconducting materials and whether the superconducting behaviour extends across this boundary, a parameter known as coherence length. It is hoped that this research will allow the development of practical methods of forming superconducting connections, once this fundamental understanding has been developed.

The consultants conclude that besides spot welding, cold pressing may be another approach to eliminate the use of lead in the scope of exemption 11. For spot welding, this statement coincides with the conclusion in the review of exemption IV-12 by Gensch et al. (2020a) that welding is a promising technique, but it will be difficult to use consistently in a production line to produce reliable bonds. Spot welding is therefore currently not used commercially for NMR or MRI. Even though COCIR's claims and objections could not be confirmed in all details, the consultants agree to their interpretation that the above developments are still in research stage and more time will be needed until they possibly can eliminate the use of lead. It is not foreseeable that these efforts will result in an industrially viable lead-free solution within the next seven years.

10.3.3. Environmental arguments and socioeconomic impacts

COCIR does not raise any environmental arguments to support the exemption request stating that no substitutes are available.

COCIR forecasts significant negative impacts on the health of EU citizens if this exemption is not renewed. In view of more than 14 million MRI scans carried out in the EU annually, it is evident that MRI devices are an important tool of medical diagnostics. Since the substitution of lead is currently not yet possible, revoking exemption IV-11 would no longer

[117] C.f. https://indico.cern.ch/event/445667/contributions/2563682/attachments/1513660/2361336/TimothyDavies_MT25_Poster.pdf; source as referenced by COCIR 2021b.

[118] Journal of Alloys and Compounds, V.848, 25 December 2020, T. Davies, C.R.M. Grovenor, S.C. Speller https://www.sciencedirect.com/science/article/abs/pii/S0925838820327092; source as referenced by COCIR 2021b.

[119] Materials & Design, Volume 176, 2019, S. Santra, T. Davies, G. Matthews, J. Liu, C.R.M. Grovenor, S.C. Speller https://www.sciencedirect.com/science/article/pii/S0264127519302746; source as referenced by COCIR 2021b.

allow placing MRI devices on the European Economic Area market. The consultants share the applicant's view that severe impacts on human health would arise from this situation.

10.3.4. 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.

MRI and NMR are operated with superconductive magnets to generate strong and homogeneous magnetic fields. The coils, wires, and bonds to coils and wires of the magnet need to be superconductive. The applicant plausibly explains that no lead-free alloy can currently substitute the lead-containing superconducting PbBi alloy used for bonds in MRI devices. Potential alternatives do not form sufficiently reliable bonds, and/or the critical temperatures, critical magnetic field strengths or the critical current density are too high. It can therefore be concluded that substitution of lead in the applications in scope of exemption IV-11 is currently scientifically and technically impracticable.

Several alternative bonding techniques are discussed to eliminate the use of lead. In academic research together with an MRI manufacturer referred to by the applicant, **spot welding** and **cold pressing** are considered as techniques which may be developed into appropriate alternatives to soldering with PbBi solders. COCIR's conclusions deviate from the authors' and the consultants' interpretations of these results. It can be agreed, however, that further research is required to overcome weaknesses of these techniques before they can be used in commercial MRI devices, and that this is not to be expected within the next seven years. Recent research follows new approaches focusing on better understanding of material phases and boundaries that may yield better insights which in the end might also allow the elimination of lead, but not within the next seven years.

As a result of the review of exemption IV-12 in 2019/2020 by Gensch et al. (2020a), it had been decided to shift NMR equipment from exemption 12 to exemption 11 so that technically identical needs of MRI and NMR equipment related to superconductive bonds are covered by the same exemption.

The current exemption specifies thermal conductivity as a function of lead alloys in MRI scanners. In the course of the review, the applicant proposed to remove the thermal conductivity from the scope of the exemption stating that this functionality is covered by exemption IV-26 already. This is applicable to NMR equipment as well.

Overall, the available information suggests that substitution or elimination of lead are scientifically and technically not yet practicable so that it could be justified by Art. 5(1)(a) to

grant the exemption. The consultants agreed on the below wording of the future exemption IV-11 with the applicant:

"Lead in alloys as a superconductor in MRI and NMR"

Superconductive bonds in MRI and NMR equipment are partially covered by exemptions IV-26 and IV-27 as explained in section "Overlaps of exemption IV-11 with other exemptions" on page 263. The scope of exemption 11 should therefore be excluded from these exemptions to avoid overlapping exemptions.

MRI devices are an important and common medical diagnostics technique, and NMR devices play a crucial role in research and development in the European Economic Area. Placing on the market these devices would no longer be legal if the exemption is not granted because their manufacturing without the use of lead alloys in the scope of exemption 11 is scientifically and technically impracticable, which would have considerable adverse impacts.

10.4. Recommendation

The accessible information suggests that substitution and elimination of lead alloys in MRI devices is scientifically and technically not yet practicable. In the consultants' view, Art. 5(1)(a) would therefore allow granting an exemption and recommend to renew exemption IV-11 with the following wording:

	Exemption	Scope and dates of applicability
11	*Lead in alloys as a superconductor in MRI and NMR*	Expires on 21 July 2028 for cat. 8 medical devices others than in-vitro diagnostic medical devices (MRI), and for cat. 9 industrial monitoring and control instruments (NMR)

The consultants recommend renewing the exemption for seven years as substitution or elimination of lead foreseeably are not likely to be scientifically and technically practicable within this maximum possible validity period.

The wording of the exemption slightly deviates from the wording of the current exemption 11. The thermoconductivity of the lead alloys was removed since the applicant stated that this aspect would be covered by exemption IV-26. This modification does not involve any scope restriction or partial revocation of the current exemption 11 since thermoconductivity remains covered by exemption 26. In the consultants' understanding, Art. 5(6) is not applicable, and a transition period therefore may not be justified.

Nevertheless, the shift might imply some administrative adaptations in the supply chain and for manufacturers so that the COM could consider to nevertheless grant a 12 months transition time in case that the changed exemption wording can still be interpreted formally as a scope restriction.

In this case the following wording is recommended:

	Exemption	Scope and dates of applicability

11	*Lead in alloys as a superconductor and thermal conductor in MRI*	Expires on [publication date + X months] for cat. 8 medical devices others than in-vitro diagnostic medical devices (MRI)
11(a)	*Lead in alloys as a superconductor in MRI and NMR*	Expires on 21 July 2028 for cat. 8 medical devices others than in-vitro diagnostic medical devices (MRI), and for cat. 9 industrial monitoring and control instruments (NMR)

The scopes of exemptions IV-26 and IV-27 partially overlap with the scope of exemption 11. It is therefore recommended to exclude the scope of exemption 11 from the scope of exemptioin 26. In the next review of exemption 27, the scope of exemption 27 should be specified to exclude exemption 11.

The consultants would like to point out that the shift of NMR devices from exemption IV-12 to exemption IV-11 requires coordination if the COM follows the wording recommended by Gensch et al. (2020a) for the renewed exemption 12. It should be ensured that NMR devices are included in the renewed exemption 11 before they are excluded from the renewed[120] exemption 12. Otherwise, the use of lead alloys in NMR devices would remain uncovered in the time between the renewal of exemption 12 and the renewal of exemption 11.

10.5. References

COCIR (2020a): Application for renewal of exemption IV-2. Online verfügbar unter http://www.rohs.biois.eu/Ex_2-IV_COCIR_Renewal-Request.pdf.

COCIR (2020b): Answers to questionnaire 1 (clarification questionnaire). Online verfügbar unter http://www.rohs.biois.eu/Ex_2-IV_COCIR_Questionnaire-1_Clarification.pdf.

COCIR (2021a): Answers to questionnaire 2 for exemption IV-11, sent via E-Mail by Emily Tyrwhitt-Jones, RINA, to Dr. Otmar Deubzer, Fraunhofer IZM, on 20 May 2021.

COCIR (2021b): Answers to questionnaire 3 for exemption IV-11, sent via E-Mail by Emily Tyrwhitt-Jones, RINA, to Dr. Otmar Deubzer, Fraunhofer IZM.

COCIR (2021c): Answers to questionnaire 4 for exemption IV-11, sent via E-Mail by Riccardo Corridori, COCIR, to Dr. Otmar Deubzer, Fraunhofer IZM.

Directive 2011/65/EU: 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 (recast). RoHS 2. Fundstelle: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065.

[120] New wording of exemption 12 recommended by Gensch et al. 2020a:
Lead in metallic bonds creating superconducting electric circuits in SQUID detectors

Current wording of exemption 12:
Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors. Expires on 30 June 2021.

Gensch et al. (2020a): Study to assess one (1) request for renewal of exemption 12 of Annex IV to Directive 2011/65/EU(Pack 19). 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 24. Unter Mitarbeit von Carl-Otto Gensch, Moch, Katja, Öko-Institut e. V. und Dr. Deubzer, Otmar, Fraunhofer IZM. Online verfügbar unter https://circabc.europa.eu/sd/a/b464981f-1173-4ade-a056-c219ef3bbba4/RoHS_Pack19_final_report_20200615.pdf.

Gensch et al. (2020b): Study to assess seven (7) exemption requests relating to Annex III and IV to Directive 2011/65/EU: request for renewal of exemptions 6(a), 6(b), 6(c), 7(a) and 7(c)-I of Annex III; request for renewal of exemption 27 of Annex IV; and request for a new exemption for lead in bismuth lead strontium calcium copper oxide superconductor cables and wire and lead in electrical connections to these wires to be added to Annex IV (Pack 18) – 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. RoHS 23. Unter Mitarbeit von Carl-Otto Gensch, Yifaat Baron, Moch, Katja, Öko-Institut e. V. und Dr. Deubzer, Otmar, Fraunhofer IZM. Online verfügbar unter https://circabc.europa.eu/sd/a/9eaaeae6-6dd2-4ab1-9715-d3a4a69fed1b/RoHS_Pack18_final.pdf.

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. Unter Mitarbeit von Paul Goodman, ERA Technology Ltd. ERA Technology Ltd. Online verfügbar unter https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

11. Exemption 13 of Annex IV: Pb in counterweights

The current wording of exemption 5 is as follows:

"Lead in counterweights"

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date was scheduled for 21 July 2023, and for IMCIs for 21 July 2024.

Declaration

In the sections preceding the "11.4 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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Information taken from applicants' documents is displayed in italics in all sections to enable its differentiation from the consultants' comments and arguments.

Acronyms and definitions

ADP	Abiotic depletion potential
DCB	Dichlorobenzene
DCM	Dichloromethane
Eq.	equivalents
GWP	global warming potential
ITIA	International Tungsten Industry Association
LCA	Life cycle assessment
MJ	Mega joule
PB	Lead
Sb-e	Antimony equivalents
SO_2-e	Sulphur dioxide equivalents

11.1. Background of Exemption and Requests

On 15 January 2020, COCIR (2020b) submitted a request for the renewal of exemption 13 of Annex IV for cat. 8 medical devices others than in-vitro diagnostic medical devices for

the maximum validity period of seven years. The applicant requested a modified scope for the renewed exemption:

"Lead in counterweights of surgical C-arm X-ray and C-arm fluoroscopy designed to have radiologist present with patient"

No stakeholders contributed to the online consultation. ITIA as relevant stakeholder was consulted individually during the evaluation.

11.1.1. History of the exemption

(Goodman 2006) had recommended the Commission to grant this exemption. It was listed on Annex IV of the Directive 2011/65/EU when it was officially published in 2011 including EEE of categories 8 and 9 into its scope. An application for renewal was submitted in time, and exemption IV-13 is reviewed for the first time to adapt it to scientific and technical progress.

11.1.2. Summary of renewal requests and stakeholder contributions

According to COCIR (2020b), "*Lead has been used as a counterweight material in medical imaging equipment for many years but since medical devices were included in scope of the RoHS Directive, manufacturers have replaced lead in counterweights wherever this is technically possible. However, in the two types of equipment described in this exemption renewal request, surgeons or radiologists need close contact with patients, but without being exposed to radiation and the larger volume required of metals with lower density than lead prevents this access. The use of metals with higher density than lead would allow access as the volumes required would be similar or less that with lead, but a full life cycle assessment shows that the overall health, safety and environmental impact of these substitutes is considerably more negative than the overall health, safety and environmental impact of lead.*"

11.2. Technical description of the requested exemption

11.2.1. Amount of lead used under the exemption

The total amount of lead placed on the market was around 200 kg in 2017 as indicated by COCIR (2020a). The data substantiating these figures are not publicly available.

11.2.2. Use and function of the restricted substance

Since exemption 13 of Annex IV was granted and included in the RoHS recast Directive in 2011, medical equipment manufacturers have been able to redesign most types of medical equipment to replace lead counterweights, usually with steel. However, this has not been possible for two specific types of medical devices. The designs and uses of these two types are described here separately.

Surgical C-arm X-ray imaging

According to COCIR (2020b), "*C-arm X-ray imaging equipment is a widely used design where the X-ray source and detector are located at either end of a moveable "C". The patient is located at the centre of the "C" and the source and detector are moved around them to*

the required imaging location. Both the X-ray source and detector are relatively heavy due to the need for radiation shielding, which is usually lead metal. So that hospital staff can easily move the C-arm to the required position by hand with minimal effort, the C-arm has to be carefully counterbalanced using weights at appropriate locations. The mass and location of weights depends on the C-arm's dimensions, the mass of the X-ray source, the size and mass of the detector, etc.

The size of counterbalance weights should not interfere with the ability of the medical staff to treat patients but in most standard non-surgical C-arm X-ray systems the radiologist and other medical staff move away from the patient during X-ray imaging to avoid exposure to harmful X-rays. In most designs, it has been possible to replace lead with less dense and therefore larger volume steel counterweights. However, as the density of lead is 11.2 g/cc whereas the density of steel is about 7.9 g/cc (depending on the alloy), the use of steel creates a significant volume increase (about 40 %), which would interfere with the ability of the surgeon to operate on a patient and use the surgical X-ray equipment simultaneously.

When the surgeon wishes to operate on the patient while the patient is being imaged, the surgeon needs to stand over the patient to look down onto them but not be exposed to X-radiation. The size of the X-ray tube shielding and counterweights is such that if lead is used for both, the surgeon is just able to stand over the patient.

Surgical C-arm equipment is used differently to most types of X-ray imaging equipment as the surgeon uses X-ray imaging as a real-time tool to visualise the inside of the patient while they are operating. As a result, space is extremely limited as shown above.

Although steel as a counterweight occupies a volume of only about 42 % more than lead, the space available for the surgeon to be able to look down onto the patient is small with lead and the surgeon's view would be obscured if bulkier steel were to be used […] the only way that the surgeon can have a clear view of the patient while being X-ray imaged, is by placing themselves within the X-ray beam, which is not acceptable as repeated exposure will cause cancer.

Three versions of surgical C-arm system are used:

- *Orthopaedic – bone surgery*
- *Vascular – imaging of arteries and veins during surgical procedures*
- *Cardiac – heart surgery while the heart is viewed in real-time*

Fluoroscopy C-arm X-ray imaging where the radiologist is present with the patient

This is a different fluoroscopic imaging technique that is used for real-time imaging of internal organs of patients, usually by use of contrast agents that enable these to be visualised using the X-ray equipment. This specific type of medical device is used, for example, to image the internal digestive system. The patient drinks a "barium meal", which shows the digestive system as it passes through the stomach, intestines and bowel. Barium sulphate is used as barium has a fairly high atomic number and so is opaque to X-rays but this substances is not harmful. This examination normally is carried out with the patient in a vertical position and usually the radiologist is in a separate room to the patient to avoid exposure to potentially harmful X-rays. However, there are some circumstances when it is necessary for the radiologist to be present with the patient, especially if the patient is very ill, is elderly or a child. The patient and radiologist are supported on a movable table that is counterbalanced to enable it to be moved easily. In these designs of equipment, it is not

possible to replace the lead counterweights with lower density material as the larger volume alternative materials prevent the radiologist from being able to have the access they need to the patient. With steel counterweights, for example, the radiologist would be further away from the patient so that they cannot provide the same level of care.

11.3. Justification for the requested exemption

11.3.1. Substitution of lead in counterweights

General requirements of a substitute for lead are described by the applicant COCIR (2020b):

- High density (of at least that of lead),
- Inert, stable, and unaffected by X-radiation
- Easily fabricated into the required shapes,
- Materials with overall environmental and health impacts that are no worse than lead should be used.

According to COCIR (2020b), "*It has been possible to use steel as an alternative counterweight material for most other types of X-ray imaging equipment because fabrication is straightforward and steel is easily recycled at end of life. Steel also has a slightly smaller overall environmental, health and safety impact compared with lead (on a life cycle basis). In the two specific applications in scope of this exemption renewal request, however, steel is unsuitable because larger volumes are needed that would interfere with the ability of the surgeon or radiologist to treat patients.*

Metals with density values that are the same or higher than lead may appear to be dimensionally suitable candidates as substitutes, but medical device manufacturers are also obliged by the Medical Devices Regulation to take account of the overall environmental and health impact of their products[121]. All alternative high density metals have a more negative overall environmental and health impact than lead."

Tungsten is considered to have the lowest environmental impact of the alternatives, but with severe technical disadvantages according to COCIR (2020b): "*The surgical C-arm X-ray equipment has very little available space for the counterweight and so the counterweights have to be made in relatively intricate shapes to fit into the space available […]. This is straightforward with lead because this metal can easily be cast into moulds with complex shapes and at fairly low temperature. However, this is impossible with tungsten metal due to its extremely high melting point of 3,410°C. […] Tungsten metal is also extremely hard and so cannot be extruded and grinding into complex shapes is impractical.*

Counterweight shape is less of an issue with fluoroscopy X-ray imaging where the radiologist is present with the patient, although the production of tungsten counterweights is far more difficult and energy intensive than with lead as tungsten metal is very hard and so difficult to fabricate even into fairly simple shapes. A potential alternative to tungsten metal is tungsten-polymer composites. This material is available commercially with the same density as lead (11.2g/cc). This material could be used in the fluoroscopy equipment

[121] Medical Devices standard EN 60601-1-9:2007 "Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design

but would be difficult to use with the surgical C-arm equipment. This is because tungsten-polymer composites are available in the form of sheets which may be suitable for fluoroscopy but is unsuitable in surgical C-arm systems which require counterweights of complex shapes […]. Extrusion of tungsten-polymer into complex shapes is possible only for small pieces and medical equipment manufacturers and their suppliers have not been able to fabricate complex pieces of the size needed for counterweights.

Another disadvantage of tungsten-polymer composites is that the X-radiation degrades the polymer causing the composite to disintegrate. If this results in dimensional changes, which is likely, this would negatively affect the counterbalance effect of the weights and would shorten the lifetime of the equipment."

11.3.2. Elimination of lead in counterweights

No alternative technology is available, which allows the elimination of lead.

11.3.3. Roadmap towards substitution or elimination of lead in counterweights

According to COCIR (2020b), *"Research into making complex shapes with tungsten composite has been carried out, but has not been successful for the counterweights needed for these applications."*

"*The eventual method of replacing lead counterweights in the two types of equipment described here may be to develop alternative medical devices that can be used to assist with the treatment of patients that give similar end results. To date this has not been possible and further research is needed. This is likely to take at least 8 years before designs with lead-fee counterweights are available for these two applications, but the timescale is very uncertain.*"

11.3.4. Environmental arguments and socioeconomic impacts

Environmental arguments

According to COCIR (2020b), "*Metals with density values that are the same or higher than lead may appear to be dimensionally suitable candidates as substitutes, but medical device manufacturers are also obliged by the Medical Devices Regulation to take account of the overall environmental and health impact of their products. All alternative high density metals have a more negative overall environmental and health impact than lead*." The values are presented in Table .

Table 11-1: Density and Global Warming Potential (GWP) values of metals with density similar to or larger than lead

Metal	Density	GWP (kg CO_2-eq/kg)
Lead	11.3	1.3
Bismuth	9.8	58.9
Thallium	11.8	376

Metal	Density	GWP (kg CO_2-eq/kg)
Mercury	13.5	12.1
Gold	19.3	12,500
Platinum	21.1	12,500
Iridium	22.5	8,860
Osmium	22.6	4,560
Rhenium	21.0	450
Tungsten	19.3	12.6
Tantalum	16.7	260
Hafnium	13.3	131

Source: COCIR (2020b)

Thereby, COCIR (2020b) state,

- *"All metals with atomic number greater than bismuth are radioactive and so are unsuitable.*
- *Thallium and mercury are very toxic and so are unsuitable*
- *Bismuth has a lower density than lead and so is less suitable (as well as having a much larger GWP)"*

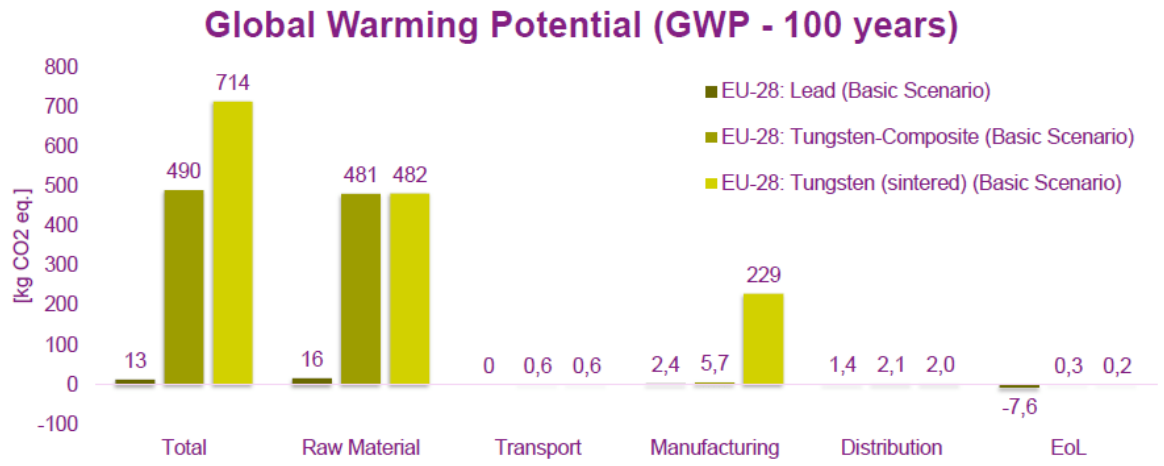
Based on this initial overview, tungsten was used for a more specific comparison. The applicant provided a comparative LCA between lead, sintered tungsten, and tungsten composite (with a polymer) for radiation shielding provided by thinkstep (2018) for exemption IV-5, with numbers adjusted to reflect the results for counterweights in the scope of this exemption (see Table). The LCA shows a basic scenario and two additional scenarios:

- *Basic scenario: 100 % of lead is recycled and tungsten goes to landfill*
- *Recycling tungsten: 100 % of tungsten is recycled (re-melting and powdering)*
- *Landfill lead: 100 % of lead goes to landfill*

According to the baseline scenario (recycling of lead, landfill of tungsten at end-of-life), lead is preferable in all impact categories with much lower environmental impact. Scenarios with recycling options of tungsten polymer reduce the difference between lead and tungsten polymer.

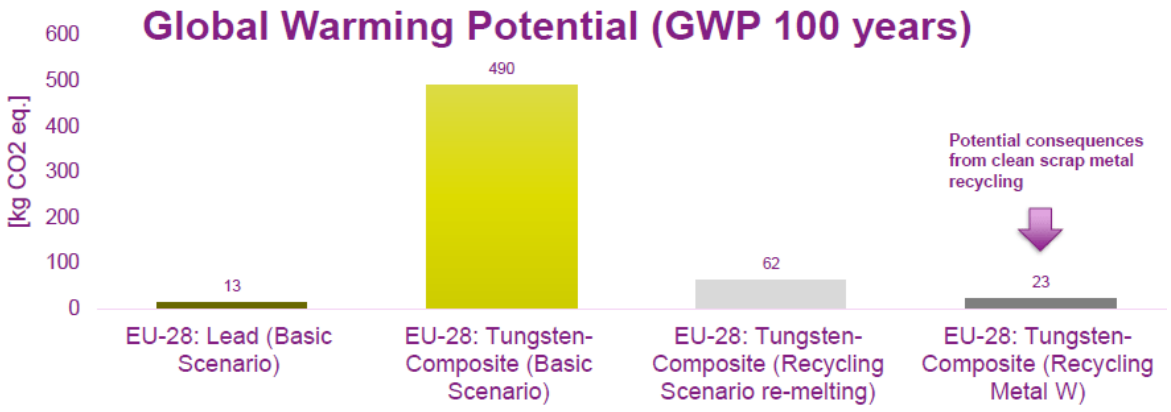
The differences in the result stem from raw material acquisition and for sintered tungsten also from the manufacturing phase (see Figure 11-1). Much of that can be reduced by assuming a material credit in the tungsten polymer recycling scenario (see Figure 11-2).

Figure 11-1: GWP for lead, tungsten polymer and sintered tungsten



Source: LCA prepared by thinkstep (2018), commissioned by COCIR

Figure 11-2: GWP for lead and tungsten composite with recycling of tungsten composite



Source: LCA prepared by thinkstep (2018), commissioned by COCIR

Table 11-2 shows the environmental impacts calculated from the LCA values determined for exemption IV-5 for the baseline scenario (100 % recycling lead, 100 % landfill tungsten) adapted to exemption IV-13.

Table 11-2: Equivalent impacts of lead, tungsten metal (sintered) and tungsten composite for exemption 13

Impact	Lead	Tungsten composite	Tungsten
Quantity [kg]	11.3	11.3	11.3
GWP [kg CO2e]	13	344	524
ADP elements [kg Sb-e]	1.4×10^{-3}	0.32	0.34
ADP fossil [MJ]	133	6,289	8,881
Acidification [kg SO2-e]	0.05	2.44	2.74
Eutrophication potential (kg phosphate eq)	0.01	0.46	0.51
Photochemical ozone creation potential (kg ethene eq)	-1.52×10^{-4}	0.07	0.17
Primary energy demand from renewable and non-renewable resources (MJ)	167	6,569	9,612
Human toxicity potential (kg DCB eq)	1.56	81.4	101.3
Terrestrial ecotoxicity potential (kg DCM eq)	0.52	0.86	2.4
Freshwater aquatic ecotoxicity (kg DCM eq)	0.04	9.83	10.1
Marine aquatic ecotoxicity (kg DCM eq)	780	37,200	46,200

Source: COCIR (2020b)

Socioeconomic impacts

According to COCIR (2020b), *"[i]f a high priced substitute were used; a) theft of expensive metals (e.g. gold) would result in the equipment not being usable which would negatively affect patients and b) the higher cost of tungsten, or gold, may prevent hospitals from buying as much new equipment as at present, resulting in the average age of their equipment increasing […] so that less reliable old equipment (and sometimes with inferior performance) has to be used for longer."*

The additional material value, if lead would be totally replaced by tungsten, would be about 275 $ per device (~10 kg lead/tungsten per X-ray device) based on a price difference of 27.500 $ per tonne material (Metalary). It is assumed that additional manufacturing would contribute to this result due to the more difficult manufacturing of tungsten compared to lead. However, these additional manufacturing costs could not be quantified by the applicants.

The initial exemption request COCIR (2020b) states a much higher material value per device, which was due to a calculation error. This could be resolved with the applicants based on email communication (RINA 2021a).

11.4. Critical review

11.4.1. REACH compliance – Relation to the REACH Regulation

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

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by*" the REACH Regulation if the requested exemption would be granted/renewed.

REACH Annex XIV (2021)[122] *lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:*

- *Lead chromate (entry 10);*
- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

The applications in the scope of the exemption at hand do not use any of the above lead compounds.

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16*[123] *and entry 17*[124] *restrict the use of lead carbonates and lead sulphates in paints;*

[122] ECHA, https://echa.europa.eu/authorisation-list?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

[123] 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

[124] 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

- *Entry 19 refers to arsenic compounds but includes a few lead compounds[125] such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*
- *Entry 28[126] addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30[127] addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 63[128] restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72[129] stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and footwear.*

The exemption for lead used in counterweights 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, the use of lead in shieldings in the scope of the requested exemption 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.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status (October 2021) 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 the respective criteria of Art. 5(1)(a) apply.

[125] 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

[126] 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

[127] 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

[128] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[129] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

11.4.2. Scientific and technical practicability of substitution or elimination of lead

Substitution of lead

According to COCIR (2020b), counterweights cannot be manufactured from tungsten due to “complicated shapes”. However, (ITIA 2021) challenge this statement claiming that these shapes can be manufactured from tungsten metal alloys with CNC milling, connecting tungsten sheets and 3D printing (niche technology currently). ITIA was contacted by the consultants during the critical review phase to gain additional information on manufacturability of tungsten and recycling rates. There are also companies producing medical equipment parts from tungsten materials.[130]

From technical perspective, similar to the situation of lead substitution in shieldings (exemption IV-5), it might be more difficult and costlier to manufacture drop-in replacements. For new designs it does not seem likely that tungsten would be a problem even though it cannot be excluded that substitution of lead might still be impossible for specific shapes of counterweights. Since, like for exemption IV-5, the applicant bases the exemption request on environmental rather than on technical grounds, the consultants focused on the review of these arguments rather than investing into detailing where substitution of lead might still be scientifically and technically impracticable.

Elimination of lead

No alternative technology is available, which allows the elimination of lead.

11.4.3. Environmental arguments and socioeconomic impacts

Environmental arguments

COCIR presented LCA results in a slide deck thinkstep (2018). A full LCA report was not available. The comparative LCA for lead versus tungsten was reviewed by a single third party RINA (2019) and not by a review panel. Therefore, the LCA is not considered fully compliant with ISO 14040 (section 7)/14044 (section 6). Additionally, the review was conducted in the light of exemption request IV-5 (radiation shielding). No specific third party review was conducted for the applicability on counterweights. Nevertheless, after consultation with the COM, the main findings were reviewed and taken into account.

The LCA results are dominated by very few data sets. The raw material acquisition phase causes the main environmental impact for tungsten polymer and sintered tungsten. this is based on one single data set for sintered tungsten according to the process plan in the provided slide deck by thinkstep, called “tungsten metal powder (expert judgement)”.

The environmental impact values of the data set itself are not accessible for the consultants. A back-calculation shows an equivalent GWP about 28 kg CO_2e/kg tungsten metal powder. Other sources state much lower values for the whole life cycle, such as 2.8 kg CO_2e/kg tungsten by probas (2012) and 12 kg CO_2e/kg tungsten by Nuss und Eckelman (2014) (as

[130] C.f. e.g. https://www.dunlee.com/a-w/3d-metal-printing.html, https://www.plansee.com/en/materials/tungsten-heavy-metal.html

also cited by the applicants in other parts of the exemption request). However, it is not clear if the data set by thinkstep covers additional processes.

The baseline LCA considers 100 % recycling of lead versus landfill of tungsten at the end-of-life. According to the applicants COCIR (2020b), "*X-ray imaging equipment is usually returned to manufacturers at end of life. Many units are refurbished for reuse and any parts that cannot be reused are recycled. By keeping the equipment under the control of the manufacturer during its life cycle, this is a closed loop method of treatment*."

According to the applicants, many parts are refurbished, non-refurbished parts are recycled COCIR (2020b). In the consultants' view, this situation might be similar for tungsten counterweights. Reuse might even be more extensive, as tungsten is extremely hard and might show less mechanical wear.

According to the applicant, "*The International Tungsten Industry Association (ITIA) report that only 35 – 40 % of used tungsten metal is recycled globally.*" COCIR (2020b). Due to the higher price of tungsten, reuse and recycling of the respective parts may be even more attractive than for lead. In that context, it is not understandable why tungsten (alloy) would not be recycled to 100 % from medical equipment like it happens for lead. According to the ITIA, recycling of tungsten is standard and the quoted 35-40 % refer to the worldwide average and not to the recycling of a specific device in a (nearly) closed loop system (ITIA 2021). Therefore, the recycling scenario seems the more realistic comparison than the landfill scenario for tungsten.

Additionally, due to missing data, two different approaches to evaluate the LCA results were applied for lead and tungsten: "*lead Model is based on net scrap approach i.e. the required secondary input for the Lead production is fed with post-consumer scrap (less credit) (state of the art)*" thinkstep (2018). Thinkstep states in the slide deck "*An application of the net scrap approach to Tungsten might have a positive impact on the results*" thinkstep (2018). How that would impact the absolute values if data would be available for both materials is not clear.

Looking at the materials which thinkstep (2018) compare in the provided LCA, (ITIA 2021) state that the material which is used for comparison would not be the material of choice for counterweights. Tungsten polymer would degrade fast under radiation as also stated by COCIR at other parts of the exemption application. Tungsten alloy would be used for counterweights. It is not completely clear how this would affect the results. COCIR (2021) state the following:

"In terms of processing, the LCA considers for Tungsten (sintered) the manufacturing process of Grinding and Sintering based on Continuous Burning Ceramic process, resulting in a 2 % loss as a best case. Tungsten heavy alloys manufactured by powder metallurgical process and CNC milling is not likely to be dissimilar to this. It is worthwhile noting that even if the alternative processing resulted in a lower loss, this has been considered for tungsten composites which considered <1 % loss, which still demonstrated a higher overall health, safety and environmental impact. We also believe that as tungsten heavy alloys are typically 95 – 97 % tungsten, the LCA will still be applicable.
Our LCA did consider a scenario where tungsten metal is recycled (but as sintered powder and as composite). The results […]are given on page 37 of the LCA report, which states (for recycling) "in the case of Tungsten (sintered) the difference would be higher (GWP of Tungsten sintered approx. 252kg CO2eq.)". The LCA concludes that the energy for recycling tungsten composites would be similar to lead, if this were technically feasible […].

The GWP for lead at 13 kg CO2eq is much lower than of sintered tungsten that is recycled at 252kg CO2eq. This large difference is likely to be due to the very hard nature of tungsten metal and its alloys which requires the consumption of considerable energy to grind these materials and also energy for sintering shapes at high temperature (typically at >1000°C).” According to RINA (2021b), the direction of impacts would be similar for the other impact categories as well. However, they were not calculated in the initial LCA.

In summary, like for the shieldings in the scope of exemption IV-5, it is very likely that the environmental impacts are higher for tungsten counter weights than for lead counter weights. The main difference thereby is caused by the manufacturing part, which is more energy intensive for tungsten. Differences between impacts of raw material acquisition of lead and tungsten are reduced with high recycling rates. Direct reuse of counter weights would reduce impacts of both materials, but would not lift the differences in environmental impacts.

Socio-economic impact

Differences in the raw material price would lead to small differences in the price of about 275 $ per device (see chapter 11.3.4). Additionally, higher raw material value would enhance the likelihood of recycling with higher revenues.

Price differences due to more energy intensive and more difficult manufacturing are likely but could not be quantified neither by the applicants nor by the reviewers.

11.4.4. 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.*

COCIR questioned the reliability of tungsten substitutes claiming that tungsten polymers for counter weights would degrade over time when exposed to X-rays. According to ITIA, tungsten alloys, not tungsten polymers, are used in counter weights. ITIA claimed that tungsten can substitute lead in counter weights. These claims regarding the technical practicability were not refuted by the applicant. Tungsten definitely has drawbacks regarding more difficult manufacturability and price, but there are companies on the market offering counter weights without lead. Whether tungsten could replace lead in all types of counter weights was not determined since the applicant had stated that the justification of the requested exemption renewal is based on environmental arguments rather than the scientific and technical impracticability of substitution.

According to the applicant, the environmental impact of substitutes is significantly higher than for lead. The LCA to support the claims was presented. It does not fulfil the requirements of ISO 14040/44 or similar standards due to a missing review by interested third parties, but after consultation with the COM, open questions were further elaborated.

Several assumptions made in the LCA (use of specific substitutes, recycling quotes of substitute) were challenged by ITIA as stakeholder during the critical review phase. In conclusion, the overall environmental impact of lead is considered to be lower than for tungsten, but with much smaller differences between the materials than presented in the provided LCA.

Finally, the applicant points out higher costs for medical equipment for hospitals, leading to a lower number of products as broken equipment will not be replaced and no additional equipment purchased. However, the pure material costs are not significantly impacting the overall costs of the medical equipment and possible higher costs due to different manufacturability of tungsten could not be provided by the applicants.

11.5. Recommendation

In the consultants' view, the available information shows that the substitution of lead in counterweights in the scope of exemption 13 is scientifically and technically practicable, but the environmental impacts of substitution of lead are likely to outweigh the environmental benefits thereof. Renewing the exemption would not infringe Art. 5(1)(a). It is recommended to renew the exemption for five years with the below wording:

	Exemption	Scope and dates of applicability
13	*Lead in counterweights*	*Expires on* - *21 July 2021 for cat. 9 other than industrial monitoring and control instruments* - *21 July 2024 for cat. 9 industrial monitoring and control instruments*
13(a)	*Lead in counterweights of surgical C-arm X-ray and C-arm fluoroscopy devices designed to have a radiologist present with the patient*	*Expires on 21 July 2026 for medical devices of category 8 other than in-vitro diagnostic medical devices*

Cat. 9 monitoring and control instruments in exemption 13: It is not clear whether cat. 9 EEE has ever actually required this exemption. COCIR had indicated that it may be of relevance for cat. 9 EEE. In the absence of renewal requests, the consultants recommend the regularly foreseen expiry dates for cat. 9 EEE in exemption 13, i.e. 21 July 2021 for cat. 9 EEE other than industrial monitoring and control instruments, and 21 July 2024 for cat. 9 industrial monitoring and control instruments.

The time period for the exemption is limited to 5 years due to the limited reliability of the provided life cycle assessment. It was concluded that at the moment the benefits outweigh the negative impacts using lead. However, some doubts are left. It is recommended to renew the life cycle assessment if a future exemption request should be based on environmental arguments. Thereby the LCA should address the aspects, which were considered critical:

- review process through interested parties including a review of the life cycle inventory data
- LCA specifically for the application on counterweights

- realistic and comparable assumptions regarding end-of-life treatment.

11.6. References

COCIR (2020a): Quantity Calculation - Request for renewal of exemption 13 of Annex IV (confidential).

COCIR (2020b): Exemption Renewal Form - Exemption 13 Annex IV. Online verfügbar unter https://rohs.biois.eu/Ex_13-IV_COCIR_Renewal-Regest.pdf.

COCIR (2021): Answer to Questionnaire 3 of Exemption Request 5, received from Riccardo Corridori, COCIR, via e-mail by Marina Proske, Fraunhofer IZM.

Directive 2011/65/EU: 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 (recast). RoHS 2. Fundstelle: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065.

Goodman, Paul (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report July 2006, amended 19 Sep 2006. ERA Report 2006-0383. Unter Mitarbeit von Paul Goodman, ERA Technology Ltd. ERA Technology Ltd. Online verfügbar unter https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf.

ITIA (2021): Email correspondence with Burghard Zeiler, ITIA: Recycling of tungsten composite?, 01.03.2021. Email an Marina Proske.

Metalary: Tungsten Price. Online verfügbar unter https://www.metalary.com/tungsten-price/.

Nuss, Philip; Eckelman, Matthew J. (2014): Life cycle assessment of metals: a scientific synthesis. In: *PloS one* 9 (7), e101298. DOI: 10.1371/journal.pone.0101298.

probas (2012): Umweltprofil Wolfram. Hg. v. Umweltbundesamt. Online verfügbar unter https://www.probas.umweltbundesamt.de/php/prozessdetails.php?id={A4A89322-AC81-4FA2-BB1C-5EE0B77E9180}.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

RINA (2019): RoHS exemption 5 Annex IV - Assessment of comparative cycle assessment for lead and tungsten. Report No. 2019-0870. Online verfügbar unter https://rohs.biois.eu/Ex_5-IV_LCA_REG0364001_COCIR.pdf.

RINA (2021a): Email correspondence with Emily Tyrwhitt Jones, RINA: RoHS Exemption Request 13-IV - questions on material price, 24.05.2021 an Marina Proske.

RINA (2021b): Answer to Questionnaire 6 of Exemption 5, received from Emily Tyrwhitt Jones, RINA, via e-mail by Marina Proske, Fraunhofer IZM.

thinkstep (2018): Comparative Life Cycle Assessment. RoHS Exemption for Lead - Project Delivery. Unter Mitarbeit von Constantin Herrmann, Marta Bonell und Brechenmacher, Timo, thinkstep. Hg. v. thinkstep. Online verfügbar unter https://rohs.biois.eu/Ex_5-IV_LCA_REG0364001_COCIR_Presentation.pdf.

12. Exemption 14 of Annex IV: Lead in ultrasonic transducers

The complete wording of the current exemption IV-14 is:

"Lead in single crystal piezoelectric materials for ultrasonic transducers"

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date was scheduled for 21 July 2023, and for IMCIs for 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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms

AC	alternate current (electricity)
cMUT	capacitative micromachined ultrasonic transducers
IVUS	in-vitro intravascular ultrasound
MPB	morphotropic phase boundary
pMUT	piezoelectric micromachined ultrasonic transducers
PZT	lead zirconium titanate
THI	tissue harmonic imaging
US	ultrasonic, ultrasound

Definitions related to ceramics

Ceramics

Definition 1 by The American Ceramic Society:
In the most simple of terms, ceramics are inorganic, nonmetallic materials. They are typically crystalline in nature (have an ordered structure) and are compounds formed between metallic and nonmetallic elements such as aluminum and oxygen (alumina, Al2O3), calcium and oxygen (CaO), and silicon and nitrogen (silicon nitride, Si3N4). In broader terms, ceramics also include glass (which has a non-crystalline or amorphous random structure), enamel (a type of glassy coating), glass-ceramics (a glass containing ceramic crystals), and inorganic cement-type materials (cement, plaster, and lime). However, as ceramic technology has developed over time, the

	definition has expanded to include a much wider range of other compositions used in a variety of applications. (The American Ceramic Society) Definition 2 by The American Ceramic Society: Ceramics are by definition natural or synthetic inorganic, non-metallic, polycrystalline materials. Sometimes, even monocrystalline materials, such as diamond and sapphire, are erroneously included under the term ceramics. Polycrystalline materials are formed by multiple crystal grains joined together during the production process, whereas monocrystalline materials are grown as one three-dimensional crystal. Fabrication processes of polycrystalline materials are relatively inexpensive, when compared to single crystals. Due to these differences (e.g., multiple crystals with various orientations, presence of grain boundaries, fabrication processes), polycrystalline materials should really not be confused with single crystals and should be the only ones included under the definition of ceramics. (The American Ceramic Society (2020)) Definition 3 by Hans Walter Hennicke: Ceramic materials are inorganic, non-metallic, in water hardly soluble, and for at least 30 % crystalline. As a general rule, they are formed at room temperature from a raw mixture and assume their typical material properties in a temperature treatment mostly at above 800 °C. Sometimes, the shaping also happens at increased temperature or even via the molten mass with subsequent crystallization. (Salmang et al. (2007)) Definition 4 by William David Kingery: We define „ceramics“ as ability and knowhow to produce and apply products which contain inorganic non-metallic materials as essential components und main constituent. (Salmang et al. (2007)) Definition 5 by the German Ceramic Industry Association: As minimum definition, ceramic materials are inorganic and non-metallic. (Verband der keramischen Industrie e. V. (2003))
d33	Piezoelectric constant defined as polarization generated per unit of mechanical stress applied to a piezoelectric material or, alternatively, the mechanical strain experienced by a piezoelectric material per unit of electric field applied. As properties of single crystal materials depend on axes, there are different constants for each axis and d33 is the constant in direction 3. With single crystals usually having higher d33 values than PZT ceramics.
K33	Electromechanical coupling coefficient, indicates a material's efficiency in converting mechanical energy from vibrations into an output electrical charge and vice-versa. K33 refers to induced strain in direction 3 per unit electric field applied in direction 3.
Kt	Thickness mode coupling coefficient, indicates the effect of thickness on the electromechanical coupling coefficient. Kt affects the impedance of a transducer element, where the best single crystal

materials have higher values. Low values can only be somewhat compensated by changing the electrical control circuit design and using multilayer piezoelectric materials.

12.1. Background and technical Information

COCIR (2020) submitted a request asking for the renewal of the above exemption with the following wording for the maximum validity period of seven years for cat. 8 medical devices others than in-vitro diagnostic medical devices:

"Lead in single crystal materials for medical ultrasonic transducers"

The insertion of "medical" in the above wording restricts the exemption scope to cat. 8 medical equipment and excludes cat. 9 industrial monitoring and control instruments. The exemption expires on 21 July 2021 for other cat. 9 EEE since no renewal request was received.

The applicant further proposes to drop the word "piezoelectric" before "materials" in the current exemption wording.

12.1.1. Summary of the requested exemption

COCIR (2020) sum up their renewal request stating that single crystal piezoelectric materials that contain lead give the best imaging performance for medical ultrasound, being superior to polycrystalline lead compounds and lead-free single crystal and polycrystalline materials. Single crystal materials are considerably more expensive than lead-based polycrystalline materials and so are used only where the superior imaging performance justifies the higher cost to EU hospitals. A considerable amount of research into lead-free substitutes has been carried out and is described in the exemption renewal request. Researchers who have reviewed lead-free substitutes have concluded that none give the same performance as lead-based materials and all are inferior. One alternative design has been developed; capacitive Micromachined Ultrasonic Transducers (cMUT), which operates in a different way to ceramic transducers but research has shown that these have much shorter lifetimes and so can be used only for certain applications.

Exemption 14 of Annex IV is related to exemption 7c-I of Annex III as both provide exemptions for lead in types of medical ultrasound transducers. These could be combined into one exemption.

12.1.2. History of the exemption

Exemption 14 of Annex IV was proposed in 2006 in the ERA study by Goodman (2006) in case that categories 8 and 9 EEE were to be included into the scope of RoHS. There was at that time and still is an exemption for lead in glass and ceramic electronic components (7c-I of Annex III), but it is not clear that this includes single crystal materials. The exemption was not granted under Directive 2002/95/EC (RoHS 1) since electrical and electronic equipment of categories 8 and 9 was included into the scope of the amended RoHS Directive 2011/65/EU (RoHS 2) only in 2011. Exemption 14 was listed on Annex IV of this Directive when it was officially published in 2011 and is now reviewed for the first time to adapt it to scientific and technical progress after the submission of COCIR's request for renewal of this exemption.

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

COCIR (2020) requests the exemption for transducers applied in medical ultrasound imaging. Medical ultrasound imaging is used to generate images of the interior of the human body, such as to examine unborn babies, to examine internal organs to look for tumours or abnormalities, muscles, tendons, blood vessels, etc. It is also used for minor surgery for example to guide hypodermic needles to the required locations.

Medical imaging uses a driver circuit to impose a broad range of alternate current (AC) frequencies onto the piezoelectric material which causes it to generate a broad range of frequency vibrations akin to sound waves. These waves travel from the transducer to an interface, such as the surface of an organ, within the patient where these waves are reflected back to the transducer where they are detected. The force from the reflected waves striking the piezoelectric material generates an electric field that is used to generate an image. COCIR (2020)

Different imaging frequencies are used depending on what is being viewed, for example higher frequencies give better image quality but lower frequencies are needed to view deeper inside the body (higher penetration). As a result, the transducer should generate a wide range of frequencies, referred to as a large bandwidth. COCIR (2020)

The ultrasound transducer obtains an image by using one or more piezoelectric elements, often as an array with many elements, which are connected to the control system which also has a display and digital recorder. Modern medical ultrasound imaging uses lead zirconium titanate (PZT) based ceramic materials that are covered by exemption 7c-I of Annex III of the RoHS Directive as well as single crystal materials in the scope of exemption 14 that give superior performance, but are more difficult to fabricate and so are more expensive than ceramic PZT transducers. Most commonly used single crystal materials are: lead magnesium niobate - lead titanate (PMN-PT) and also PIN-PMN-PT where PIN = lead indium niobate. COCIR (2020)

Superior quality medical ultrasound imaging is carried out using single crystal piezoelectric materials rather than polycrystalline (ceramic) materials that are typically used by the electronics industry as buzzers, loudspeakers and actuators and also used for less demanding medical ultrasound applications (and are covered by exemption 7c-I of Annex III of the RoHS Directive). Single crystal materials are superior because of the lack of grain boundaries that would cause loss of signal so that the efficiency and sensitivity are superior to polycrystalline ceramic material. Single crystal technology enables an increase in bandwidth, offering enhanced signal to noise ratio and enhanced axial resolution and penetration. They have larger coupling coefficients and piezoelectric coefficients that lead to better medical diagnostics, i.e. more accurate diagnosis and ability to detect very small features earlier. COCIR (2020)

Two main properties are desired in medical ultrasonic transducers according to COCIR (2020):

- High imaging resolution
- High depth of penetration

To achieve these, the following properties are needed (COCIR (2020)):

4) *High bandwidth – this improves axial resolution and contrast resolution*
5) *High sensitivity - high frequency at greater depth = higher centre frequency = better lateral resolution*

COCIR (2020) defines ultrasound materials by six piezoelectric parameters:

6) *Coupling factor*
7) *Piezoelectric constants*
8) *Dielectric constant*
9) *Insertion and other losses*
10) *Depoling and Curie temperatures*
11) *Velocity*

Coupling Factor (COCIR (2020))

While there are many properties of piezoelectric materials that have a bearing on the quality of the ultrasound image that they provide, only one property continuously improves the output as it is increased, which is the coupling factor. Coupling factor describes the efficiency of the material with which it converts mechanical energy from vibrations into an output electrical charge and vice-versa.

The coupling factor is the most fundamental property. If ultrasound energy is not efficiently converted from electrical to mechanical energy or vice versa, then there is a reduction is sensitivity. A high coupling factor is therefore essential as it is impossible to compensate for inferior coupling factors for example by design changes. Most other properties can be altered with alterations to the circuit of the device or the way that the material is cut or produced, although these will have limitations that can affect performance. The coupling factor is closely related to and dependent on the piezoelectric constants of the material. (COCIR (2020))

Electric Constants (COCIR (2020))

These define the properties of the material. Crystals are usually anisotropic and so these properties may be expressed as different values in the three axes. Properties include the Piezoelectric Charge Constant and the piezoelectric voltage constant, both of which define the performance of the material. The piezoelectric charge constant is the mechanical strain experienced by a piezoelectric material per unit of electric field applied, and piezoelectric voltage constant is the mechanical strain experienced by a piezoelectric material per unit of electric displacement applied. The piezoelectric constants should be as high as possible. The piezoelectric charge constant is measured in coulombs per Newton.

Dielectric Constant (COCIR (2020))

This is a primary parameter that affects the impedance of a transducer element. It is possible to compensate to some extent for low values such as by changing the electrical control circuit design and using multilayer piezoelectric materials, but this increases circuit

complexity and difficulties with fabrication. Dielectric constant therefore is important and the best single crystal materials have relatively higher values.

Losses (COCIR (2020))

Insertion loss is proportional to the material's sensitivity and so can be an important parameter for image quality. Ultrasound crystals can also suffer from a loss of energy. A loss in performance can be dealt with by increasing power (applied current), but this heats the crystal, which if the temperature becomes too hot can cause loss of performance (sometimes due to a phase change) or even exceed the Curie temperature (c.f. next paragraph), resulting in depoling. Cooling is an option but is impractical with medical ultrasound transducers. Losses cannot be zero, but should not be greater than 10 %. (COCIR (2020))

Depoling/phase transition temperatures (COCIR (2020))

Piezoelectric materials undergo a series of phase transitions with increasing temperature. For example, above the Curie temperature, they lose their ferroelectric properties due to the depoling process which makes them unusable for ultrasound transducer applications. Each phase transition is accompanied by a corresponding strain within the piezoelectric material structure. This internal strain can either result in cracking the material or changing its properties. Therefore, piezoelectric materials with low phase transition temperatures show unstable performance during the operation of an ultrasound transducer which normally runs at temperatures higher than room temperatures (due to internally generated heat). In addition, low Curie temperature materials can partially depole during shipping or storage in areas with hot environment. This partial depoling will have an adverse effect on the performance of ultrasound transducer. The Curie temperature of piezoelectric transducers for use in ultrasound equipment should therefore be sufficiently high so that use and storage and if possible also solder bonding do not degrade performance. Piezoelectric properties degrade if the material is heated to temperatures close to and above this temperature.

Velocity (COCIR (2020))

Speed at which ultrasonic sound waves travel through a medium. Low ultrasound velocity requires a thinner transducer, but thinner materials have higher capacitance, which is good for smaller elements - but fabrication is more difficult.

Anisotropic properties of single crystal materials (COCIR (2020))

Single crystal materials may be anisotropic with different properties along each of their three axes. Crystals need to be oriented to maximise their performance. Table 12-1: indicates typical values of commercially available PMN-PT piezoelectric single crystals used in medical ultrasound transducers.

Table 12-1: Typical values of PMN-PT piezoelectric single crystals in medical ultrasound transducers

Characteristic	Value
Electromechanical coupling coefficient K33	Up to 95%
Electromechanical coupling coefficient Kt	Up to 62%
Piezoelectric constant (d33)	Up to 2300 pC/N
Curie temperature	145 to 210°C

Source: COCIR (2020)

12.1.4. Amount of lead used under the exemption

COCIR (2020) indicate the content of lead in single crystal PZT (homogeneous material) as a range of 40 % to 65 % (weight) in the material and estimate the amount of lead used under the exemption to be about 500 g per year in the in EU. This estimate is based on the mass of single crystal material used annually for transducers supplied to the EU market with an average of 60 % of lead content. This has been estimated by one manufacturer using the amount they ship into the EU and their estimated market share.

12.2. Applicant's justification for the requested exemption

COCIR (2020) explain that lead-based piezoelectric ceramics and single crystals which are commercially used in fabricating ultrasound transducers for medical imaging possess a unique combination of electromechanical properties such as high dielectric constant, high piezoelectric constant, high coupling coefficient, and relatively high depolarization or Curie temperature. These properties have been optimized for specific medical imaging applications to enhance the performance of the transducers and hence the image quality. As a result, there are different grades of lead-based piezoelectrics with wide range of electromechanical properties which cover a wide range of medical imaging applications performed at different frequencies. Lead-based single crystals, for example, offer a remarkably high dielectric constant and coupling coefficient. This resulted in a revolution in medical imaging industry by introduction of matrix arrays for high quality 3D imaging. Lead-based piezoelectrics are also thermally stable across the working temperature range in which the ultrasound transducers operate.

12.2.1. Substitution of lead

COCIR (2020)) report that research into substitute piezoelectric materials for medical ultrasound imaging has been carried out in recent years. A wide variety of dielectric

materials have been produced and tested and some are commercially available. However, none of the lead-free materials can achieve the same high performance of the best performing lead compounds, especially single crystal PMN-PT. A recent review of research[131] compared the properties of PMN-PT with a wide variety of lead-free potential medical ultrasound substitutes. Table 12-2 shows a summary of published data of piezoelectric materials from Taghaddos et al and data from other sources.

Table 12-2: Performance characteristics of piezoelectric materials[132]

Material	Dielectric constant $\varepsilon_{33}/\varepsilon_0$	Piezoelectric constant D_{33}	Coupling coefficients		Comments
			K_{33}	K_t	
PMN-T[4]	Up to 7000	1 620	0.93	0.62	Optimal performance
Barium sodium titanate – barium potassium titanate – barium titanate BNT-BKT-BT	1000	181	0.56		Typical values for barium titanate based piezo-materials
Unusual Barium zirconium titanate – barium calcium titanate ceramic (BZT – BCT)	2820	Up to 560-620			Has too low a Curie temperature ca. 93°C
Potassium sodium niobate – lithium titanate – lithium antimonite (KNN-LT-LS)	506 – 1865	175 – 315		0.39	
Potassium Sodium Niobate – Lithium Titanate (KNN-LT)	890	245		0.42	
Barium niobium titanate – barium titanate (BNT-BT) ceramic	730	125	0.55	0.52	

[131] Lead-free piezoelectric materials and ultrasonic transducers for medical imaging, by Elaheh Taghaddos, Mehdi Hejazi and Ahmad Safari, Journal Of Advanced Dielectrics, Vol. 5, No. 2 (2015) 1530002 (15 pages) ; source as referenced by COCIR 2020.

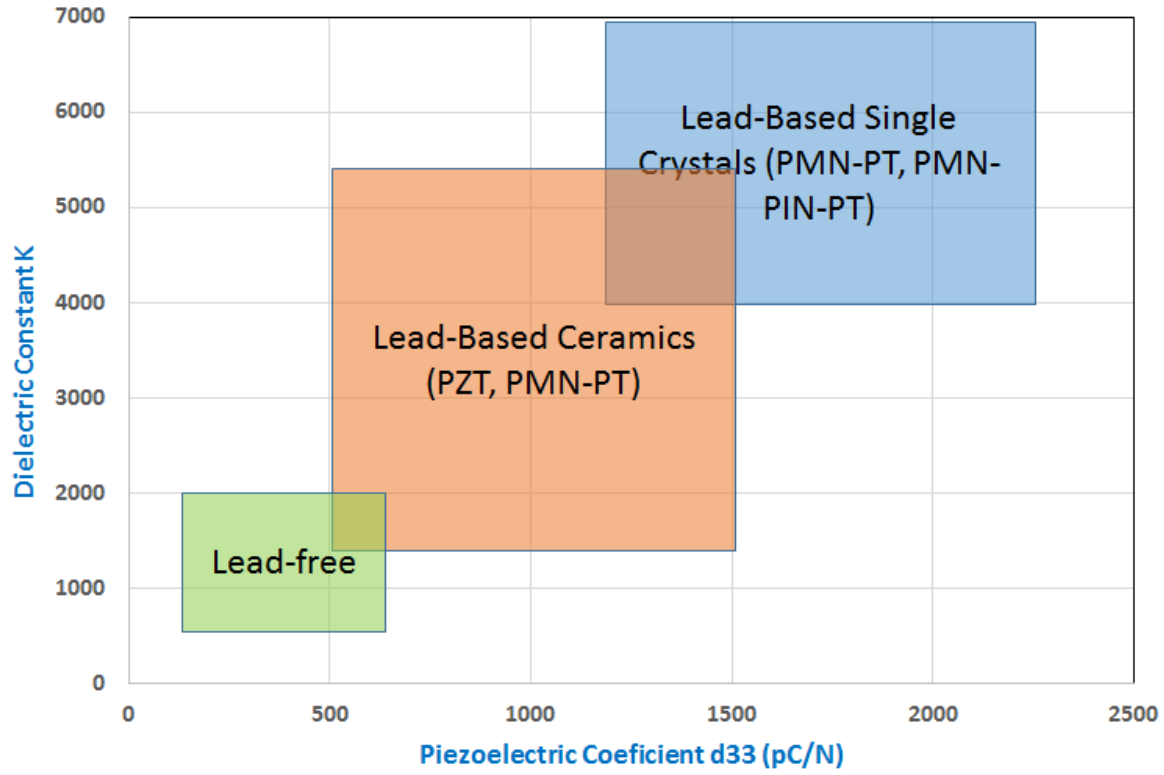
[132] Most data is from "Lead-free piezoelectric materials and ultrasonic transducers for medical imaging", Taghaddos et. al., Journal of Advanced Dielectrics, Vol. 5, No. 2 (2015); Source as referenced by COCIR 2020.

Barium niobium titanate – barium titanate (BNT-BT) single crystal	1000	430		0.63	
Potassium, sodium niobate antimonate – Bismuth sodium potassium zirconate KNNS-BNKZ		490			Highest D_{33} value for lead-free material listed in review by Hong[5].
Bismuth sodium titanate[6]	700	120	-	0.40	Commercially available ceramic piezoelectric material
Potassium Sodium Niobate (KNN)thick film	90			0.34	Coupling coefficient and dielectric constant are too low
Lithium niobate single		35		0.49	Very high Curie temperature
Crystal					Too low D_{33} and K_t. Used for non-destructive testing of industrial equipment

Source: COCIR (2020)

COCIR (2020) conclude that no lead-free material achieved the performance of PMN-PT. Figure 12-1 *summarizes the electromechanical properties of most common lead-based and lead-free piezoelectrics.*

Figure 12-1: Electromechanical properties[133] of most common lead-based and lead-free piezoelectrics



Source: COCIR (2020)

COCIR (2020) conclude that lead-free piezoelectrics have lower electromechanical properties and inferior thermal stability compared to their lead-based counterparts. Tested lead-free materials as well as transducers made using various lead-free piezo materials showed improvement of properties of lead-free materials in the last two decades, but there is still an appreciable deficit compared to Pb-based materials used in medical imaging applications. Pb-based piezoelectric ceramics and single crystals with rhombohedral structure offer a stable performance. Rhombohedral compositions are widely used in the medical ultrasound market. A few lead-free compositions with rhombohedral structure have been developed recently. They all suffer from low electromechanical properties or high coercive field requiring very high voltages for operating the ultrasound transducers which would not be practical. Another prohibitive factor in using lead-free piezoelectrics in medical imaging transducers is that the manufacturing process of these material is not mature and very well understood yet. Lead-free materials have complex chemistries containing elements such as K, Na, and Li which are light and volatile and therefore difficult to control during the synthesis process. The data available in the literature mostly relate to the materials prepared on the laboratory scale as opposed to commercially available materials. There is no viable lead-free composition commercialized for medical imaging applications.

[133] Consultants' remark: "Piezioelectric coefficient" refers to the piezoelectric coupling coefficient, see table "

Coupling Factor" on page 28 and Table 12-1: on page 30.

COCIR (2020) is concerned about medical imaging transducers made with lead-free piezoelectrics having lower performance and image quality compared to commercially available lead-based materials. The manufacturing of lead-free materials is not mature yet and there is still great amount of work need to be done before lead-free single crystals can be commercialized. The risk of medical misdiagnosis using lead-free transducers would be very high, and therefore, their use for medical applications is not possible at the present time. COCIR (2020) presents a summary of some of the mostly studied lead-free piezoelectric materials in literature:

Barium Titanate (BT): *BT ceramic has relatively high electromechanical properties, high dielectric constant, but low Curie temperature (T_C ~ 120 °C). BT-based ceramics have been mainly used for capacitor applications. Their low Curie temperature restricts the working temperature range in which these materials can be used. The highest electromechanical properties were achieved at BZT–50BCT composition around the morphotropic phase boundary. A piezoelectric coefficient d_{33} of 560–620 pC/N was attained for this composition which was noticeably higher than that of other BT-based ceramics. However, due to low Curie temperature of about 90 °C, this composition is thermally unstable and not suitable for medical imaging applications.*

Bismuth Sodium Titanate (BNT): *Pure BNT ceramics, however, suffer from high conductivity and a large coercive (73 kV/cm) field, which makes the poling process difficult. Therefore, they are not usable for making ultrasound transducers. In order to enhance the electromechanical properties and decrease the coercive field, binary or ternary solid solutions in the vicinity of MPB have been developed. BT, $Bi_{0.5}K_{0.5}TiO_3$ (BKT), $Bi_{0.5}Li_{0.5}TiO_3$ (BLT) are the most widely used materials which have been added to BNT ceramics to improve their electromechanical properties. MPB compositions are not attractive for medical imaging application due to their thermal instability. Rhombohedral BNT based ceramics have been used in high power devices due to their high coercive field and thermal stability. However, they are not suitable for medical transducers because of their very low dielectric constant and high operating voltage.*

Potassium Sodium Niobate (KNN): *KNN has the most complex chemistry among the lead free piezoelectrics. This makes it difficult to process high density ceramics or single crystals with stoichiometric compositions. A dielectric constant of 1255, d_{33} of 230 pC/N, and k_p of 0.5 for $(K_{0.5}Na_{0.5})_{0.07}Li_{0.03}(Nb_{0.8}Ta_{0.2})O_3$ ceramics was reported. The simultaneous addition of Li and Sb via $LiSbO_3$ decreased the tetragonal–orthorhombic phase transition temperature while not significantly affecting the Curie temperature. Shifting the transition temperature down to room temperature considerably improved the electromechanical properties. However, this results in highly unstable thermal properties which are not acceptable for medical imaging transducers.*

12.2.2. Elimination of lead

COCIR (2020) mention an alternative design technology that has been developed, which is capacitive micromachined ultrasonic transducers (cMUT), which do not contain lead. They function completely differently than piezoelectric ultrasound transducers and so it is not possible to compare the technical characteristics of cMUT with those of single crystal piezoelectric materials. cMUTs have the potential to be a lead-free alternative for ultrasound imaging with potentially wider bandwidths and smaller feature size. However, cMUT technology has yet to overcome significant technical limitations necessary to be a clinically

viable alternative to lead based single crystals and PZT ceramics for medical imaging. These limitations include output pressure, reliability, and linearity.

COCIR (2020) report[134] a deficit in insertion loss – the loss of signal power from introducing a component into the signal path – which includes both transmit and receive losses - of ~15 dB compared to PZT which would result in an unacceptable loss in penetration (depth of imaging inside the patient) and flow sensitivity (e.g., ability to image and measure blood flow) for core clinical applications. This comparison did not use harmonic imaging mode which is today's standard for difficult to image patients. Harmonic imaging insertion loss would further increase the transmit loss since tissue-generated transmit pressure is proportional to the square of the transmit pressure. Losses compared with PZT for harmonic modes would then be an additional 5 dB for this transducer.

COCIR (2020) put forward further research results[135] which they deem to perhaps be the best cMUT reliability results found in the published literature, but of only a 2-year lifetime achieved for low duty cycle modes, which are therefore even shorter for high duty cycle modes. This is well short of the desired 5 to 10 years lifetime of a clinical transducer that may also use high duty cycle modes such as shear wave imaging, which is a relatively new technique used for detecting viscosity abnormalities, which can be caused by serious internal injuries such as internal bleeding, brain injury, and concussive organ damage. Lifetimes significantly degrade as pressures are increased towards routinely applied pressures used and achieved with PZT and single crystal materials. Some desirable configurations such as 2D arrays for 3D imaging (these use arrays of many elements) use a common bias for all elements. However, if an individual cMUT element fails in such a way as to short the bias, the whole array will no longer function.

Further on, COCIR (2020) state, cMUTs are fundamentally non-linear devices since their pressure (force of transmitted wave) is proportional to the square of the applied voltage (signal + bias). This causes difficulties with harmonic imaging since it is important not to transmit second harmonic energy, which would distort images or make them illegible. Solutions to this issue have been presented[136] but require the substantially added complexity of a high voltage arbitrary waveform transmit generator. This complexity presents technical and design challenges for handheld devices (the device will be too large and heavy), and with matrix devices which use an array of transducers, with each transducer element requiring its own control circuitry.

Recognizing these limitations, researchers have focused their investigations on applications that play to the strengths of cMUTs, namely their ability to produce small feature sizes and wide bandwidths. These applications include catheters, endoscopic probes, high frequency linear arrays and probes with wide clinical coverage. Transducers for these applications cannot be fabricated easily using PZT or single crystal technology and therefore accept the

---

134 Mathias Engholm, Hamed Bouzari, Thomas Lehrmann Christiansen, Christopher Beers, Jan Peter Bagge, Lars Nordahl Moesner, Søren Elmin Diederichsen, Matthias Bo Stuart, Jørgen Arendt Jensen, Erik Vilain Thomsen, "Probe development of CMUT and PZT row–column-addressed 2-D arrays", Sensors and Actuators A: Physical, Volume 273, 2018, Pages 121-133; source as referenced by COCIR 2020.

135 Zhao, Danhua, Simopoulos, Costas & Zhuang, Steve. (2017). Long term reliability test results of CMUT Ultrasonics Symposium (IUS), 2017 IEEE International, 1-3. doi:10.1109/ULTSYM.2017.8092902; source as referenced by COCIR 2020.

136 Savoia, Alessandro Stuart, Caliano, Giosue, Matrone, Giulia, Ramalli, Alessandro, Boni, Enrico & Tortoli, Piero. (2016). Nonlinear ultrasound imaging experiments using a CMUT probe *Ultrasonics Symposium (IUS), 2016 IEEE International*, 1-4. doi:10.1109/ULTSYM.2016.7728699; source as referenced by COCIR 2020.

reduced acoustic output performance associated with cMUTs. Also, single use catheter devices can accept limited lifetimes as they are disposed of after one use. (COCIR (2020))

Due to the current limitations of the cMUT technology, COCIR (2020) deem lead based sensor technology as necessary to achieve the adequate clinical performance in core imaging modes. Given it took 20 years to mature cMUTS to their current performance, they deem unlikely that sufficient performance will be obtained for at least another 5-10 years.

12.2.3. Roadmap towards substitution or elimination lead

COCIR (2020) put forward considerable research into lead-free piezoelectric materials in the last 20 years by academics as well as by piezoelectric material manufacturers. Medical device manufacturers have investigated new materials but no lead-free substitutes come close to reaching the high performance of lead-based materials. Use of materials with lower coupling coefficient and piezoelectric constants will give inferior image quality which is unacceptable to health professionals. High image quality is essential for accurate and early diagnosis and for treatment of patients.

COCIR (2020) deem research into lead-free materials likely to continue. Some industry sectors that do not need such high performance can use less efficient and sensitive piezoelectric lead-free materials, but others including medical require the highest possible sensitivity and efficiency. There is a limit to the combinations of elements that can be tested and as shown in the recent reviews, all obvious candidates have already been assessed and even the best is very inferior to PMN-PT. It seems unlikely at present that a combination of substances will be found soon that can equal the best PMN-PT materials and so this exemption will be needed for at least the maximum validity period permitted by RoHS.

12.2.4. Environmental arguments and socioeconomic impacts

COCIR (2020) state that environmental impacts from the use of lead in the PZT materials of singly crystal US transducers are not applicable to this renewal request, and that the same would apply to health impacts. If this exemption is not renewed, they expect negative impacts on EU citizens' health if this exemption is not renewed due to inferior image quality from lead-free substitutes.

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 criteria: 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.

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by"* the REACH Regulation if the requested exemption would be granted/renewed.

Annex XIV of the REACH Regulation lists a few substances, the use of which would require an authorisation in the European Economic Area:

- *Lead chromate (entry 10);*
- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

As the exemption for lead in solders used within the scope of the requested exemption does not regard pigments nor substances used in paints and dyes, it is concluded that a renewal of the exemption would not weaken the protection afforded by the listing of substances on the REACH Authorisation list (Annex XIV).

Annex XVII of the REACH Regulation also contains entries restricting the use of lead compounds:

- *Entry 16*[137] *and entry 17*[138] *restrict the use of lead carbonates and lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds*[139] *such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*
- *Entry 28*[140] *addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30*[141] *addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they shall not be*

[137] 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

[138] 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

[139] 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

[140] 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

[141] 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

placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;

- *The above restrictions are not applicable to the use of lead in MCT, PbS or PbSe. Further on, the substances are part of an article and thus are not placed on the market or used as substances, constituents of other substances or mixtures supplied to the general public.*
- *Entry 63*[142] *restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72*[143] *stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

The exemption for lead in single crystal materials used 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, the use of lead in solders in the scope of the requested exemption 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 there is no risk that the PZT material containing the lead may come into direct contact with skin during the use of the US transducers. The above entries of Annex XVII of the REACH Regulation do not apply.

No other entries relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status March 2021). Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

12.3.2. Potentially overlapping scopes of exemptions IV-14 and III-7(c)(I)

According to COCIR (2020) "Exemption 14 of Annex IV is related to exemption 7cI of Annex III as both provide exemptions for lead in types of medical ultrasound transducers. These could be combined into one exemption." They add that "[…] it is not clear that [exemption 7(c)(I), the consultants] *includes single crystal materials. Ultrasound piezo single crystal materials are not glass (as they are crystalline, whereas glass is amorphous) nor are they what is normally regarded as a typical ceramic which would be a polycrystalline material […]" and so exemption IV-14 was deemed to be necessary when medical equipment was included into the scope of Directive 2011/65/EU (2011) (RoHS 2).*

[142] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[143] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

The current wording of exemption 7(c)(I) is: “Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectric devices, or in a glass or ceramic matrix compound”.

The consultants found various accessible144 definitions of ceramics (c.f. section “Definitions” on page 287, from which some stipulate that ceramics are polycrystalline while other do not. Overall, there is no generally and internationally acknowledged definition of ceramics.

The consultants recommend maintaining the status quo and keep the two exemptions separate but demarcating the scopes of these two exemptions by excluding the application in the scope of exemption 14 from the scope of exemption III-7(c)(I) to avoid those identical applications of restricted substances like lead in the case at hand are covered by different exemptions.

12.3.3. Scientific and technical practicability of substitution or elimination of lead

Substitution of lead

In Table 12-2 on page 294, COCIR (2020) explain and show the electromechanical properties of “*[…] most common lead-based and lead-free piezoelectrics.”* The applicant was asked whether there are any less common lead-free piezoelectrics which may have promising properties, even though they might have other disadvantages*. COCIR (2021a) claimed that all lead-free piezoelectric solutions have been considered including research materials as well as commercially available materials.*

Table 12-2 substantiate COCIR’s claim that lead-free piezoelectric materials cannot achieve the performance of the lead-containing ones. Nevertheless, they might be good enough for certain applications. The consultants found a publication where (Yan et al. 2013) had employed a BZT-50BCT lead-free ceramic to develop a high-frequency (~30 MHz) needle-type ultrasonic transducer. *In vitro* intravascular ultrasound (IVUS) was applied for the first time and tested in imaging of a human cadaver coronary artery. The experimental results suggest, according to the authors of the paper, that the BZT-50BCT ceramic is a promising lead-free piezoelectric material for high-frequency intravascular imaging applications.

COCIR (2021f) commented that the devices do not offer suitable performance to be identified as a suitable alternative. Comparing a few attributes as an example (also see Table 12-2):

- *The electromechanical coefficient outlined by this paper is only 0.4 compared to >0.5 on PZT ceramic and single crystal.*
- *The dielectric constant outlined by this paper is 2800, compared to 6000 for single crystal*
- *The piezoelectric coefficient outlined by this paper is 600 pC/N, compared to 1500 pC/N for single crystal*

[144] Some definitions are part of standards, e.g. the Definition of “Advanced Ceramics” according to ISO 15165:2001-10, and are not publicly available.

- *The materials Curie temperature is 93 °C, compared to 130-140 °C for single crystal, meaning that the piezoelectric depolarisation occurs at much lower temperature, causing aging and operational depolarization in imaging modes that require high acoustic output (for example shearwave elastography which is commonly used for cancer detection.*

COCIR (2021f) further criticize that the research white paper only shows the possibility of using BZT-50BCT at high frequencies (30.5 MHz) for a needle (IVUS) transducer. That frequency range is well above the typical centre frequency used on the medical applications. Although the authors compare their BZT-50BCT transducer to two transducers - one is the built with single crystal and one is built with PZT ceramic - this is not a like for like comparison due to the discrepancy between the frequencies, as the other two transducers have a higher frequency ~45 MHz. This imbalance puts the single crystal at a disadvantage purely based on frequency since acoustic attenuation drastically increases and sensitivity decreases with frequency. The first thing would be to compare at the same frequency. COCIR (2021f) conclude that the performance of BZT-BCT may prove to be suitable for non-medical applications where high performance is not required, but COCIR has no knowledge of these.

The consultants can follow COCIR's above explanations, but they seem to target the use of this lead-free material as a kind of general replacement for single crystal materials so that it is not quite clear whether the lead-free transducer might not be good enough for IVUS. The paper was published in 2013, however, which would have left enough time to further develop this technique, but the consultants' investigations showed no further publications concerning this research or lead-free ceramic medical US transducers placed on the market. This could confirm COCIR's conclusions as to the appropriateness of the lead-free material transducers.

Overall, the consultants conclude that lead-free ceramic materials currently cannot substitute lead-containing single crystal materials in US transducers of medical devices. No research results could be identified that point to a foreseeable substitution within the coming seven years.

Elimination of lead - general information

COCIR (2020) mention the cMUT technology as a future potential replacement for lead-containing single crystal piezoelectric materials in transducers for at least some applications in the scope of exemption 14. COCIR (2021b) point out that cMUT applications are developing which utilize the benefits of cMUT technologies such as the wide clinical coverage. COCIR (2020) report that researchers have focused their investigations on applications that play to the strengths of cMUTs, namely the ability to produce small feature sizes and wide bandwidths. Such applications include catheters, endoscopic probes, high frequency linear arrays and probes with wide clinical coverage. Transducers for these applications cannot be fabricated easily using PZT technology and therefore the reduced acoustic output associated with cMUTs can be accepted. Single use catheter devices can also accept the limited lifetimes of cMUTs.

The consultants found that in 2018 already, Philips (2018) considered cMUT and pMUT as "*New Technology Platform for Medical Ultrasound*" and *"[…] promising new technologies*

for US medical imaging." According to Fraunhofer IMPS[145], "*[…] piezoelectric micromachined ultrasonic transducers (PMUTs) are MEMS-based piezoelectric ultrasonic transducers for acoustic imaging of the environment. Unlike solid piezoelectric transducers, which use the thickness motion of a plate made of a piezoelectric ceramic, PMUTs are based on the bending motion of a thin membrane coupled with a thin piezoelectric film.*"

Elimination of lead - content of lead in pMUTs compared to PZT materials

pMUTs contain piezoelectric material which, according to COCIR (2021e), can be fabricated from polycrystalline lead zirconium titanate (PZT) ceramic not covered by exemption IV-14 but by exemption III-7c-I. *COCIR (2021e) state that other polycrystalline compositions not including lead are also utilised for pMUTs, for example aluminium nitride which, however is not used in medical imaging applications where a high degree of performance is required, but rather in applications such as air flow measurements.*

As a rough estimate of the amounts of lead used, a bulk PZT device uses 100 µm thick PZT ceramic single crystal, while an equivalent pMUT device would use membranes about 1.5 µm thick, so about 1.5 % of the bulk ceramic volume. The pMUT "drums" are populated at a maximum of 60 – 70 % of the surface area of each element, so the 1.5 % estimate would be reduced to only about 1 % of the ceramic volume required for a pMUT device compared to a bulk PZT device.

COCIR (2021e) highlight that the above estimation does not take into consideration the potential difference in service life. For example, some catheters utilising non-single crystal solutions are designed to be single use, whereas other catheters which utilise single crystals can have an expected product life for 10 years. This would of course significantly impact the amount of lead utilised for each solution. Although there are differences in the amount of lead used in pMUTs compared to those with single crystal piezoelectric materials, they cannot be an accurate point of comparison due to the different diagnostic capability each of them offers.

From the above it can be concluded that pMUT devices would require an exemption for lead as well. This lead use is currently covered by the scope of exemption 7(c)(I). The applicant's above explications show that pMUTs would contain far less lead than transducers based on poly- or single crystal PZT, but that this advantage would be at least considerably reduced or could even be overcompensated due to the technically shorter life time of the pMUT devices. The consultants have, however, doubts whether the applicant's comparison of a single use pMUT catheter with a 10 years use single-crystal catheter is actually valid, first because the applicant stated that no such catheters are available on the EU market yet, and second because it is not clear whether single crystal transducer catheters cannot be single use catheters as well.

Since no pMUT US transducers in medical devices could be identified in the course of this review, this question was not further followed up.

[145] Fraunhofer IPMS: https://www.ipms.fraunhofer.de/en/Components-and-Systems/Components-and-Systems-Sensors/Ultrasonic-Sensors/Piezoelectric-Micromachined-Ultrasonic-Transducers-PMUT.html

Elimination of lead –pMUT and cMUT transducers in medical devices

The consultants' investigations showed that ultrasonic devices operating with cMUT and pMUT[146] techniques are not only a subject of research and development, but are already placed on the market.[147] COCIR (2021c) upon request allocated the medical ultrasonic applications which they list as those benefitting from the strengths of cMUT/pMUT technology to the devices that are already placed on the market and provided their opinion as to the possibilities to eliminate lead in ultrasonic medical devices:

Catheters

Exo Imaging Inc., https://www.exo.inc/technology/ One of the potential applications listed on their website includes catheters, however this is based on the pMUT technology, not cMUT. *COCIR (2021d) point out that pMUT sensor based transducers, although similar in technology to cMUT, are much worse in image quality than single crystal material transducers.*

Endoscopic probes

No product/application examples were found which use cMUT or pMUT for this application. COCIR (2021d) are only aware of limited research and development activities which have been undertaken, which have not been developed beyond an academic study. These would have to undergo multiple stages of development for them to be at a level of development where products could be marketed, if at all possible.

COCIR (2021d) add that for some applications, such as Intravascular ultrasound, additional hardware items would also be required to be developed to allow the technology to be potentially implemented. This would take a significant length of time to be developed, and certainly beyond the maximum validity period potentially granted for the exemption as some development activities need to occur sequentially.

High frequency linear arrays

Verasonics, https://verasonics.com/ge-transducers-for-vantage-systems/ *COCIR (2021c) demand that high frequency transducers especially must be evaluated even more stringently than the lower frequency transducers, due to the expected higher resolution and anatomy differences trying to be discerned. In particular, THI performance is even more essential because naturally higher frequencies offer lower tissue penetration, and the THI performance associated with cMUT transducers has been either entirely absent until recently (Hitachi) because of fundamental physics problems of unwanted multiple frequency bands overlapping. For instance, low transmit pressure and nonlinearity of cMUT are not good for tissue harmonic imaging. Proof of adequate performance cannot be overstated.*

Probes with wide clinical coverage

[146] To avoid misunderstandings with the previous paragraph: the identified pMUT products turned out to be no medical devices.

[147]: C.f. the following web pages: https://www.butterflynetwork.com/; https://www.hitachi-medical-systems.co.uk/products/ultrasound/transducers/4g-cmut.html; https://www.exo.inc/; https://verasonics.com/ge-transducers-for-vantage-systems/; https://verasonics.com/cmut-hf-transducers/

Butterfly network, https://www.butterflynetwork.com/
COCIR (2021c) state that in this case, the "wide clinical coverage" must only be considered from the perspective of a point of care clinical use. That is, the market and clinical value of the device is designed for point of care diagnoses which are less performance based (from an absolute clinical image quality viewpoint) because the prominent diagnoses are primarily for emergency medical use and such things as pregnancy assessments, etc.

COCIR (2021c) add that the performance level of the cMUT based transducer as compared to a ultrasound cart-based system + transducer (non-cMUT) requires exhaustive, careful, lengthy analysis to fully understand subtle yet "make or break" detail resolution, which takes years to undertake.

Fujifilm, https://www.hitachi-medical-systems.co.uk/products/ultrasound/transducers/4g-cmut.html (now https://hce.fujifilm.com/products/ultrasound/transducers/4g-cmut.html) [148]

COCIR (2021c) reason that similar to the above Butterfly clinical use cases, it is a lengthy proposition in order to factually determine if the Hitachi cMUT transducer can perform adequately in clinical situations that require, for example, THI (tissue harmonic imaging) for difficult patients, by merely trying to compare data sheets or images presented. Harmonics are extremely important, and very widely used, yet the performance differs greatly as a feature in ultrasound systems. Again, the full analysis would require a timeframe in many months, if not years.

COCIR (2021c) add that despite these examples of products that do not require exemption IV-14, given the criticality of function these products perform, a multitude of tests and analyses are required to undertake a comparative study. There are also concerns over the insufficient acoustic output pressures which degrades penetration and overall produces poor image quality. These tests need to be undertaken in a number of clinical situations where equivalency must be proven and important "end cases" where a misdiagnosis could result are not missed. Until such clinical equivalence has been proved, cMUT devices cannot be deemed as substitutes.

The consultants' intention was not to target the complete replacement of single crystal material transducers but to understand the practical role of these products in medical examinations where otherwise (single crystal) PZT materials may have been used or where they may open new US imaging opportunities. The consultants assumed that each of the pMUT- and cMUT-based products placed on the market passed a qualification and certification according to the legal requirements so that years of investigations and testing as claimed by the applicant may not be required. The consultants assumed that medical products which are insufficient, inadequate and unsafe for their foreseen uses hopefully cannot acquire the certificates necessary for placing them on the market in the EEA since this would endanger patients' lives. *COCIR (2021d) confirm that certification includes an assessment of whether the equipment is safe for its intended uses and is capable of safely carrying out the procedures for which they are specified but does not differentiate between performance levels offered by different product types.*

[148] Note: Fujifilm has taken over Hitachi's Diagnostic Imaging-related business on 31 March 2021

Since COCIR had stated earlier that cMUTs and pMUTs are used in applications which play to their strengths and where their weaknesses can be accepted, the consultants investigated the certified applications of the cMUT-based products assuming that the disadvantages COCIR puts forward are acceptable for their intended uses. Verasonic, according to their web site, do not offer medical US products. The certificates and certified applications of the Fujifilm cMUT-products could not be found on their web pages. The consultants contacted the manufacturer via e-mail – the web page did not offer contact phone numbers - but did not receive any feedback and therefore dropped this part of the investigation.

Butterfly Networks' cMUT-based product(s), Butterfly iQ/iQ+, are "*[…] indicated for use in environments where healthcare is provided to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and paediatric patients for the following clinical applications:*

- *Peripheral Vessel (including carotid, deep vein thrombosis and arterial studies)*
- *Procedural Guidance*
- *Small Organs (including thyroid, scrotum and breast)*
- *Cardiac*
- *Abdominal*
- *Urology*
- *Foetal/Obstetric*
- *Gynaecological*
- *Musculoskeletal (conventional)*
- *Musculoskeletal (superficial)*
- *Ophthalmic*

Butterfly Network (2021) confirm that they have been certified by the BSI[149] in regard to the design and manufacture of general use portable ultrasound systems for the purpose of diagnostic imaging for use by qualified and trained healthcare professionals. They have an Annex II device and were tested and found to meet the quality assurance requirements for a Class II imaging device utilizing non-ionizing radiation.

COCIR (2021f) state that the Medical Device Regulation does not set detailed performance levels for the image quality of ultrasound devices. Instead, it requires devices to be placed on the market in line with the (clinical) state-of-the-art. The manufacturer has the obligation to define the intended use of the device and then ensure that the image quality is sufficiently high to allow this intended use (e.g. sufficient precision for diagnosis). The manufacturer is then required to provide evidence for this claim, via technical and clinical data collected and analysed as part of the clinical evaluation. This evidence is reviewed by the Notified Body (on a sampling basis). This is usually determined by comparing the new device to a predicate device. The manufacturer can select a predicate device that was previously

[149] Federal Office for Information Security, https://www.bsi.bund.de/EN/Home/home_node.html

approved for the same clinical indication. However, it can be an older device which at its time might have been excellent but is no longer so in today's standards.

According to COCIR (2021f), it is important to understand that different professional users have *different requirements for imaging the same target organ, for example the heart. In the emergency room, a quick look from an approved hand-held device may provide critical information, such as detection of a pericardial effusion which can be diagnosed from one single view of the heart. While the same imaging device would be considered grossly inadequate in the hands of a Cardiologist, because of inability to visualize the all the structures and/or measure the blood velocities he/she needs to perform even a standard exam.*

COCIR (2021f) say that for some diagnostic procedures, the minimum requirement might be sufficient; for others, better quality of the diagnostic equipment translates into higher confidence of diagnostic result. For example, consider detecting a malignant tumour. If it is a large tumour, a moderately good ultrasound system can detect that. But if the tumour is small and has echogenicity similar to surrounding tissue then the quality of the ultrasound plays a crucial role for the doctor to come to the correct diagnosis. The problem is that medical images can be ambiguous, yet the doctor has to make a decision on what to do next. For example, images which have good signal to noise ratio help in that decision process. The issue with cMUT, pMUT or other materials that do not provide the best image quality is loss of diagnostic value or diagnostic confidence.

COCIR (2021f) state that a cMUT device can be used to diagnose a cancer (or any of the other indicated uses), but many healthcare providers will select a device that gives a higher chance of getting the correct diagnosis. This is why the clinicians are willing to pay tens or maybe hundreds of thousands of Euros instead of paying €2000 for a hand-held device. Both have their place in the medical practice, but they do not replace each other.

The consultants understand from the above argument that cMUT-based US devices may not be substitutes for single crystal materials, but have a current role and future potential in the daily clinical practice. *Philips (2018) explain that PZT-single crystal based US devices are labour intensive to produce and therefore expensive compared to cMUT and pMUT US devices. COCIR points out that cMUT enables producing small feature sizes and wide bandwidths, which are properties that may be implemented in handheld US devices like the one described above.*

To further clarify the relevance of cMUT transducers, the consultants checked the internet for handheld devices with US transducers based on PZT single crystal materials to see whether US transducers for handheld devices are offered with single crystal materials at all. Several handheld US devices[150] were found, where it was, however, not indicated whether their US probes are offered with single crystal or with cMUT transducers. The applicant was therefore asked to provide examples of such handheld devices which apply single crystal PZT transducers. *COCIR (2021g) replied that they identified three Philips Lumify[150] transducers, "[…] all of which use PZT ceramic, however they are not single crystal."*

These uses of lead in these transducers is covered by the scope of exemption III-7(c)(I) and not by exemption IV-14. They are not an example of single crystal PZT materials used in

[150] C.f. the examples of Claris and Philips next to Butterfly Network, https://bestportableultrasound.com/

handheld US devices. The consultants therefore proposed to exclude handheld US devices from the scope of exemption 14 with the below wording:

"Lead in single crystal piezoelectric materials for ultrasonic transducers used in medical ultrasonic devices other than handheld ones"

COCIR (2021h) do not agree with the proposed wording potentially limiting the performance of handheld devices by banning single crystal materials for handheld devices. They put forward that there is no accepted definition of handheld and so COCIR cannot confirm that there are no single crystal transducers used in handheld devices but that in fact it appears that there are some single crystal handheld products already on the market.

The explanation that single crystal materials are probably already used in handheld devices is not plausible. Upon the first request, COCIR (2021g) could not indicate a single handheld device operating with a single crystal material. They could obviously handle the term "handheld" to identify one system built with polycrystalline PZT material in a handheld device and had not even mentioned that handheld is not classified so that they could not identify a single crystal US transducer used as handheld device. The above statement of COCIR (2021h) that "[…*in fact it appears that there are some single crystal handheld products already on the market […]"* is intransparent since they do not mention any specific product examples. There is thus no evidence that single crystal materials are used in handheld devices. Nevertheless, given the possibility that handhelds with single crystal transducers may actually be under development already and the fact that they are in the market only for a couple of years[151] only according to COCIR (2021i), the consultants would refrain from excluding them from the scope of the exemption.

COCIR (2021h) highlight again that the cMUT and/or pMUT technology may never offer the image quality performance achieved by single crystal US, even in a handheld device, than more conventional transducer technology can offer. Single crystal handhelds will be developed and used in the future to provide enhanced diagnostic imaging and performance. In fact, this is very likely to occur due to growing future medical requirements. If handheld devices can continue to make advances using better technology this will include single crystal allowing for handheld devices to replace larger, non-portable (or less easily portable) systems for more difficult patient diagnoses.

As a matter of fact, the information provided allows the general conclusion that the cMUT and pMUT technology have technical limitations and can currently not replace single crystal materials in transducers where their state-of-the-art high performance is required. They can at least be a complement where their specific advantages over single crystal materials are more relevant than their weaknesses. The product examples underpin this conclusion, and after several years of further research and development cMUT and pMUT transducers may find a broader range of applications, the more as Philips considers cMUT and pMUT as promising new technologies for US medical imaging.

Despite several efforts, it was not possible to discuss this current and future actual or potential role of cMUT and pMUT transducers with the applicant who essentially answered respective questions with highlighting the shortcomings of these technologies and that they cannot replace single crystal materials.

[151] Butterfly Network was contacted as well to obtain information as to since when their cMUT-based handheld system is available on the EU market, but did not answer this question.

12.3.4. Environmental arguments and socioeconomic impacts

COCIR did not provide environmental impacts to justify their exemption request. They expect, however, negative impacts on EU citizens' health if this exemption is not renewed due to inferior image quality from lead-free substitutes. The consultants share this concern. It is their mandate to ensure that the exemption will not be revoked or restricted in scope if it results in situation where the applicant's concerns could materialize.

12.3.5. 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.

COCIR request the renewal of exemption IV-14 for the maximum seven years. It is well explained that lead-free single crystal materials cannot substitute the lead-containing single crystal materials since they cannot achieve the high diagnostic performance of the lead-containing single crystals and therefore so far have not been considered to be used in US medical devices.

cMUT and pMUT transducers are a new technology which COCIR mention in their renewal request as a technology more in research and development status than in application, while the consultants' investigations showed that cMUT US transducers are already placed on the EU market in handheld US medical devices. Based on the available information, the consultants follow the applicant's reasoning that these new technologies cannot replace single crystal materials in US transducers where the latters' strengths are required. It seems that for the time being, they are a complement for US imaging tasks where their weaknesses are less relevant than their strengths, and possibly offer new opportunities of medical US imaging. At least for handheld devices, where a medical product operating with cMUT transducers could be identified, the applicant could not name any example of single crystals used in handheld devices but claimed that such handheld US devices are under development. The consultants therefore refrain from excluding handheld devices from the exemption scope.

The consultants tried to clarify the current and future role of these new technologies with the applicant, also given the background that Philips, among others a producer of US medical devices, considers these technologies as promising. The applicant did, however, not want to get involved in this discussion and instead answered respective questions with highlighting that cMUTs and pMUTs cannot replace single crystal materials.

Overall, the consultants recommend renewing the exemption following the applicant's technical arguments that lead-containing single crystal materials in US transducers scientifically and technically cannot yet be substitute or eliminated. Given the unclear

current and future role of cMUT and pMUT technologies and their proclaimed future potential in US imaging, it is recommended to grant the exemption for four years only instead of the requested seven years. A significant change can happen in the four years and this can be further substantiated in the next evaluation of the exemption.

12.4. Recommendation

The available information suggests that substitution or elimination of lead are scientifically and technically not yet practicable. It is therefore recommended to renew the exemption.

New US technologies based on cMUT and pMUT transducers are available, and cMUT-based US medical devices are already placed on the market. They seem to be a complement for single crystal US medical devices, but their current and future role in US medical imaging could not be clarified with the applicant. These new technologies are, however, seen as a promising. The consultants therefore recommend to renew the exemption for four years only instead of seven years as requested by the applicant.

The applicant suggested to alter the exemption wording restricting the exemption to medical ultrasound transducers and removing “piezoelectric”. The consultants think that the reference to “single crystal materials” instead of “single crystal piezoelectric materials” would formally widen the exemption scope without any further justification, even though technically it may not have any effect.

Additionally, the current exemption in principle still includes cat. 8 in-vitro diagnostic medical devices and cat. 9 industrial monitoring and control instruments, for which the exemption remains valid beyond 21 July 2021.

The consultants therefore recommend to renew the exemption in the current wording, and restrict the scope in a possible next review after 2024, if no applications for the renewal of this exemption for cat. 9 industrial monitoring and control instruments had been submitted.

	Exemption	Scope and dates of applicability
14	*Lead in single crystal piezoelectric materials for ultrasonic transducers*	*Expires on* - *21 July 2023 for cat. 8 in-vitro diagnostic medical devices* - *21 July 2024 for cat. 9 industrial monitoring and control instruments* - *21 July 2025 for cat. 8 medical devices other than in-vitro diagnostic medical devices*

In the absence of an internationally and generally acknowledged definition stipulating that ceramics have to be polycrystalline, the consultants recommend excluding exemption IV-14 from the scope of exemption III-7(c)(I) to avoid overlapping scopes. Otherwise, assuming that exemption IV-14 would be revoked, producers of cat. 8 and cat. 9 EEE could use ex. 7(c)(I) arguing that there is no internationally acknowledged single definition which denies that single crystals are ceramics as well.

12.5. References

Butterfly Network (2021): Answers to questionnaire 1 received from Butterfly Network support by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail.

COCIR (2020): Request for renewal of exemption 14 of RoHS Annex IV. Online verfügbar unter http://www.rohs.biois.eu/Ex_14-IV_COCIR_Renewal-Request.pdf.

COCIR (2021a): Answers to questionnaire 2 received from Emily Thyrwitt-Jones, RINA, to Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail on 29 January 2021 on behalf of COCIR.

COCIR (2021b): Answers to questionnaire 3 received from Riccardo Corridori, COCIR, by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail on 11 May 2021.

COCIR (2021c): Answers to questionnaire 4 received from Emily Tyrwhitt Jones, RINA, by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail.

COCIR (2021d): Answers to questionnaire 5 received from Emily Tyrwhitt Jones, RINA, by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail on 11 May 2021.

COCIR (2021e): Answers to questionnaire 5 received from Emily Tyrwhitt-Jones, RINA, on behalf of COCIR, by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail on 8 July 2021.

COCIR (2021f): Answers to questionnaire 6 received from Emily Tyrwhitt Jones, RINA, by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail.

COCIR (2021g): Answers to questionnaire 7 received from Emily Tyrwhitt Jones, RINA, by Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail.

COCIR (2021h): Answers to questionnaire 8 sent via e-mail by Riccardo Corridori, COCIR, to Dr. Otmar Deubzer, Fraunhofer IZM.

COCIR (2021i): Answers to questionnaire 9 sent via e-mail by Emily Tyrwhitt-Jones, RINA, on behalf of COCIR to Dr. Otmar Deubzer, Fraunhofer IZM.

Directive 2011/65/EU (2011): 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 (recast). RoHS 2. European Union. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065, zuletzt aktualisiert am 01.07.2011, zuletzt geprüft am 05.10.2012.

Goodman (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report (amended). ERA Report 2006-0383. Unter Mitarbeit von Paul Goodman. ERA Technology Ltd. Online verfügbar unter http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf.

Philips (2018): CMUT and PMUT: New Technology Platform for Medical Ultrasound. Unter Mitarbeit von Rob van Schaijk, Philips Innovation Services, MEMS & Micro Devices. Online verfügbar unter https://www.engineeringsolutions.philips.com/app/uploads/2019/03/CMUT-and-PMUT-Rob-van-Schaijk-November-2018.pdf.

Salmang et al. (2007): Keramik. Unter Mitarbeit von Hermann Salmang, Horst Scholze, Rainer Telle. Berlin, Heidelberg. Online verfügbar unter https://docplayer.org/12466589-H-salmang-h-scholze-keramik.html.

The American Ceramic Society: Definitions of “ceramics” on the web pages of The American Ceramic Society. The American Ceramic Society. Online verfügbar unter

https://ceramics.org/knowledge-center/ceramic-resource-center, and https://ceramics.org/about/what-are-engineered-ceramics-and-glass/structure-and-properties-of-ceramics, zuletzt geprüft am 2020.

The American Ceramic Society (2020): Definition of “ceramics” version 2. The American Ceramic Society. Online verfügbar unter https://ceramics.org/about/what-are-engineered-ceramics-and-glass/structure-and-properties-of-ceramics.

Verband der keramischen Industrie e. V. (2003): Brevier TECHNISCHE KERAMIK. Association of the German Ceramic Industry: Guideline Technical Ceramics. Online verfügbar unter http://www.keramverband.de/brevier_dt/3/3_1.htm.

Yan et al. (2013): Lead-free intravascular ultrasound transducer using BZT-50BCT ceramics. In: *IEEE transactions on ultrasonics, ferroelectrics, and frequency control* 60 (6), S. 1272–1276. DOI: 10.1109/TUFFC.2013.2692.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

13. Exemption 15 of Annex IV: Lead for bonding to ultrasonic transducers

The complete current wording of the exemption is:

"Lead in solders for bonding to ultrasonic transducers"

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCI). For IVD, the exemption expiry date was scheduled for 21 July 2023, and for IMCI for 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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

Drop-in solution	1:1 exchange of lead-solder by lead-free solder without any other changes required
IVD	in-vitro diagnostic medical devices
IMCI	industrial monitoring and control instruments
US	ultrasonic

13.1. Background and Technical Information

COCIR et al. (2020) request the renewal of the exemption with the current wording for another seven years, which is the maximum possible validity period. The renewed exemption shall cover cat. 8 medical devices others than in-vitro diagnostic medical devices (IVD), and cat. 9 monitoring and control instruments including industrial monitoring and control instruments (IMCI).

13.1.1. History of the Exemption

Exemption 15 of Annex IV was proposed in 2006 in the ERA study by Goodman (2006) in case that categories 8 and 9 EEE were to be included into the scope of RoHS. Exemption 15 was listed on Annex IV of Directive 2011/65/EU (RoHS 2) when it was officially published in 2011 and is now reviewed for the first time to adapt it to scientific and technical progress.

13.1.2. Summary of the requested exemptions

COCIR et al. (2020) summarize their exemption request as follows:

"Medical ultrasound transducers are very sensitive to the method of bonding electrical connections and any change in bonding alloy or bond design can have a detrimental effect on image quality. Manufacturers design new transducers with lead-free bonding methods, but it has not been possible, for technical reasons, to redesign all types of transducer without lead-based solders. Those types of transducer that require lead solders cannot be replaced by different types of transducer as each model has unique characteristics and performance. Some medical diagnostic and treatment procedures are possible only with one or a very few types of transducer. Further research is needed to replace lead solders but this will take many years and EU citizens' health may be negatively affected if engineering time is spent on substitution rather than developing innovative new transducers that give superior diagnostics and treatment performance."

JBCE (2021b) add for category 9 that *generally lead-free solder needs higher soldering temperatures than lead solder. US [ultrasonic, the consultants] transducers are designed with a Piezoelectric Effect, so the temperature is critical for the element to avoid damage on its performance. To maintain the piezoelectric effect in the element, this exemption is requested.*

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

COCIR et al. (2020) describe that tin-lead solder with 36 % to 40 % of lead is used to contact medical US transducers. One manufacturer produces 2,590,928 solder bonds per year whereby each contact requires around 0.0404 mg of solder. This results in around 105 g of solder of which 37 % are lead, i.e. 39 g of lead worldwide. Around 20 % of this lead are placed on the EU market in products using exemption 15, around 7.7 g of lead per year.

COCIR et al. (2020) do not know the quantities of lead used by other manufacturers of cat. 8 equipment but expect this to be at least as much again. The total quantity of lead would be of the order of 15 – 20 grams per year.

COCIR et al. (2020) did not provide data for the volumes of lead used under exemption 15 for cat. 9 equipment. JBCE (2021b)state that such data are not available.

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

COCIR et al. (2020) explain that *medical ultrasound transducers are made from lead zirconate-titanate (PZT) ceramic or from single crystal piezoelectric materials such as lead magnesium niobate – lead titanate (PMN-PT) which must be accurately cut and mounted in the correct orientation to achieve the optimum performance. Electrical connections must be made to the two ends of each element of the ceramic or crystal to apply an electric field or to measure the electric field across the material. Each transducer has two to 512 connections, most having more than 100 solder bonds. The bonds must not interfere with the operation of the transducer as this can cause distortion of images. Crystals, as produced, have optically flat surfaces that are difficult to make reliable bonds to, but the bonding surface can be etched to improve adhesion. Some manufacturers of piezoelectric materials produce piezoelectric ceramics or crystals that are pre-poled and which are supplied to medical device manufacturers with the two bonding surfaces metallised to enable electrical connections to be made*.

COCIR et al. (2020) state that *commercial medical transducers are produced in a variety of designs that depend on the medical diagnosis required. Very small devices are made with single piezoelectric elements that can be inserted inside arteries, but most have multiple elements in arrays that are used to create a two dimensional image. Two and three dimensional arrays are used, each element of an array is very small so that making a solder bond without damage to the element requires skill and experience. The ceramic and single crystal materials are brittle and can be damaged by the thermal shock caused by the rapid temperature rise caused by soldering.*

Essential for the bonding with solders is, according to COCIR et al. (2020):

- *Electrical connections must be made to piezoelectric materials without imposing strain on the ceramic or crystal as this will cause distortion of images. Also, excessive strain due to sudden rapid temperature rise can cause cracks in ceramics and single crystal materials.*
- *Medical ultrasound ceramic and crystals oscillate at frequencies typically from 1 MHz to 18 MHz with some niche uses using over 100 MHz. The bond and the metallisation must not be detrimentally affected by this severe vibration for the normal lifetime of the equipment.*
- *Medical ultrasound transducer manufacturers obtain pre-poled crystals from suppliers. The bonding process should ideally not cause depoling or a phase change to the crystal structure, but repoling after bonding is possible if the equipment is available. PMN-PT crystals experience phase changes in the range 80 °C to ~130 °C and have Curie temperatures of about 85 to 170°C, depending on composition. The Curie temperature for PZT suitable for medical ultrasound can be < 200 °C*
- *Medical ultrasound modules used by medical personnel may have one piezo element or an array of typically up to 256 piezo elements, all of which must be bonded without causing any distortion or damage to any of the elements.*

13.2. Applicant's justification for the requested exemption

13.2.1. Substitution and elimination of lead

Scientific and technical impracticability of lead-free solder use

COCIR et al. (2020) claim that medical device manufacturers have carried out research into alternative bonding methods such as with lead-free solders and conducting adhesives since they learned that medical devices would be included in the scope of RoHS. Since 2014 new designs and models have used lead-free solders or conductive adhesives where this has been technically possible, and products have been proven to be reliable. New design products need to be tested for reliability, then clinical trials must be carried out and finally assessed by a Notified Body for Medical Devices Regulation approval. This is a time consuming and complex process which has been possible for new designs, but it has not been possible to use lead-free solders or conducting adhesives as drop-in replacements with the many types of older models that are on the market and are still needed by EU hospitals. A limitation in the number of technical experts and design engineers needed to carry out the redesign research is a significant barrier to substitution as was pointed out by

Goodman (2006) concerning the ability of category 8 and 9 manufacturers to modify their products. Unfortunately, lead-free solders and conducting adhesives cannot be used as drop-in replacements for lead-based solders as is explained below and so it has not been feasible to substitute lead in all of the designs of ultrasound device currently used in the EU. The justification for this exemption is that without this exemption, all older designs could not be sold in the EU and this would have a negative impact on healthcare in the EU.

COCIR et al. (2020) give more technical explanations as to lead-free solders and conductive adhesives and the related constraints to show that their use cannot be achieved as drop-in (1:1 exchange of lead-solder by lead-free solder without any other changes required). Since substitution and/or elimination of lead are, however, scientifically and technically practicable, these explications are not relevant in the context of the further review and are therefore not further detailed in this report. The details are available in the renewal request of COCIR et al. (2020).

13.2.2. Roadmap towards substitution or elimination of lead (COCIR et al. (2020))

COCIR et al. (2020) state that since 2014 all new designs of ultrasound probes have been designed with lead-free electrical connections and these have replaced some old models that have been phased out. Gradually in the future, new transducer designs will be developed that have superior performance to old designs. As these are developed, it will be possible to phase out old models except where they are needed by EU hospitals that have older types of scanners that need these probes either as replacement spare parts or as additional probes. COCIR et al. (2020) expect this to take about 7 – 10 years.

13.2.3. Environmental and socioeconomic impacts

Lacking availability of US devices

According to COCIR et al. (2020), transducers are usually designed to be used with one type of scanner and so EU hospitals that already own a scanner and want to buy additional transducers can usually only use those types that are designed to be used with their scanner. If a transducer were to fail, they can be replaced as spare parts but if a different type of transducers is needed then this would be regarded as new electrical equipment. It is relatively straightforward to use additional transducer probes with some manufacturers' scanners, but this is not always the situation. With some models more significant changes are needed to accept new transducers.

Overall health, safety and environmental impact without renewal of this exemption

COCIR et al. (2020) claim that the work required to replace lead solder bonding requires skilled engineers and takes at least one year for each type of transducer. This assumes that the engineers work on nothing else, such as new product development. Very few suitably trained and experienced engineers are available as they need to have experience in bonding to piezoelectric elements because the bonding method and design can detrimentally affect image quality or reliability. Typically, each manufacturer would have at most the resources to substitute lead solder in one type of transducer at a time in one year. However, one manufacturer could have 10 – 15 types of transducers that use lead solders and so the timescale (without the time needed to gain approvals) is at least 10 – 15 years and only if this proves to be technically possible, which will not be the case with all older

designs. If manufacturers were forced to stop selling these types of transducer in the EU, this would have two negative impacts on EU hospitals and clinics.

Negative impact 1: Impact of restriction of choice for EU hospitals and clinics

COCIR et al. (2020) are afraid that, if this exemption is not renewed, some EU hospitals will not be able to buy additional transducers for their ultrasound scanners that they already own. They might wish to buy additional transducers for their different diagnostic capabilities to treat more patients and for more conditions. Without this, some patients may not be treated by the optimal methods, or they may need to travel further to different hospitals.

COCIR et al. (2020) further put forward that the many ultrasound scanners that are on the EU market have different performance characteristics, as well as being designed for different diagnostic applications and treatments. If some scanners and their transducer probes were no longer available, as these transducers require exemption 15, this would limit the choice available to EU hospitals and clinics.

Some models of ultrasound transducer give superior performance to other types of transducer including those types that use lead-free bonding. One example is the Philips C51 transducer which has exceptional performance in a wide range of abdominal imaging applications. Specific examples of medical procedures include:

- *Scanning "Technically Difficult Patients" where failed examinations with conventional technology on patients with high BMI (Body Mass Index) were successfully imaged with the Philips C5-1 transducer (but cannot be imaged with other transducer types),*
- *Liver Assessment where the imaging using the C5-1 transducer in combination with contrast agent imaging and shear wave elastography allows clinicians to assess liver fibrosis and characterize lesions,*
- *Vascular and Fusion Navigation where the C5-1 transducer provides real-time fusion with historical CT/MR data to reduce repeat costly examinations and allow collaboration with other modalities to facilitate treatment planning and interventional procedures.*

The loss of these capabilities in EU hospitals and clinics would have a negative impact on patients.

Similarly, a pump for medical purposes is one example of the medical devices in which the same principle (piezoelectric elements) is used. The pumps for medical purposes require the administration of drug solutions with a high degree of accuracy. Air bubble sensors are useful for detecting the presence or absence of air bubbles in the drug solutions, and for preventing excessive bubbles from being administered to the patient by stopping the pump if a certain amount of bubbles is entrained. Typical pumps for medical purposes incorporate a bubble sensor. If the bubble sensors were no longer available, as these transducers require exemption 15, this would limit the choice available to EU hospitals and clinics.

Negative impact 2: Inhibiting new product innovations and development

COCIR et al. (2020) fear that diverting engineers away from new product development to replacing lead solders in ultrasound transducer could negatively affect future health of EU citizens. This is because the only reasons for development of new medical devices is to produce new designs with superior diagnostic capability and improve treatments, whereas

substitution for lead in an existing product gives no medical treatment benefits to EU patients.

COCIR et al. (2020) mention one recent example of a newly developed ultrasound product (this was not a substitute for a lead soldered model) that illustrates the benefits of developing new technology is the eL18-4 ultrasound imaging transducer. The eL18-4 has enabled a wide range of new capabilities that allows exceptional imaging performance providing critical clinical information across a wide range of applications. Development of the eL 18-4 required a significant effort whereas the engineers who developed this product would not have been able to do this if they were diverted to substitution work with existing products, which as explained above, is not straightforward and is very time consuming. These engineers are not able to do both.

Environmental impacts

COCIR et al. (2020) state that *quantitative life cycle comparison of the two scenarios of a) developing new medical devices or b) replacing lead in existing medical devices, is not possible as the positive and negative impacts of each scenario are not directly comparable with each other and some impacts are for hypothetical future developments and so cannot be quantified.*

COCIR et al. (2020) provide qualitative comparisons for these two scenarios. Scenario b) is, however, not relevant for this review. The crucial question is why the old models have not been redesigned in the past 10 years to achieve RoHS compliance without relying on exemption 15. The comparison was therefore not adopted to this report. The information is available in the exemption renewal request of COCIR et al. (2020).

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 criteria: 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.

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV as an element. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by*" the REACH Regulation.

REACH Annex XIV (2021) lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- *Lead chromate (entry 10);*

- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

According to JBCE (2021a), none of the above substances are either added to MCPs or contained in MCPs. A renewal of the requested exemption would not weaken the protection afforded by the listing of substances on the REACH Authorisation list (Annex XIV).

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16[152] and entry 17[153] restrict the use of lead carbonates and lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds[154] such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*
- *Entry 28[155] addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30[156] addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they 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 above restrictions are not applicable to the use of lead in MCT, PbS or PbSe. Further on, the substances are part of an article and thus are not placed on the market or used as substances, constituents of other substances or mixtures supplied to the general public.*
- *Entry 63[157] restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This*

[152] 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

[153] 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

[154] 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

[155] 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

[156] 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

[157] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).

- *Entry 72[158] stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

The use of lead alloys 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 in alloys 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.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status July 2021). Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

13.3.2. Scientific and technical practicability of substitution or elimination of lead

The substitution and elimination of lead in applications in the scope of exemption 15 is scientifically and technically practicable. The applicants' justification for the exemption shows that it can be achieved after a redesign of the devices. New models designed and placed on the market from 2014 on do not use exemption 15. COCIR et al. do not report any cases of lacking reliability of these models since 2014 to justify their exemption request, nor any cases of specific US models for which substitution or elimination would be impracticable or insufficiently reliable.

COCIR et al. (2020) provide technical explanations as to lead-free solders and conductive adhesives and the related constraints to show that their use cannot be achieved as drop-in. This fact does not harm the correctness of the above statement that the replacement of lead is technically feasible with adequate reliability after a redesign of the US transducers. The need to redesign EEE to avoid lead in solders is not specific to cat. 8 or cat. 9 EEE, but applies to all categories of EEE, and it is expected if RoHS compliance can be achieved according to Directive 2011/65/EU (2011) (RoHS): An exemption can be granted if, among others, "*[…] elimination or substitution via* ***design changes*** *or materials and components which do not require any* [restricted; the consultants] *materials or substances […] is scientifically or technically impracticable.*"

As a result, the renewal of exemption 15 cannot be justified by technical arguments as to the scientific and technical impracticability of lead substitution or elimination or the not ensured reliability of substitutes.

13.3.3. Environmental arguments and socioeconomic impacts

If this exemption is not renewed, US medical devices with US transducers still depending on exemption 15 to achieve RoHS compliance may no longer be placed on the EU/EEA

[158] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

market. Since US medical devices are important diagnostic tools, the applicant's reasoning can be followed that the health care in the EU/EEA may suffer and human lives be endangered.

In the justification of the exemption renewal request, the applicant focuses on the socioeconomic and health aspects which the applicants put forward to justify that the US transducers and the devices in which they are used have not yet been redesigned in the past 10 years to implement the scientifically and technically practicable substitution and elimination of lead by lead-free solders and conductive adhesives.

COCIR (2021) state that the choice to redesign models depends on the market needs of clients and it always driven by the need to maintain a differentiated portfolio of products to always meet the need of any client. The manufacturer can decide to design a new product as the technological advancements can make it possible to have a better one to substitute the older ones for the same market niche or the manufacturer can decide to redesign an older model, adding some improvement anyway, as there has not been any advancement to justify releasing a new model for such clinical indications. Other older models could have not been redesigned as their useful market life was almost at the end and new models could be used as replacements.

COCIR (2021) further detail the approach saying that a manufacturer selects a few models based on the consideration reported above and assigned engineering teams to the redesign, while other teams are assigned to the design of new models. The design of new models that have better clinical performances must have the priority for the interest of patients and healthcare. According to COCIR et al. (2020), the conversion to lead-free of one type of transducer keeps a skilled engineer busy for at least one year. The number of suitably trained and experienced engineers is limited. Typically, each manufacturer would have at most, the resources to substitute lead solder in one type of transducer at a time, and one manufacturer could have 10 – 15 types of transducers that use lead solder resulting in a timescale of 10 to 15 years without the time needed to gain approvals.

The applicant was asked for examples of manufacturers having 10 to 15 types of transducers in their portfolio. COCIR et al. (2021) state that their members have no information about which other competitor needs the exemption as this is sensitive competitive information. Many companies list the large number of US transducers they currently sell on their respective websites.[159]

The above statements show that achieving RoHS compliance in the foreseen time until the expiry of exemption 15 in 2021 obviously was no criterion to initiate redesigns of US transducers and the related devices. COCIR justify their approach among others arguing that skilled engineers are scarce and need to be allocated to the development of new better performing devices with priority.

[159] Examples provided by COCIR et al. 2021: (https://www.philips.co.uk/healthcare/solutions/ultrasound/ultrasound-transducer)https://www.siemens-healthineers.com/en-uk/ultrasound/ultrasound-transducer-catalog; https://www.gehealthcare.co.uk/products/ultrasound/ultrasound-transducers; https://hcap.fujifilm.com/solutions/transducers/, https://samsunghealthcare.com/en/products/UltrasoundSystem; https://us.medical.canon/products/ultrasound/;

COCIR et al. (2020) provide the example of a *specific newly developed US medical device*[160] *to show the progress for clinical diagnostic progress, e.g. in the below findings summarized from clinical tests*[161] *of a new US device compared to its predecessor model in different hospitals on obese patients:*

- *Exam times reduced by 2 % to 38 %*
- *A reduction in pain and fatigue from scanning in 29 % to 85 % of the cases*
- *Sonographers felt that they had to push less in 48 % to 93 % of the cases in order to achieve penetration of an organ or structure*
- *Marked improvement in colour sensitivity in 31 % to 86 % of the cases*
- *Prevention of recommendations for additional studies with CT and/or MR due to an inadequate ultrasound study in 8 % to 69 % of the cases*

The consultants can follow the manufacturers' point of view that they do not want to put all efforts into redesigning US transducers to enable lead-free solder bonds to the PZT materials in the transducers without any other technical/diagnostic improvements compared to the previous status. This proceeding would bind engineering time which cannot be dedicated to technical progress towards better diagnostic abilities.

In the light of Art. 5(1)(a), manufacturers are expected to achieve RoHS compliance as soon as reliable substitution or elimination of restricted substances is scientifically and technically practicable unless 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 forced redesign of US transducers to achieve RoHS compliance without additional diagnostic benefit would reduce the engineering capacities available for new developments. Slowed down or even temporarily blocked innovation may induce a situation where the total

---

[160] C.f. the following publications referenced by COCIR et al. 2020: http://incenter.medical.philips.com/doclib/enc/14747777/Philips_Affiniti_Ultrasound_Customer_Story_Synergies_in_Ultrasound_Cleve...pdf %3ffunc %3ddoc.Fetch %26nodeid %3d14747777; incenter.medical.philips.com/doclib/enc/fetch/2000/4504/577242/577260/593280/593786/C5-PureWave-TDP-Study-Whitepaper.pdf %3fnodeid %3d9724460 %26vernum %3d-2; https://www.ncbi.nlm.nih.gov/pubmed/24782633; https://www.usa.philips.com/b-dam/b2bhc/us/topics/shearwave/LiverAssessment_DrBarr_WhitePaper_V4_LR.pdf; https://www.usa.philips.com/c-dam/b2bhc/us/feature-details/purewave/45229112881_EPIQ_PureWave_DataSheet_FNL_lr.pdf; https://www.usa.philips.com/c-dam/b2bhc/us/feature-details/purewave/45229112881_EPIQ_PureWave_DataSheet_FNL_lr.pdf; http://incenter.medical.philips.com/doclib/enc/fetch/2000/4504/577242/577243/577244/582196/582197/Combining_modalities.pdf %3fnodeid %3d11799952 %26vernum %3d-2; https://www.philips.com/c-dam/b2bhc/master/landing-pages/epiq/pdfs/case-study/case-study-carotid.pdf; https://www.philips.com/c-dam/b2bhc/master/landing-pages/epiq/pdfs/case-study/case-study-el18-4-neckpathology.pdf; https://www.usa.philips.com/c-dam/b2bhc/master/sandbox/marketing-catalog/ultrasound/general-imaging/pdfs/case-study-freeman.pdf; https://www.philips.com/c-dam/b2bhc/master/landing-pages/epiq/pdfs/case-study/case-study-breast-masses.pdf; https://www.philips.com/c-dam/b2bhc/master/landing-pages/epiq/pdfs/case-study/case-study-microflow-imaging-breast-abnormalities.pdf; https://www.usa.philips.com/c-dam/b2bhc/master/sandbox/marketing-catalog/ultrasound/general-imaging/pdfs/case-study-musculoskeletal.pdf; https://www.philips.com/c-dam/b2bhc/master/landing-pages/epiq/pdfs/case-study/case-study-placenta-accreta.pdf; http://incenter.medical.philips.com/doclib/enc/fetch/2000/4504/577242/577260/593280/593431/Philips_PureWave_crystal_technology.pdf %3fnodeid %3d1659121 %26vernum %3d-2;

[161] http://incenter.medical.philips.com/doclib/enc/fetch/2000/4504/577242/577260/593280/593786/C5-PureWave-TDP-Study-Whitepaper.pdf %3fnodeid %3d9724460 %26vernum %3d-2

negative health impacts caused by substitution are likely to outweigh the total health benefits thereof. To avoid such adverse impacts, the consultants think that renewing the exemption could be justified by Art. 5(1)(a).

Nevertheless, the legal obligation to achieve RoHS compliance remains. Based on COCIR's statement that manufacturers can redesign one US transducer type per year (excluding approval) and a portfolio of 10 to 15 models, the conversion should be finalized until 2029 latest (2014 + 15 years). The exemption should therefore be renewed for seven years until 21 July 2028. It is expected that by that time, the conversion process is finalized, or that the exemption will at most be needed for another one or two years. Since most of the innovation in US medical examinations goes back to innovation in the devices rather than in the transducers, the renewal of the exemption should not delay innovation.

13.3.4. Renewal of exemption 15 for EEE of cat. 9 EEE

Even though COCIR and JBCE had submitted a joint renewal request, the application did not contain information related to cat. 9 equipment. JBCE was therefore requested to substantiate their renewal request for cat. 9 equipment.

JBCE et al. (2021) *stated that they cannot give examples of cat. 9 EEE which uses exemption 15. They confirm that the technical issues raised in the renewal request for cat. 8 EEE apply to the US transducers used in cat. 9 other than industrial monitoring and control instruments as well.* The consultants asked JBCE whether the producers of cat. 9 EEE have the same socioeconomic limitations to achieve RoHS compliance with all their US transducer models like the cat. 8 manufacturers.

JBCE (2021d) said that it is not easy to describe the socioeconomic limitation due the very long supply chain in cat. 9. JBCE (2021c) generally procure the parts or components which use this RoHS exemption and install it into equipment in Category 9, so we have tried to collect the information of the effect from supplier chain in case of the IV-15 termination and it is not so easy to have the precise information. JBCE (2021c) support their request with the report of Goodman (2006): "The new product development time for many Category 8 and 9 products over 4 years and can be 7 years or longer." This timeframe is required to be undertaken, such as, engineering changes of electric circuits and mechanical components, durability testing, reliability test, evaluation of performance in service, establishment of production lines, and submission for product specific approvals if required. Therefore, we JBCE (2021c) would like to have the seven year period for substitutions.

The information provided by the applicant does not substantiate the request to renew the exemption. Additionally, the above justification of seven years and more of development time for cat. 9 equipment other than industrial monitoring and control instruments has passed already since 2014. The information provided by the applicant is thus not sufficient to justify recommending the renewal of the exemption for cat. 9 EEE other than industrial monitoring and control instruments.

13.3.5. Conclusions

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

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

COCIR request the renewal of exemption 15 for the maximum validity period of seven years for cat. 8 medical devices other than in-vitro diagnostic medical devices. After a redesign of the US transducers, lead in the solder joints to the PZT materials in the transducers is scientifically and technically practicable and the reliability of the substitutes is ensured. Redesigned US transducers without lead solders have been placed on the EU/EEA market since 2014. According to the applicant, manufacturers can redesign one type of US transducer per year without reducing engineering capacities for new developments to a degree that may hamper technical progress towards better diagnostic abilities. With up to 15 types of US transducers per manufacturer, the redesign process may thus take a total of up to 15 years without the time required for approval.

Technical progress in the case of US medical devices can improve health care and save lives. An accelerated redesign of US transducers forced by RoHS resulting in lead-free soldered US transducers without any additional technical progress towards better diagnostic performances would bind engineering capacities. Engineers may then not be available for new developments, which may induce a situation that the total negative health impacts caused by substitution are likely to outweigh the total health benefits thereof.

The consultants therefore recommend to renew the exemption for seven years until 21 July 2028 to avoid these negative health impacts. The redesign processes of US transducers should be finalized by 2029 latest (2014 + 15 years) so that it is expected that, in case the exemption is requested to be renewed at all, a maximum of one or two years may still be required. Since ultrasonic transducers in devices with first Declarations of Conformity after 31 December 2013 are redesigned to accommodate the specific properties of lead-free solders for the relialibity of the ultrasonic transducers, substitution of lead is scientifically and technically practicable with proven reliability and the exemption is no longer required for these devices.

JBCE request the renewal of the exemption for cat. 9 EEE other than industrial monitoring and control instruments. The applicant could, however, not substantiate the request so that the consultants cannot recommend the renewal of the exemption for these cat. 9 devices.

13.4. Recommendation

The accessible information suggests that substitution and elimination of lead in US transducers in the scope of exemption 15 is scientifically and technically practicable and that the substitutes' reliability is ensured after a redesign or new design of the devices accommodating the specific properties of lead-free solders. The redesign requires more time to balance and to combine the RoHS compliance activities with the development of new products. A higher redesign rate of the US transducers would reduce the manufacturers' capacities to develop new devices with higher diagnostic performance. This can induce a situation that the total negative health impacts caused by substitution are likely

to outweigh the total health benefits thereof, which in the consultants' opinion justifies renewing the exemption in line with Art. 5(1)(a) to avoid such adverse health impacts.

In cat. 8 medical devices others than in vitro diagnostic medical devices with first Declarations of Conformity after 31 December 2013 substitution of lead is scientifically and technically practicable with proven reliability so that they can be excluded from the exemption scope. The conversion process should be finalized in 2029 latest for all ultrasonic transducers placed on the market. The consultants therefore recommend the maximum validity period of seven years until 21 July 2028.

To reflect the current status of lead substitution in US transducers, the consultants recommend the below wording for the renewed exemption 15:

	Exemption	Scope and dates of applicability
15	*Lead in solders for bonding to ultrasonic transducers*	*Expires on* - *[Date of the COM's decision + 12 months] for cat. 9 monitoring and control instruments others than industrial monitoring and control instruments;* - ***{**[Date of the COM's decision + 12 months] for cat. 8 medical devices other than in vitro diagnostic medical devices**};*** - *21 July 2023 for cat. 8 in-vitro diagnostic medical devices;* - *21 July 2024 for industrial monitoring and control instruments;* - *21 July 2028 for cat. 8 medical devices other than in vitro diagnostic medical devices **{**for which the Declaration of Conformity is issued for the first time before 1 January 2014**}.***

In case the COM wishes to renew the exemption for cat. 8 medical devices others than in vitro diagnostic medical devices without the reference to the Declaration of Conformity, the respective two sections in **{**brackets**}** should be omitted in the above "Scope and dates of applicability" field. If the COM decides to adopt the reference to the first Declaration of Conformity, the COM should take over these sections in **{**brackets**}**. Medical devices with this Declaration issued after 31 December 2013 are then excluded from the renewed exemption scope, differently from the current situation which has no reference to such a Declaration. The consultants are of the opinion that formally, RoHS Art. 5(6) requires a transition period of 12 to 18 months in this case since the COM would renew the exemption with a restricted scope even though the applicant had requested the renewal with the current scope, which can be considered at least a partial rejection of the requested renewal request. The consultants recommend a transition period of 12 months. Devices with lead-free bonds in ultrasonic transducers and Declarations of Conformity after 31 December 2013 have been available on the market since 2014 already so that only administrative adaptations should be required for manufacturers and their suppliers.

The renewal of exemption 15 was requested also for cat. 9 monitoring and control instruments other than industrial monitoring and control instruments. The applicant could, however, not substantiate the renewal request so that in the absence of sound evidence Art. 5(1)(a) does not give the consultants a base to recommend the exemption to be

renewed for this type of EEE. If the COM does not renew this part of the exemption, Art. 5(6) requires a transition period prior to the exemption expiry of 12 to 18 months starting on the day after the COM's decision not to renew the exemption. Given the fact that the applicant failed to provide information about the use of this exemption in the respective cat. 9 EEE, the consultants recommend 12 months.

13.5. References

COCIR (2021): Answers to questionnaire 2 sent via e-mail by Riccardo Corridori, COCIR, to Dr. Otmar Deubzer, Fraunhofer IZM.

COCIR et al. (2020): Request for renewal of exemption 15 of RoHS Annex IV. Unter Mitarbeit von JBCE COCIR. Online verfügbar unter http://rohs.biois.eu/Ex_15-IV_COCIR-JBCE_Renewal-Request.pdf.

COCIR et al. (2021): Answers to questionnaire 4 sent via e-mail by Emily Tyrwhitt Jones, RINA, on behalf of COCIR, to Dr. Otmar Deubzer, UNITAR.

Directive 2011/65/EU (2011): 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 (recast). RoHS 2. European Union. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065, zuletzt aktualisiert am 01.07.2011, zuletzt geprüft am 05.10.2012.

Goodman (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report (amended). ERA Report 2006-0383. Unter Mitarbeit von Paul Goodman. ERA Technology Ltd. Online verfügbar unter http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf.

JBCE (2021a): Answers to questionnaire 3, received from Takuro Koide, JBCE, via e-mail by Dr. Otmar Deubzer, Fraunhofer IZM, on 10 June 2021.

JBCE (2021b): Answers to questionnaire 1 received via e-mail from Takuro Koide, JBCE, by Dr. Otmar Deubzer, Fraunhofer IZM.

JBCE (2021c): Answers to questionnaire 2 sent via e-mail by Takuro Koide, JBCE, to Dr. Otmar Deubzer, Fraunhofer IZM.

JBCE (2021d): Answers to questionnaire 3, sent via e-mail by Takuro Koide, JBCE, to Otmar Deubzer, UNITAR.

JBCE et al. (2021): Answers to questionnaire 4, sent via e-mail by Takuro Koide, JBCE, to Otmar Deubzer, UNITAR.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

14. Exemption 17 of Annex IV: Pb in portable emergency defibrillators

The exact wording of exemption 17 is as follows:

"Lead in solders of portable emergency defibrillators"

The exemption expires on 21 July 2021 for EEE of category 8 medical devices other than in-vitro diagnostic medical devices. In principle, since the exemption scope is not further defined, the exemption applies to all other EEE of cat. 8 and cat. 9 as well, but the exemption wording shows that it is only relevant for cat. 8 devices which are not in-vitro diagnostic devices.

Declaration

In the sections preceding section 14.4 (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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and definitions

AED	Automated External Defibrillator
COCIR	European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries
COM	European Commission
RoHS 1	Directive 2002/95/EC
RoHS 2, RoHS	Directive 2011/65/EU

14.1. Background

COCIR (2020a) submitted a request for the renewal of exemption 17 of Annex IV (category 8) until the end of 2025. No responses were received during the online consultation.

14.1.1. History of the exemption

Goodman (2006) recommended the Commission (COM) to grant this exemption in its current wording. The COM adopted the exemption proposed above as no. 17 of Annex IV in the RoHS Directive 2011/65/EU when cat. 8 EEE was included into the scope of the RoHS Directive in 2011.

An application for renewal was submitted in time, and exemption 17 will thus be reviewed for the first time to adapt it to scientific and technical progress.

14.1.2. Summary of renewal request

COCIR (2020a) submitted a request for the renewal of this exemption on behalf of its members. The requested wording of exemption 17 is identical to the existing wording under Annex IV of RoHS Directive 2011/65/EU. No consultation responses were received.

According to COCIR (2020a): "Portable emergency defibrillators are used to save lives when people suffer from heart attacks. Patients whose hearts have stopped must be treated within 10 minutes for survival to be possible. Defibrillators must be very reliable as any defects could result in a fatality. There are many types of defibrillators sold in the EU that rely on exemption 17 and manufacturers have been working on substitution for many years, however substitution of lead is not straightforward. Usually redesign is necessary […] Defibrillator manufacturers have estimated that the current work on new models will be completed, and approvals granted by the end of 2025, at which time the lead soldered models can be discontinued."

COCIR (2020a) added that the replacement of the Medical Device Directive by the Medical Device Regulation requires all medical devices sold in the EU to be re-approved by EU Notified Bodies. This causes additional time requirements for the changeover to lead-free product lines.

No other requests for renewal were submitted, an no other stakeholders contributed to the online stakeholder consultation.

14.2. Technical description of the requested exemption

14.2.1. Amount of lead used under the exemption

In the exemption renewal form COCIR (2020a) stated that the estimated total amount of lead from all manufacturers in the defibrillators placed on the EU market is about 100 kg per year. COCIR submitted additional confidential information and calculations to support the stated figure. The actual amount will be higher, since not all manufacturers have supplied data.

14.2.2. Use of lead in portable emergency defibrillators

COCIR (2020a) stated that portable emergency defibrillators must be very reliable as any malfunction can result in a patient's death and therefore extremely high reliability is the most important characteristic of these products.

Lead is a constituent of solder to make electrical connections between electronic components, circuit boards and wires in emergency defibrillators. There are many designs of defibrillators with different requirements for reliability in harsh environments. Models that are used on the go will experience the most vibration, the largest temperature fluctuations and are most likely to be regularly dropped. Examples of such uses are in ambulances, police vehicles, at sporting events, in helicopters and for military purposes. COCIR provided an example of a defibrillator instruction manual (Physio-Control 2019).

For sufficient reliability of the connections under sometimes harsh conditions, a redesign of these models is necessary. According to COCIR (2020a), *"Factors such as corrosive atmosphere (for example cleaning agents containing ammonia or chlorides), temperature*

extremes, temperature cycling, humidity, vibration and mechanical drop can affect RoHS lead-free solder connections more harshly. Furthermore, RoHS lead-free soldered circuits have an increased risk of creating 'Tin Whiskers' where a whisker grows from one surface to another surface causing an electrical short inside the product. All of these reliability issues must be addressed in new designs; requiring very lengthy research and testing to ensure very high reliability that is required for these safety critical devices."

According to COCIR (2020a) the essential combination of required characteristics of solder bonds are:

- *Be sufficiently ductile – to avoid damage due to thermal expansion mismatch between laminate and components.*
- *Melting temperature 160 °C to 220 °C – to avoid damage to components.*
- *Suitable for mass production using reflow soldering of surface mount components, as well as wave and hand soldering.*
- *Solder bonds must be resistant to cyclic thermal fatigue, intense vibration and drop-shock.*
- *None of the solder bonds inside defibrillators must fail.*

14.3. Justification for the requested exemption

14.3.1. Substitution and elimination of lead

Lead is used in solders to make electrical connections between electronic components, circuit boards and wires. Elimination of solder is impossible; lead-free solders are common practice to substitute lead. Thus, lead-free solders are widely available; but they are no drop-in replacements – substitution can affect reliability, which is a key feature of portable defibrillators related to their functionality. COCIR (2020a) explained:

"Manufacturers will usually not be able to use a different (lead-free) solder with the same circuit design because older models will use components that are incompatible with lead-free solders. The components either cannot withstand the higher soldering temperature required, or they contain tin/lead solder inside the components. An example is ball grid array (BGA) integrated circuits, which may contain tin/lead balls which cannot be soldered to circuit boards with lead-free solders as bonds would be unreliable (as well as containing lead). Therefore, complete circuit redesign is usually necessary as lead-free versions of previously used components are often not available and as this will probably mean that newer and different microprocessors are used, the software will also need to be rewritten."

The manufacturers are on the way switching to completely lead-free production. With the redesign of a model, defibrillators must be re-approved as medical devices in all countries where they are sold. COCIR (2020a) stated that it can take up to two years after a new or redesign to complete testing, trials and time-consuming compliance procedures. This process is required for each type or model, and each manufacturer may produce 10 to 20 different types of defibrillators. They estimate that this should be complete by the end of 2025.

14.3.2. Roadmap towards substitution or elimination of lead

COCIR (2020a) stated that field data for lead-free defibrillators are still very limited, with very few in use for more than five years and some manufacturers having less than two years' experience with only a small number of designs. Therefore, uncertainty about the reliability of new lead-free products is still a concern. They state manufacturers have developed new defibrillators with lead-free solders since 2014 with research and re-design work originally started before 2014. Typical timescales for a new defibrillator design according to COCIR (2020a) are:

Table 14-1: Timescales for a new defibrillator design

Phase	Elapsed time per model
Design of new circuit using lead-free solders	1 year
Rewrite software	1 year
Reliability testing – thermal cycling drop-shock, vibration, etc.	1 - 2 years
Clinical trials	1 - 2 years

COCIR (2020a) explained further: "Due the limited number of suitably trained and experienced engineers available to replace all current lead soldered models, COCIR estimate that design, test and approvals of new models that can replace all current models will not be complete until the end of 2025." *In a second questionnaire* (COCIR 2021 b) stated that there is a subset of defibrillators which are specifically designed for the most demanding environments, such as emergency responder vehicles. But all defibrillator models provide high durability and reliability (drops, vibration, operating temperature, water resistance, dust resistance, cleaning, high voltage etc.).

14.3.3. Environmental arguments and socioeconomic impacts

No environmental arguments were presented in the context of this exemption.

Regarding possible socioeconomic impacts, COCIR (2020a) states that a price increase in fixed costs – the costs of redesign, testing, trials and gaining approvals – will be passed on to the customers. They further state: *"Many people die in the EU each year from heart attacks. Some could be saved if portable emergency defibrillators are available and are accessible within a few minutes. Currently, only 12.8 % at best and 1.7 % at worst of heart attack victims are treated with defibrillators in EU Member States. As a result, a high proportion of the 300,000 heart attack victims in the EU die annually. This death rate could be reduced by an increase in the availability of defibrillators which will occur if prices are as low as possible and there are no supply shortages, but this would not occur if most models could not be sold in the EU because this exemption is not renewed."*

14.4. Critical review

14.4.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the 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.

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by*" the REACH Regulation if the requested exemption would be granted/renewed.

REACH Annex XIV (2021)[162] *lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:*

- *Lead chromate (entry 10);*
- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

The applications in the scope of the exemption at hand do not use any of the above lead compounds.

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- Entry 16[163] and entry 17[164] restrict the use of lead carbonates and lead sulphates in paints;

[162] ECHA, https://echa.europa.eu/authorisation-list?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

[163] 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

[164] 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

- *Entry 19 refers to arsenic compounds but includes a few lead compounds165 such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*
- *Entry 28*[166] *addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30*[167] *addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 63*[168] *restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72*[169] *stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

The exemption for lead in solders used 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, the use of lead in solders in the scope of the requested exemption 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.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status (October 2021) 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 the respective criteria of Art. 5(1)(a) apply.

[165] 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

[166] 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

[167] 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

[168] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[169] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

14.4.2. Scientific and technical practicability of substitution or elimination of lead in portable emergency defibrillators

The submitted information suggests that the substitution of lead is scientifically and technically practicable but that the implementation is limited by the necessary time for design and approval procedures. Upon request, COCIR (2021a) confirmed that: *"It is not possible to accelerate this process due to a limit on the number of expert engineers that are available, the elapsed time required for testing and the time needed to gain approvals."* The argument that devices not designed for use of lead-free solders need to be redesigned reflects the experience with lead-free soldering collected in the past around 15 years. COCIR (2020b) explained that lead-free versions of previously used components are often not available. Therefore, newer and different microprocessors are used which requires the software to be rewritten.

An internet search for lead-free models available on the market was not productive. In random samples, no information could be found in web stores as to whether a model is lead-free or contains lead. This does not seem to be a sales criterion so far.

Progress and timing of the conversion

The precise timing of the transition to lead-free models was unclear, as some phases may run in parallel, but most are iterative. When asked, COCIR (2020b) explained that each round of testing at each phase consists of approximately 140 tests. To qualify a Class III medical device like defibrillators, at least three phases of testing must be performed, and each phase may require more than one round of testing. In a further questionnaire COCIR (2021a) explained that tests are performed for the largest possible number of affected products so that the results can be used for more than one system. In summary, the conversion to lead-free equipment is both sequential and parallel. The applicant's time schedule foresees a complete transition by the end of 2025.

COCIR (2020b) stated that COCIR members' proportion of lead-free devices is approximately 10 % of the models, so 90 % still require lead-based solders (status 2020). They knew of two approvals of lead-free defibrillators in the process for an existing product line that includes several products. COCIR (2020b) indicated that additional approvals might be underway but that they cannot confirm this due to the limited timeframe. In response to a renewed request for new information on ongoing approvals in June 2021, COCIR (2021a) wrote that *"no further information can be shared at this time, other than the project to update affected AED products to comply with RoHS without the need for RoHS Annex IV, Exemption 17 is on-going."*

In a short internet investigation for lead-free defibrillators – lead-free in the sense that they do not contain lead in applications in the scope of the exemption at hand – to possibly substantiate the applicant's above figures, no such defibrillators could be identified. Two online shops were contacted, but no information could be obtained as to whether they sell such lead-free defibrillators. The investigation thus did not yield a solid result. The fact that no lead-free models could be identified can simply go back to the fact that all defibrillators in shops are marked as "RoHS-compliant" only, which they are even if they contain lead due to exemption 17. Products that do not use exemption 17 may be placed on the market, but possibly are not highlighted as "lead-free" in this sense.

In a further questionnaire, the consultant followed up on the only 10 % of converted models since 2011, and how the remaining 90 % are to be reached in four years. COCIR (2021a) stated that research and re-design work originally started before 2014 when Medical

Devices entered the scope of RoHS, therefore the four years to transition to lead-free only refers to finalize the work on models whose conversion had started earlier already, and not to the whole transition time for the remaining 90 % of models. COCIR (2021a) explained: *"Wherever possible testing is undertaken to reflect the largest number of affected products so that the testing requirements are able to be utilized for more than one system. Of course, there are limitation to this strategy, for example when a circuit has to be redesigned, as well as gaining global approvals. It is not possible to accelerate this process due to a limit on the number of expert engineers that are available, the elapsed time required for testing and the time needed to gain approvals."*

For the consultants, it is not clear what actions have been taken by the applicant since 2011 to advance the conversion to lead-free solders. This could not be presented by the applicant with concrete figures/percentages. The conversion is undoubtedly associated with additional effort which, however, all producers of EEE in the scope of the RoHS Directive had to go through since the transition to lead-free in the end is product specific and thus confidential for manufacturers or their contract assemblers. It is unclear whether the manufacturers could have achieved faster success. Complicating matters further, not all AED manufacturers are represented by COCIR. No other applications or inputs in the stakeholder process have been received. The consultant followed up on why it appears that only a small portion of AED manufacturers are represented by COCIR and yet no other applications or input was received in the stakeholder process.

COCIR (2021e) answered that sometimes there is the assumption that the same scope of the exemption will be granted when an exemption is requested to be renewed. COCIR (2021e) described their experience in the AED market this way: "*From experience with the past years, it is common to see companies that are based extra-EU but sell in the EU, understanding that if an exemption is requested for renewal, then the renewal is granted. However, the mechanism of RoHS is not very clear to most companies and EC public consultations normally reach the same companies that are active already. This is even more true for companies manufacturing the components that are used in applications included in finished products (e.g. O_2 sensors)."*

Differentiation from other industries with harsh environments

Further, the applicants were asked to explain why the transition appears to be more complicated for defibrillators than for the automotive industry and for medical devices such as MRIs and PETs. *Regarding automotive industry COCIR (2020b) explained that "Unlike the automotive industry, drop shock performance is a critical parameter as during defibrillators' normal operations, they could easily experience drops from 1 m or above. It is foreseeable that defibrillators can be transported in helicopters and in ambulances where they suffer from severe vibration or be located at locations where they experience large temperature fluctuations, high humidity, marine environments or are used in factories where they may be exposed to corrosive chemicals. All of these types of situations represent a range of harsh environments which are experienced by relatively few types of products and of these, none have the same, very high reliability requirement."*

Subdivision according to operation conditions

Following the applicant's above statement, the consultants proposed to differentiate the defibrillators into those who are designed to operate in harshest environments and others. The replacement of lead should be technically less demanding if milder environmental influences prevail. A subdivision of defibrillators into indoor (in hospitals, medical practices,

in companies, in public buildings such as schools and authorities) and outdoor operations such as ambulances, helicopters, military purpose and big events was discussed in an online meeting with the applicant and in questionnaires COCIR (2021b), (2021c), (2021e).

In the end, this approach is not applicable because the producers' strategy is not based on the technical difficulty of lead substitution, which would result in the early substitution of devices that operate in milder environments, and a later substitution in defibrillators for very harsh environments. Producers follow the strategy to link redesigns to substitute lead with a technical upgrade of the device.[170] Differentiating defibrillators based on the place of use or specific use conditions is thus not compatible with the producers' RoHS compliance approaches. The approach was therefore dismissed.

Subdivision according to date of certification

To reflect the status of conversion to lead-free portable defibrillators in the scope of exemption 17, the consultant proposed a distinction based on the date of certification. Following this approach, the exemption could be narrowed as follows to reflect conversion already done and to reflect this progress in the exemption scope:

"Lead in solders in portable emergency defibrillators for which the Declaration of Conformity is issued for the first time before 1 January 2015"

Expires on 31 December 2025

The idea of the certification approach is to exclude devices from the exemption that were certified after 31 December 2014 and to renew the exemption until 31 December 2025 for models of defibrillators certified before 1 January 2015 which are not yet redesigned and still contain lead. After that date, all defibrillators placed on the market have to be lead-free. COCIR clearly stated in the exemption request that the remaining models are scheduled to be converted by the end of 2025. (COCIR 2021d) agreed to the above approach and wording.

14.4.3. Environmental arguments and socioeconomic impacts

The applicants did not provide environmental arguments to justify the exemption. As socioeconomic arguments, the applicant puts forward that redesigns include lead-free design, but conversion to lead-free is not an occasion for redesign. COCIR (2020a) stated that *"in practice, due to the very long time required for redesign, the technical difficulties involved and the uncertainty over reliability means that manufacturers focus their effort to develop new products that utilise the latest medical knowledge to improve the likelihood of saving a life rather than substitute lead in existing models."*

(COCIR 2020 a) furthermore argued with price increases due to the costs of redesign, testing, trials and gaining approvals, which will be passed on to the customers. From the consultants' point of view, this conversion is necessary anyway and is also announced to be accomplished until the end of 2025. The argued costs will therefore be incurred as legal compliance cost like it happened in all other categories of EEE when RoHS compliance had to be achieved. It can, however, be followed that this cost may be reduced if it is linked to a technical upgrade instead of converting, testing and qualifying a current defibrillator design

[170] See section 14.4.3 on pae 347

into a lead-free design and upgrade the device technically later requiring testing and certification again.

If the exemption is not granted, the applicant foresees more deaths due to non-available or insufficiently reliable portable defibrillators. (COCIR 2020 b) summarized that “automated External Defibrillators (AED) devices are intended to be operated by lay users with no previous training, while in a chaotic and nerve-racking situation.” The consultant can follow this approach – complete restriction of the exemption may result in supply shortages as devices can no longer be placed on the market and, in turn, in preventable deaths. Nevertheless, future wording of the exemption should reflect progress in the development of lead-free AEDs.

14.4.4. Conclusions

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

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

In their exemption renewal request, COCIR described the difficulties of a conversion to lead-free designs, which in turn entails a complete redesign and re-certification of the devices. This resource- and time-intensive process limits the rapid conversion of the remaining lead-containing models.

Substitution of leaded solders is scientifically and technically practicable. The reliability of the substitutes can be ensured for new designs which accommodate the specific properties of lead-free soldiers and their processing.

However, if the exemption would not be granted, supply bottlenecks and less AEDs would be available in the field, given the fact that the applicant indicates that only 10 % of the AEDs are actually lead-free soldered ones. Since each manufacturer follows an individual lead-free conversion plan for the models in the portfolio, it cannot be excluded that important models with specific properties, even though offered by different manufacturers, in the end would no longer be available. The quantity and status of other manufacturers who are not COCIR members is unknown. In the end, the lacking availability of AEDs on the market may entail severe consequences such as additional deaths.

14.5. Recommendation

The available information suggests that the substitution of lead in portable emergency defibrillators in the scope of exemption 17 of Annex IV is scientifically and technically practicable, but that it requires time to redesign and/or replace older models by new ones and achieve the approval by notified bodies. The process according to the applicant started

in 2014 and is supposed to be ongoing until end of 2025. An immediate restriction of the exemption would lead to supply shortages and associated avoidable deaths may occur. In the consultants' view, Art. 5(1)(a) would therefore allow renewing the exemption.

The consultants recommend the below wording to reflect the current status of the lead-free conversion process:

	Exemption	***Scope and dates of applicability***
17	*Lead in solders in portable emergency defibrillators*	*Expires on [Date of the COM's decision + 12 months] for cat. 8 medical devices other than in-vitro diagnostic medical devices.*
17(a)	*Lead in solders in portable emergency defibrillators for which the Declaration of Conformity is issued for the first time before 1 January 2015*	*Expires on 31 December 2025 for cat. 8 medical devices other than in-vitro diagnostic medical devices*

In case the COM decides to adopt the reference to the first Declaration of Conformity in exemption 17(a), cat. 8 medical devices others than in vitro diagnostic medical devices with this Declaration issued after 31 December 2014 are excluded from the renewed exemption scope, differently from the current situation which has no reference to such a Declaration. The consultants are of the opinion that formally, RoHS Art. 5(6) requires a transition period of 12 to 18 months in this case since the the exemption would be renwed with a restricted scope even though the applicant had requested the renewal with the current scope. This situation can be considered at least a partial rejection of the requested renewal request. The consultants therefore recommend a transition period of 12 months to allow the obligatory administrative adaptations in the supply chain and at producers.

In case the COM wishes not to follow the above certification-based approach, the consultants recommend the renewal of the exemption with its current wording and an expiry date of 31 December 2025:

	Exemption	***Scope and dates of applicability***
17	*Lead in solders in portable emergency defibrillators*	*Expires on 31 December 2025 for cat. 8 medical devices other than in-vitro diagnostic medical devices*

14.6. References

COCIR (2020a): Request for renewal of exemption 17 of RoHS Annex IV. Online verfügbar unter http://www.rohs.biois.eu/Ex_17-IV_COCIR_Renewal-Request.pdf.

COCIR (2020b): Answers to questionnaire 1 (clarification questionnaire). Online verfügbar unter http://www.rohs.biois.eu/Exe-17-IV_COCIR_Questionnaire-1_Clarification.pdf.

COCIR (2021a): Answers to questionnaire 2, sent via e-mail by Emily Tyrwhitt Jones (RINA Tech UK Ltd.) to Jana Rückschloss, Fraunhofer IZM, via e-mail.

COCIR (2021b): Answers to questionnaire 3.

COCIR (2021c): Answers to questionnaire 4.

COCIR (2021d): Expert round, 22.09.2021. video call an Fraunhofer IZM. microsoft teams meeting.

COCIR (2021e): Answers to questionnaire 4, part 2.

Goodman (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report (amended). ERA Report 2006-0383. Unter Mitarbeit von Paul Goodman. ERA Technology Ltd. Online verfügbar unter http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf.

Physio-Control (2019): LIFEPAK 15 monitor/defibrillator. Operating Instructions. Physio-Control, Inc. Redmond, WA USA.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

RoHS Directive 2011/65/EU: 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 (recast). RoHS 2. European Union (1 July 2011). Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065.

15. Exemption 26 of Annex IV: Lead in solders of applications used below – 20 °C

The complete current wording of the exemption is:

> *Lead in the following applications that are used durably used at a temperature below – 20 °C under normal operating and storage conditions:*
>
> *(a) solders on printed circuit boards;*
>
> *(b) termination coatings of electrical and electronic components and coatings of printed circuit boards;*
>
> *(c) solders for connecting wires and cables;*
>
> *(d) solders connecting transducers and sensors.*

Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C.

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date was scheduled for 21 July 2023, and for IMCIs for 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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

CT	computer tomography
MRI	magnetic resonance imaging
MRT	magnetic resonance tomography
PET	positron emission tomography
Pb	lead

15.1. Background and Technical Information

COCIR et al. (2019) request the renewal of the exemption with the current wording and the below numbering:

I) Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions:

(a) solders on printed circuit boards;

(b) termination coatings of electrical and electronic components and coatings of printed circuit boards;

(c) solders for connecting wires and cables;

(d) solders connecting transducers and sensors.

II) Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C.

Duration Part I):

- Low helium content MRI (<10 kg/scanner): Maximum validity period of 7 years
- Standard MRI: Until 30 June 2027

Duration part II):

- Categories 8 and 9 equipment: Maximum validity period of at least 7 years

15.1.1. History of the Exemption

COCIR (2011) applied for the first part of the exemption IV-26, i.e. the part enabling the use of lead in applications durably stored at a temperature below – 20 °C in 2011. Gensch et al. (2012) recommended the COM to grant the exemption in 2012. The last section of the exemption (Lead in solder of electrical connections to temperature measurement sensors …) was not included into this exemption request in 2012. Lake Shore (2014) requested this part of the exemption in 2014. Gensch et al. (2015) reviewed the exemption request and the COM adopted it as an add-on to the above exemption, which resulted in the current wording of exemption IV-26.

15.1.2. Summary of the requested exemptions

COCIR et al. (2019) summarize their exemption request as follows:

"*Medical magnetic resonance imaging (MRI) scanners are large and very complex and utilise liquid helium cooled superconducting electromagnets. Associated with these magnets are wires, cables, sensors and control electronics some of which are at locations where the temperature is very low. Everything inside of the vacuum vessel of an MRI magnet during normal operation is at ~40 K = -233 °C (or less) and ~4.2 K = -268.8 °C (or less). Everything at/on the outer vacuum vessel including service turret elements must withstand storage conditions to -25 °C. During helium filling, ramping, quenching the service turret elements will experience temperatures below -150 °C as air is known to be liquefied in these conditions (oxygen liquefies at -183 °C); the service turret and vent area is at cryogenic temperatures during such periodic operations or events.*

Manufacturers have built MRI circuits using tin/lead and lead-free solders and tested these at realistic use conditions of low temperature and vibration to compare the reliability with different solders. At low temperatures, the lead-free soldered circuits failed sooner than the tin/lead circuits due to bond failure. It is not possible to determine whether tin pest failures will occur in the normal lifetime of an MRI because this failure mode cannot be accelerated and research has shown that this takes at least eight years to occur. MRI system once installed may be used for 15 – 25 years so published data on tin pest suggests that there may be a reliability concern with lead-free solders during this timescale, although this cannot be proven. However, the risk posed by tin pest is extremely high – if/when it occurs and impacts the entire magnet of the MRI system which would need to be replaced. The average cost of a single magnet replacement is >$250,000 which most EU hospitals can ill-afford. This exemption is justified as reliability of substitute solders is not ensured. MRI scanner designs are reviewed and modified by manufacturers to improve diagnostic capability and this may also reduce the amount of lead solders needed in some designs.

The latest magnet design of MRI uses only 7 litres of liquid helium instead of the usual ~1500 litres of liquid helium. This design includes control circuits that are at low temperature and suffer from vibration and so will continue to need this exemption. Examples of components with soldered lead connections are contactors that thermally disconnect the cold components after the magnet has been energized, as well as temperature and voltage sensors to monitor the condition of the magnet. This will be required until research can be carried out that determines whether any substitutes exist that will be reliable for up to 25 years lifetime.

COCIR et al. (2019) also request the renewal of exemption 26 for lead in solders to temperature sensors for both category 8 and 9 applications, for which Lake Shore (2019) provide the below summary:

"We request that the Commission renew […] Exemption 26 […] that exempts the use of lead in solders used to make electrical connections to include use at and cycling through cryogenic temperatures for Categories 8 and 9, as it currently reads.

Cryogenic sensors are used by many types of customers in the EU, from OEMs [original equipment manufacturers; the consultants] *that integrate sensors into measurement and control and medical equipment to research labs and departments large and small, who are advancing technological progress. Each use case is different, but the need for reliable measurement at cryogenic temperatures is the same.*

The cryogenic sensor industry produces, and customers have come to expect, high quality, durable sensors which provide accurate and reliable measurements over long periods, ten to twenty years in many cases. The use of leaded solders has enabled this long-term use and reliability for sensors including those cycled from ambient to cryogenic temperatures used by commercial enterprises and research organizations.

The quality requirements of alternative solders which will enable the cryogenic sensor industry to continue to support business and research organizations with accurate, repeatable, long life sensors requires thorough, long term testing. To date, tests show that alternative methods and materials produce an unreliable, unacceptable, short-lived device with unacceptable performance.

Denying this extension would harm researchers and businesses in the EU who require these devices in their operations and in their scientific and material research. This paper summarizes some of the findings since our original application."

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

COCIR (2020) indicate less than 1 kg of lead entering the EU market annually due to the exemption for MRI. The substantiated calculation is not publicly available. Lake Shore (2021) quantify the annual amounts of lead placed on the EU market in cryogenic sensors with a maximum of 10 kg.

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

General information about MRI devices (COCIR)

According to COCIR et al. (2019), the exemption is relevant for Medical Magnetic Resonance Imaging (MRI) equipment, MRI/PET (positron emission tomography), and MRI/CT (computer tomography). Lead is used as an alloy constituent in solder that is used to make electrically and thermally conducting connections that are stable and reliable at low temperatures. The tin-lead solder alloys typically contain 36 % to 40 % of lead by weight.

The technical background of the exemption was described in the reports of Gensch et al. (2012) and Gensch et al. (2015)[171]. This section therefore is focused on the additional information required to be able to follow the background of the renewal requests.

COCIR et al. (2019) describe that MRI use a large round, very powerful electromagnet into which the patient is inserted. Superconducting electromagnetic coils must be cooled to the temperature of liquid helium (4.2 K = -269 °C) to generate the powerful magnetic fields. The construction of the cold elements of the magnet require many wires, cables, speciality components such as current switches, heaters for emergency use, circuits and sensors that are all connected electrically and thermally with tin-lead solder. Control of the magnetic field requires complex electronics, such as temperature sensors and control electronics, also additional compensation coils that adjust and stabilise the magnetic field to optimise image quality. COCIR et al. (2019) highlight that the electrical circuitry needs to be located close to the magnets and liquid helium where they will need to operate reliably at below -20 °C for at least 25 years. These include components that are part of the electrical circuit of the magnet, which are disconnected from the outside world for thermal reasons. Examples are diodes, switches and heaters for quench protection and components that control the current in the magnet coils to maintain a steady field in the presence of moving metallic objects outside of the magnet.

COCIR et al. (2019) further explicate that long lifetime, reliable electrical circuits are created using lead solders because these have very low electrical resistance and good thermal conduction properties, including at low temperature and, after many decades of use, have been proven to be reliable. Solders used to make electrical circuitry must melt at a temperature that does not damage either the printed circuit boards or the electronic components and all reliable solder alloys are based on tin. Tin metal however exists as two allotropic forms: white and grey. At ambient temperature above 13.2 °C, such as occurs in hospitals, tin exists in the white form. Below 13.2 °C, tin can transform into the brittle grey

[171] C.f. Gensch et al. 2012 pages 61 et sqq., and Gensch et al. 2015, pages 45 et sqq.

form and the transformation causes the solder bonds to disintegrate and form a grey powder with no electrical connection.

COCIR et al. (2019) state that lead has been added to tin as a constituent of solder for many decades and is used to make electrical connections that can be used at low temperature at which they have been found to very significantly retard the phase transformation of tin and tin-based alloys from the white to grey forms. MRI scanners with tin/lead solder have been in use for many decades (> 30 years) and the tin-lead solder bonds at low temperature have proven to be reliable during the lifetime of the MRI.

MRI devices with new magnet design (COCIR)

COCIR et al. (2019) inform that MRI manufacturers of have carried out research into lead-free soldering of low temperature electrical connections of MRI since medical devices were included in scope of the RoHS Directive. Research has shown that early bond failures occur due to the combination of severe vibration that occurs with MRI and the low temperatures that make lead-free solders harder and so more brittle than solders that contain lead. Longer term testing to determine whether tin pest occurs is not complete so the reliability of low temperature lead-free MRI circuits is not ensured.

COCIR et al. (2019) point out that any solder bonds that are within 1 metre of the isocentre of the electromagnet would be covered by exemption 27 of Annex IV. With most standard design MRI, relatively few low temperature solder bonds are located outside of 1 m from the magnets' isocentre and these include bonds to sensors, contactors, connectors and components. Also, one manufacturer has developed a new design of MRI that has many performance and other advantages over standard MRI and this has more solder connections at > 1 m of the magnet's isocentre than traditional MRI. This MRI uses a new design of magnet that has the advantage that it can operate with only seven litres of liquid helium instead of 1,500 litres in a standard MRI. The two designs are illustrated below.

Figure 15-1: Standard MRI with 1500 litres of liquid helium and new design MRI with new magnet containing only 7 litres of liquid helium (in pale blue)

Source: COCIR et al. (2019)

COCIR et al. (2019) see several advantages of this new magnet design:

- *Helium is a very scarce element on the Earth. MRI scanners consume 20 % of the earth's available supply and it is expected that demand is likely to increase for all uses of helium, so an ability to use considerably smaller quantities in each MRI would help to ensure that MRI scanners can continue to be produced and maintained and patients treated/diagnosed using this essential diagnostic technique. At the same time, the environmental impact arising from the extraction, processing and use of this very scarce element is reduced.*
- *1,500 litres of liquid helium inside each MRI pose a known safety risk that is generally mitigated by a vent pipe system. If the magnet quenches[172], more than 1,000,000 litres of helium gas must safely be vented outside of the building. Over the decades long lifecycle of the MRI the terminus and full path of the vent system must never become blocked or impeded, otherwise potentially catastrophic failure can occur due to overpressure. For this reason, the MRI customers/sites have the burden to maintain, inspect, clean as necessary the vent system over the lifecycle. Also, helium must safely vent if the equipment has to be ramped down (magnet power reduced to zero), either because a piece of magnetic metal accidentally enters the bore or in an emergency with a patient. When this happens, some of the liquid helium in standard MRI vaporises and needs to be vented. With the new magnets, only seven litres of liquid helium can vaporise, the pressurised helium gas is retained within the MRI and no venting is required. MRI magnets are relatively heavy (typically 3.7 tonnes) and so are usually located on the ground floor of hospitals. However, many hospitals are multi-story and the vent outlet must be above the roof. This increases the disruption to hospitals when MRI are installed as well as increasing the hospital's costs. Avoiding a vent system means that the hospitals can spend the money saved on installing a vent on providing healthcare to patients instead.*
- *MRI with only seven litres of liquid helium typically weigh 900 kg less than a standard MRI with the same magnet energy. This is a big advantage, not only in conserving raw materials, but as the MRI is lighter, it may be possible (depending on floor strength) to locate the MRI on upper floors of hospitals, which may allow patients to be transferred from wards to the MRI scanner more quickly in an emergency.*
- *After a magnet quenches, the time to restart the MRI, re-liquefy the helium and make up for any vented gases, then ramp up the magnetic field, is on average seven days and can and can be weeks in some world regions with standard MRI due to limited access and logistics of helium delivery. This poses a health risk to patients that cannot be scanned while this is being carried out. MRI with seven litres of liquid helium can be passively cooled down and then ramped up and be back in operation in about two days after a loss of field and in even less time after a controlled ramp down. A survey[173] of hospitals found that 60 % had an issue with magnetic parts stuck in the bore during a three-year period and so required ramp-down, so this is a fairly common problem.*

[172] Escape of helium gas as a result of the MRI-magnet's superconductivity

[173] Marketech June 2017 study, http://www.marketechcorp.com/; source as referenced by COCIR et al. 2019.

Besides these advantages, COCIR et al. (2019) see the only disadvantage that these new magnet designs require more complex control circuitry, sensors, tin-lead solder based thermal connections between cold components to maintain liquid helium and keep the magnet cool than standard MRI designs. They require permanently installed energization leads and i unique control components inside the cold zone to ensure a reliable electrical and/or thermal communication between elements, as well as maintaining minimum heat conduction into the cold space.

MRI are made with various bore diameters. The new designs have larger (70 cm) bores than many MRI on the market, which makes them suitable for very large and claustrophobic patients. However, a larger bore means that more circuitry will be placed at more than 1 m distance of the magnet's isocentre.

Cryogenic temperature sensors (Lake Shore (2019))

Gensch et al. (2015) reviewed the applicant's 2014 exemption request and described the technical background of this exemption request in detail in their report (pages 45 et sqq.). No additional information concerning the technical background was received from the applicant. The technical aspects of the cryogenic sensors are still the same like at the time of the previous reviews.

15.2. Applicant's justification for the requested exemption

15.2.1. Substitution and elimination of lead

Scientific and technical impracticability of lead-free solder use in MRI scanners

COCIR et al. (2019) claim in their exemption renewal request that neither lead-free solders nor alternative bonding technologies are scientifically and technically practicable solutions to substitute or eliminate the use of lead. COCIR (2011) raised most of these arguments already in their exemption request in 2011. They were reviewed and discussed by Gensch et al. (2012) and resulted in the current exemption IV-26. The details of these arguments are available in the report of Gensch et al. (2012) and in the exemption renewal request of COCIR et al. (2019). These arguments were not included into this report as *COCIR (2020) state that the exemption is no longer needed for standard MRI after 2027, while this will take more time for the new design MRI scanners with only seven litres of helium content*.

COCIR et al. (2019) claim that MRI manufacturers currently are carrying out research into lead-free substitutes. Each manufacturer has their own proprietary designs of MRI and so is likely to be investigating different substitution strategies, however as results of this research has not yet been patented, it is not possible for MRI manufacturers to divulge this information. It seems reasonable to COCIR et al. (2019) to assume that options being considered for IV-26(I) are likely to be both the redesign of the MRI and use of various lead-free solder alloys. Manufacturers are also likely to be considering these options as substitutes for other applications, but this is expected to take longer.

Substitution of lead in contacts to cryogenic temperature sensors

Lake Shore (2014) argued in their 2014 exemption request that neither substitution of lead by lead-free solders nor its elimination via alternative contacting techniques are scientifically and technically practicable. Lake Shore (2019) inform that since the previous application,

significant research has been conducted to better understand reliability issues with lead-free solder alloy substitutes. Although this research has been ongoing, Lake Shore (2019) claim the issues associated with tin pest, maintaining non-magnetic terminals, and solder ductility described in the previous application still to be applicable. They are likely to impact reliability and must be thoroughly investigated before transitioning to a substitute lead-free solder alloy. This is supported by recent studies into low temperature solder reliability, ductility and tin pest/tin whiskers.

Through continued literature exploration and material testing, Lake Shore (2019) state that they have not found:

12) *Research on alternative solders over time periods required to evaluate tin pest development,*
13) *Any alternative manufacturing methods to eliminate the use of tin-lead solder with 37 % of lead in these devices, or*
14) *Any RoHS compliant solder that makes reliable electrical connections for cryogenic temperature sensors.*

Lake Shore (2019) point out that since their previous exemption request many studies have been conducted on the reliability of compliant solders, but the results of these studies are often conflicting. Where one study might demonstrate that a particular alloy had superior performance, another study of the same alloys has shown that a different alloy was superior. Researchers acknowledge that the results of their studies are affected by many factors, including the substrate stiffness, bond pad composition, temperature range and dwell time at temperature extremes. Because solder performance is so application specific, Lake Shore (2019) state that they are extensively testing different solder alloys under test conditions most representative of cryogenic temperature sensor environments and duty cycles. Due to the many and varied applications of these sensors, comprehensive testing requires considerable time to acquire informative results.

Lake Shore apply the below testing program:

- *Solder usability and wetting;*
- *Thermal cycling;*
- *Wire pull;*
- *Terminal strength;*
- *Elevated temperature storage;*
- *Cryogenic temperature storage;*
- *Realtime long term tin pest/ whisker growth study;*
- *Long term reliability studies on solders while undergoing temperature cycling.*

Lake Shore (2019) say that they have been testing several solders with promise which they continue to evaluate, next to upcoming solders:

- *SAC305 (tin-silver-copper solder with 3 % silver and 0.5 % copper)*
- *Sn96Ag4 (tin-silver alloy with 4 % of silver)*

- *SN100C (tin-copper alloy with 0.7 % of copper and additions of nickel and germanium)*[174]

15.2.2. Roadmap towards substitution or elimination of lead (COCIR et al. (2019))

Medical devices like MRI scanners must be approved by independent Notified Bodies in the EU before they can be placed on the EU market. In order to obtain approval for a new device or for a redesigned MRI such as a lead-free soldered version (as redesign is likely to be necessary and may not be successful), the manufacturer must prove that the medical device will be safe to use and will be reliable (or at least equally reliable as current MRI). If an MRI suddenly and unexpectedly fails due to tin pest or other bond failure mechanisms, this would pose a potential safety risk to patients as they could not be diagnosed and delays to treatment can be very harmful.

Obtaining confirmation that tin pest failure will not occur during a normal lifetime of MRI, i.e. up to 25 years, would be very difficult to obtain and may take up to 25 years to determine. As tin pest is not fully understood and accelerated testing cannot be used, reliability can only be determined by extensive test and lengthy testing combined with novel (currently unknown) designs that minimise vibration and limit the bonds that have to be in cold zones. If this work is successful, then Medical Devices Regulation (MDR) approval could be obtained. However, for the low helium MRI designs, this would require at least 15 years to complete the trials, plus time needed to gain approval and there is no guarantee of success. Timescales for standard MRI that have less electronics in cold zones is expected to take less time so that exemption 26 is not expected to be required for standard-design MRI after June 2027 unless efforts to find reliable solutions are not successful.

15.2.3. Environmental and socioeconomic impacts

COCIR et al. (2019) report that MRI are very commonly returned to the original manufacturer for refurbishment and reuse. Parts from used MRI are also reused. Any parts that cannot be reused are recycled for materials recovery. As this entire process is under the control of the original equipment manufacturer, this is a closed loop system.

Other environmental or socioeconomic aspects than that are, according to COCIR et al. (2019), not applicable to this exemption request. They claim that the exemption is needed because the reliability of substitutes are not assured. Lake Shore (2019) also base their exemption request on technical aspects without pointing out any environmental or socioeconomic impacts.

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

[174] C.f. http://m.balverzinn.com/lote-407.html

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.

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by"* the REACH Regulation if the requested exemption would be granted/renewed.

REACH Annex XIV (2021)[175] *lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:*

- *Lead chromate (entry 10);*
- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

The application in the scope of the exemption at hand (lead in solder alloy) do not use any of the above lead compounds.

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16*[176] *and entry 17*[177] *restrict the use of lead carbonates and lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds178 such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*

The above applications are not applicable to the use of lead in the applications in the scope of the exemption at hand.

[175] ECHA, https://echa.europa.eu/authorisation-list?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

[176] 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

[177] 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

[178] 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

- *Entry 28*[179] *addresses substances which are classified as carcinogen category 1A or 1B listed in REACH Appendices 1 or 2, respectively. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 29*[180] *lists several lead and lead compounds including those which are not mentioned elsewhere in Annex IV.* These substances shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures, for supply to the general public.
- *Entry 30*[181] *addresses substances which are classified as reproductive toxicant. Like for entry 28, entry 30 stipulates for some lead compounds and lead compounds which are not mentioned in these annexes that they 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 above restrictions are not applicable to the use of lead in solder alloys. Further on, the substances are part of an article and thus are not placed on the market or used as substances, constituents of other substances or mixtures supplied to the general public.

- *Entry 63*[182] *restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72*[183] *stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

Lead is used in solders in MRI scanners. In the scope of the exemption at hand, lead is thus not used in wristwatches or any other jewellery in the scope of entry 63, nor are conditions foreseeable where lead components or the related equipment may be placed in the mouth by children. Further on, EEE in the scope of the RoHS Directive 2011/65/EU is excluded from the scope of entry 72.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status (October 2021) of these Annexes, the requested exemption would not weaken the environmental and health

[179] 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

[180] 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

[181] 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

[182] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[183] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

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. Overlapping scopes of exemption 26 with other exemptions

Several overlaps in the current scopes of Annex-IV exemptions related to MRI scanners were addressed and resolved in past reviews and in this review. Still, several exemptions whose renewal has been recommended are related to the use of lead in solders. The below table lists the recommended renewed wordings of these exemptions and the core technical justification for the use of lead which is specific for each of these exemptions.

Table 15-1: Overlapping scopes between exemption 26 and other exemptions

	Exemption	Scope and Expiry	Core justification for lead use
11	*Lead in alloys as a superconductor in MRI and NMR*	Expires on 21 July 2028 for cat. 8 medical devices others than IVD (MRI), and for cat. 9 IMCI (NMR)	Superior superconductivity of lead solders
*26(a)**	*Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions in MRI devices:*	Expires on - 30 June 2026 for cat. 8 med.devices other than IVD, i.e. low helium content MRI scanners (< 10 kg/device)) - 30 June 2027 for cat. 8 med. devices other than IVD, i.e. MRI scanners for which the Declaration of Conformity is issued for the first time before 30 June 2024)	Reliability of lead-solders under cryogenic conditions
	(I) solders on printed circuit boards;		
	(b) termination coatings of electrical and electronic components and coatings of printed circuit boards;		
	(II) solders for connecting wires and cables;		
	(III) solders connecting transducers and sensors.		
27	*Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors*	Expiry on 30 June 2027	Reliability of lead solder for soldering to nickel-free components
	d) in MRI equipment including integrated coils, which are used in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment with a certification issued by a notified body before 30 June 2024.*		

* Numbering of the recommended renewed exemption, c.f. section 15.4 on page 362

The scope of exemption 26(a) overlaps with the scopes of the current as well as with the recommended renewed exemption IV-11. Superconductive alloys are used durably under

20 °C, and they are used for solder connections e.g. between wires and the coil (wires and cables). Exemption 26(a) therefore covers this use of lead in MRI devices while not all applications durably used at -20 °C do imply superconductive lead alloys in the scope of exemption 11. The scope of exemption 11 should therefore be excluded from the scope of exemption 26(a).

Exemption 26(a) also overlaps with exemption 27(d) for uses of lead in applications which are used durably below -20 °C and within the 1 m radius sphere around the magnet's isocentre. For an approach to separate the scopes, it must be considered that exemption 26(a) defines a clear physical condition – the durable use at below -20 °C – while exemption 27(d) only defines a specific range of locations for the use of lead, i.e. the use within 1 m of the magnet's isocentre. Excluding the scope of exemption 27 from the scope of exemption 26 therefore does not make sense because it would exclude the location in which most of the applications in the scope of exemption 26(a) are positioned from the scope of exemption 26(a). In the next review of exemption 27, the scopes of these two exemptions could be separated by adding the core technical justification for this exemption for exemption 27(d), i.e. the use of lead for soldering to nickel-free components, to the exemption wording. Alternatively, it could also be considered to exclude the scope of exemption 26(a) from the scope of exemption 27 so that equipment used durably below -20 °C would no longer be covered by exemption 27.

15.3.3. Scientific and technical practicability of substitution or elimination of lead

Substitution and elimination of lead in in conventional design MRI devices

COCIR et al. (2019) say that exemption 26 will no longer be needed for standard MRI scanners after 30 June 2027. COCIR was also requested to explain remaining steps towards RoHS compliance for the conventional design MRI scanners. They did, however, not provide specific steps and related timelines. *COCIR (2021a) instead said that MRI manufacturers are carrying out research into lead-free substitutes, as well as investigating if the connections can be located outside of the cold area. Each manufacturer has their own proprietary design and is investigating different options according to the alternative that shows the most promise with their design. The results of such activities have not yet been patented so cannot be divulged at this stage.*

For manufacturers who are investigating alternatives, testing of key parameters has led to a number of alternative solders to be deemed unacceptable. The remaining potential alternatives are now being tested against a broader range of requirements, which include long term reliability which is expected to take years due to the inability to shorten test timeframes. The testing also needs to include examples of all material compositions which are expected to be used over all models, as well as demonstrating the functional use in an operating MRI magnet

By moving connections outside of the cold area, the requirements for testing are significantly changed, manufacturers are therefore also considering this approach. But unlike the prior approach these decisions can only be grouped according to the similarity in design of each model.

This answer is vague, no timelines or any specific steps are indicated. The period until 2027 for achieving RoHS compliance without exemption 26 is, however, at least congruent with the review of exemption IV-27 in 2020 by Gensch et al. (2020). It was found that lead could

be substituted and/or eliminated in the applications in MRI scanners in the scope of exemption IV-27 after 30 June 2027 after their redesign. It was further assessed that new models with a Declaration of Conformity after 29 June 2024 will not depend on exemption IV-27 so that the consultants recommended to exclude these models from the scope of the renewed exemption 27.

It can be assumed that the redesign to enable lead-free solutions for applications of lead in the scopes of exemption 27 and those of 26 are taking place at the same MRI devices at the same time so that it is plausible that exemption 26 will still be required until 2027 like in exemption 27.

COCIR (2021b) confirm this assumption. The time until 2027 is required to convert the whole portfolio of conventional MRI scanner models to lead-free soldered ones which would no longer require exemption 26 and 27. In congruence with exemption 27, the first models that comply with RoHS without exemption 26 can foreseeably already be placed on the market in 2024.

To reflect this situation in the exemption, the consultants proposed the same certification based approach like for exemption 27. COCIR (2021b) agreed to the consultants wording below based on this approach for conventional MRI equipment:

	Exemption	*Scope and dates of applicability*
	Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions: *(a) solders on printed circuit boards;* *(b) termination coatings of electrical and electronic components and coatings of printed circuit boards;* *(c) solders for connecting wires and cables;* *(d) solders connecting transducers and sensors.*	Expiry on - 30 June 2027 for cat. 8 (conventional) MRI scanners for which the Declaration of Conformity is issued for the first time before 30 June 2024

Substitution and elimination of lead in in MRI devices with reduced helium content

In past reviews the general line of argumentation mostly was that lead can be avoided in new design medical devices like MRI scanners provided substitution and/or elimination of a restricted substance are scientifically and technically practicable. This does not apply now to the MRI scanners with new magnet design.

COCIR was requested to explain why these new type MRI scanners were not from the very beginning designed to accommodate lead-free solutions. *COCIR (2021a) put forward that the new design of MRI scanners has been placed on the market since 2017. The design of such an innovative and unprecedented system takes an extremely long time to develop from a concept stage to one which is ready to be placed on the market. COCIR (2021b)*

specify that the development time is more than seven years but cannot further detail the timeline for confidentiality reasons.

The designs of the first of these low helium MRI devices placed on the market from 2017 on was thus started before 2011, when the current RoHS Directive was enacted which covered cat. 8 EEE. In the consultants' view, applicants cannot be obliged to undertake RoHS compliance efforts before there is legal certainty that would call for compliance efforts.

To further specify the time required for RoHS compliance, the applicant was requested to provide a more detailed overview of the actions to be taken and the related time lines. *COCIR (2021b) state that the steps to transition to a lead-free alternative in these MRI scanners are the same as traditional designs, but the timeframes are expected to be much longer given the larger number of affected components and the complexity of the system design. The next generation of low-helium MRIs would probably be RoHS-compliant unless the testing and design would prove the need for this exemption for an extended period of time. They indicate the below remaining steps:*

- *Identification of lead-free solder that does not exhibit tin pest or tin whisker development in the applicable temperature range. (1.5 years in total, 0.5 year remaining into this development);*
- *Evaluate selected candidate solders on assemblies in the production line (0.5 year);*
- *Develop alternative assembly methods and perform component and assembly level reliability testing (2 years);*
- *Monitor performance of magnets in MRI scanners that use the candidate solders (2-3 years – the nature of tin pest prohibits accelerated life testing);*
- *Update part and assembly drawings, manufacturing instructions and workstations for all products to replace lead-based solder with lead-free (0.5 year);*
- *Release all changes into the product structures, production lines and supply chain with regulatory compliant processes (2-2.5 years)*

The above steps cover a time span of minimum 7.5 years up to 9 years until new design low helium MRI scanners could become RoHS compliant without exemption 26.

With view to apply a certification approach for the low helium MRI scanners like for the conventional ones, the applicant was asked whether any models of these low helium MRI scanners could achieve compliance without exemption 26 prior to the exemption expiry in 2028. *COCIR (2021b) expect more than seven years until the first models of low-helium MRIs are placed on the market which no longer require exemption 26.*

This situation raises questions in the context with the previous review of exemption IV-27 by Gensch et al. (2020), where the following wording was agreed with COCIR for the MRI scanners (the body coils included in the exemption 26 as well were dropped because they are not relevant in this context) for the renewed exemption 27:

Exemption		Dates of applicability and comments
27	*Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors*	*Expiry on 30 June 2027*
	in MRI equipment including integrated coils, which are used in-magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment for which the Declaration of Conformity is issued for the first time before 30 June 2024.	

There is no differentiation in exemption IV-27 between conventional and low helium MRI scanners, which means that the latter cannot use exemption 27 if they are certified on 30 June 2024 or thereafter. The applicant was therefore asked whether new models of low helium MRI scanners with a declaration of conformity after 24 June 2024 would be redesigned to achieve RoHS compliance without exemption 27 would also be designed to comply without exemption 26. Otherwise, it would have to be assumed that new design low helium MRI scanners which do not require exemption 27 would be redesigned again later again to substitute lead used under exemption 26.

COCIR (2021c) explicate that this depends on the manufacturer in question. Some have all of the circuitry with lead solder durably at a temperature below – 20 °C and would not require exemption 27. Whereas others have solder bonds that are not durably at a temperature below – 20 °C, so both exemption 26 and 27 are required.

In the consultants understanding, this does not clarify the question whether a co-redesign for exemption 26 and 27 would be undertaken so that the first models of low helium MRI scanners could be placed on the market prior to 2028. In further efforts to shed light on the situation, *COCIR (2021d) explain that the typical time after one MRI scanner is launched until the next model is designed and launched is 7-10 years, but one model of MRI scanner can be marketed for longer (the time depends on the type of MRI). The low helium MRIs were approved for use in the EU only a few years ago and there were not easy solutions to implement and took many years of effort to develop. This was possible only by use of lead-solders. We can expect that all the teams are now working on redesigning other models, some of them, to use the same low-He magnet technology, that will be carried over for a while (not different from car engines that are carried over several generations of cars). Hopefully RoHS compliance can be achieved by developing alternative soldering that does not require redesigning a just developed technology. At the same time, all COCIR members who are developing low-helium MRI are considering the use of leadfree solders in new designs and will use these if reliability can be assured. The same subject matter experts are also required to redesign the standard MRI scanners, which they expect to achieve by July 2024, so there are limitations on how many projects can be worked upon at any one time by the limited number of trained technical experts that are available.*

Overall, this does not allow a clear view on the situation whether new models of low helium MRI scanners could be placed on the market between 2024 and 2028. Taking into account

- that the substitution of lead needs a redesign and thus time to ensure the reliability of substitutes;
- that the first low helium scanners were placed on the market in 2017;
- and that the redesign of low helium MRI devices takes around seven to ten years;

renewing the exemption would be justified by Art. 5(1)(a) and recommend the renewal for five years only until 2026. If at all, new design low helium MRI scanners may not necessarily be placed on the market in 2024 already since older models can still be sold. Nine years from 2017 to 2026 leave time for the redesign, and it should be clearer by then whether new design low helium MRI scanners that do not use exemption 26 have been or foreseeable will be placed on the market.

Substitution and elimination of lead in contacts to cryogenic temperature sensors

Lake Shore (2019) report the below testing programme:

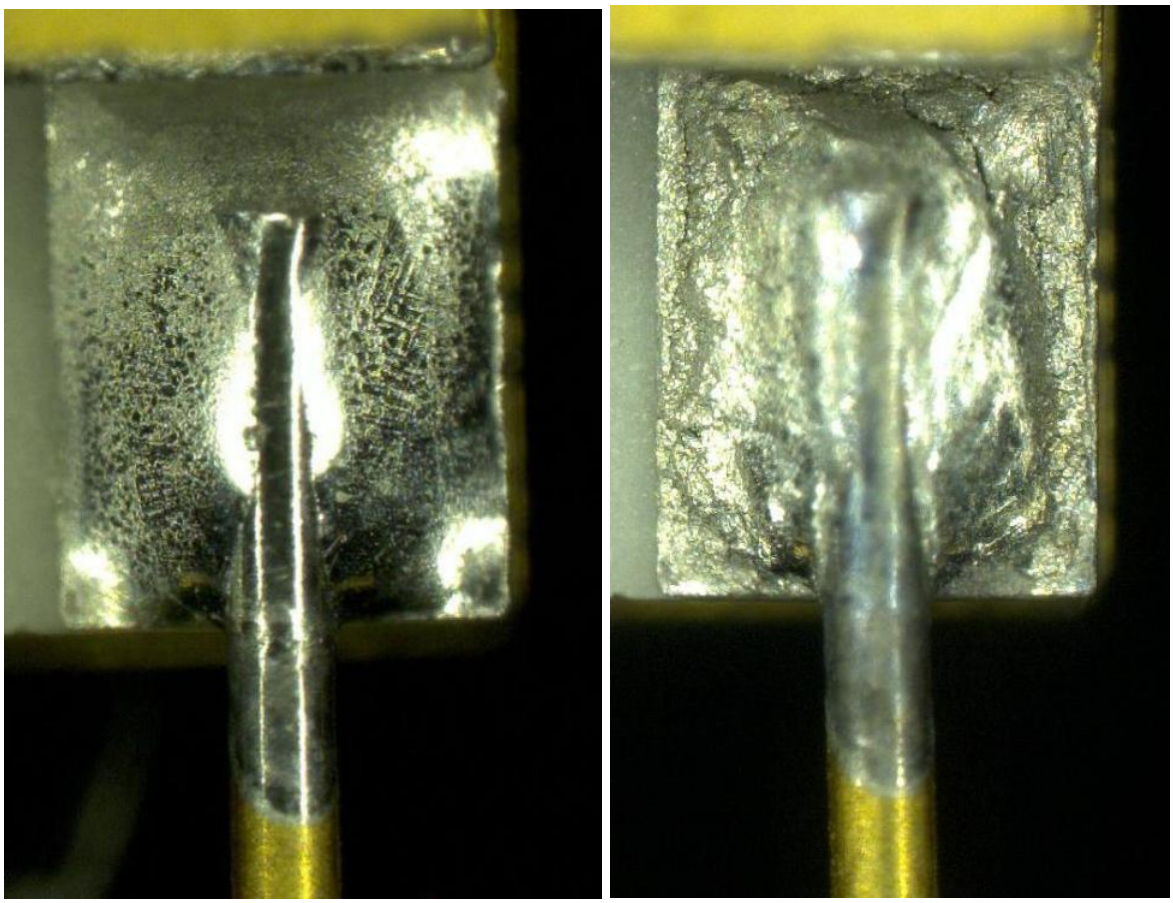
- *Solder usability and wetting;*
- *Thermal cycling;*
- *Wire pull;*
- *Terminal strength;*
- *Elevated temperature storage;*
- *Cryogenic temperature storage;*
- *Realtime long term tin pest/ whisker growth study;*
- *Long term reliability studies on solders while undergoing temperature cycling.*

Lake Shore (2019) say that they have been testing several solders with promise which they continue to evaluate, next to upcoming solders:

- *SAC305 (tin-silver-copper solder with 3 % silver and 0.5 % copper)*
- *Sn96Ag4 (tin-silver alloy with 4 % of silver)*
- *SN100C (tin-copper alloy with 0.7 % of copper and additions of nickel and germanium)*[184]

The applicant was requested to provide more insights into results of the above test and further steps. *Lake Shore (2021) has been evaluating and testing RoHS compliant solders for over 7 years in search of an acceptable compliant solder. Testing has revealed that performance is undesirable among the different alloys that have been tested so far. Some recently developed alloys, commercially released following Lake Shore's original exemption request, exhibit more promising results. However, longer-term tests are still ongoing. Below are pictures showing degradation of a common Pb-free solder after repeated thermal cycling.*

Figure 15-2: Comparison of lead (left) and lead-free solder joint after thermal cycling



Source: Lake Shore (2021)

Lake Shore (2021) points out the original joint on the left produced with lead solder which shows an ideal, smooth convex shape. Shown on the right is the same joint after repeated thermal cycles, now having a wrinkled, cracked appearance and with some solder material appearing to be missing.

The applicant was requested to give insights into the next steps and the respective timelines as to their efforts to achieve RoHS compliance in the coming years. Lake Shore (2021) *state that failure mechanisms, such as tin pest, that are associated with long-term cryogenic use cannot be accelerated by conventional means of accelerating testing by increasing temperature or some other environmental stress. Some long-term cryogenic failure mechanisms accordingly must be evaluated in real-time. Since these failures can occur over long durations, testing requires similarly long durations. Many customers use Lake Shore products in applications with service lives spanning several decades. For this reason, Lake Shore presently expects to continue long term testing of RoHS compliant sensors for at least one decade into the foreseeable future, to better educate customers of reasonable expectations for product life. Evaluating the results of long-term testing over the next several years will allow Lake Shore to determine which solders perform well in long term applications in addition to performing well in already completed testing.*

Lake Shore (2021) also highlight that d*ue to the long calendar time required for many of these tests they chose to keep the entire process in-house. Lake Shore technicians have years of experience creating these small cryogenic solder joints and more importantly, can do this with excellent consistency. They aim to remove as many variables from these tests*

as possible. The risk of introducing doubt in results due to some potential inconsistencies and having to repeat tests is unacceptable to Lake Shore. Lake Shore (2021) also have adequate space and the right equipment in their testing facility to conduct these tests. Their goal has and continues to be finding a viable alternative in the shortest amount of time.

The above information shows that at least Lake Shore cannot substitute or eliminate the use of lead now and in the foreseeable future. The consultants agree with the applicant's explanation.

Status of lead substitution and elimination of other temperature sensor manufacturers

Lake Shore is the only applicant for the temperature sensor part of exemption 26, and no other manufacturers support Lake Shore's exemption request during the online consultation. To ensure that substitution and elimination of lead in the solder joints of temperature sensors in the scope of this exemption are scientifically and technically impracticable, Omega and Scientific Instruments were contacted via e-mail and phone to investigate whether their cryogenic temperature sensors can be connected without using lead solders, i.e. whether RoHS compliance can be achieved without exemption 26.

Scientific Instruments (2021) reacted confirming that *"Manufacturing cryogenic temperature sensors without leaded solder presents many challenges, including tin whiskers, which can ultimately affect the reliability of the measurements. The use of leaded solder is absolutely required for the proper manufacturing of these type of sensors and the exemption should be continued. We share the concerns of Lakeshore Cryotronics, that "the combination of essential properties and durability requirements by customers and researchers at these temperatures and the small size of these sensors requires adhesion with leaded solders. Not extending the exemption for these devices would negatively affect those doing scientific and materials research."*

The above statement together with Lake Shore's arguments suggest that substitution and elimination of lead in the temperature sensors are actually scientifically and technically impracticable, and that the reliability of substitutes is not yet ensured. Renewing the relevant part of exemption 26 in the consultant's opinion would therefore be in line with Art. 5(1)(a).

15.3.4. Environmental arguments and socioeconomic impacts

COCIR did not provide information as to environmental impacts, or socioeconomic issues in the case that the exemption would not be renewed. It is nevertheless to be considered that impacts on health care would be severe if MRI scanners could no longer be placed on the EU/EEA market.

Lake Shore (2019) state that denying this extension for the temperature sensors would harm researchers and businesses in the EU who require these devices in their operations and in their scientific and material research. Given their essential role in temperature measurements, it can be followed that their absence would cause the above adverse impacts.

15.3.5. Conclusions

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

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

COCIR request the renewal of exemption IV-26 with a slightly modified wording claiming that new types of MRI scanners - MRI with low helium content – require exemption 26 for the next seven years while the exemption can expire in 2027 for conventional designs of MRI equipment. The exemption is requested for cat. 8 others than in-vitro diagnostic medical devices. No stakeholder inputs were received during the stakeholder consultation.

Substitution and elimination of lead are scientifically and technically practicable in conventional design MRI scanners, but the devices need to be redesigned to ensure the reliability of the substitutes. This redesign requires time to ensure the reliability of substitutes and should be achieved for the first new Lake Shore (2019) request the renewal of the exemption for the cryogenic temperature sensors which are also covered by exemption IV-26..

Substitution or elimination of lead would normally be aspired to be achieved in a co-design enabling lead-free solutions for both exemption 26 and 27, and this could also be expected to happen to new models of low helium MRI devices depending on exemption 27 with a Declaration of Conformity from 30 June 2024 on. The applicant claimed that no new model low helium MRI scanners would be placed on the market between 2024 and 2028 which do not require exemption 26, despite the need for a redesign of at least those low helium MRI devices which still depend on exemption 27 for RoHS compliance. The information provided did not allow clear insights into the situation.

For the low helium content scanners, in the light of the above unclear situation, and taking into account

- that a redesign is required to ensure the reliability of lead-free solutions;
- that the first low helium scanners were placed on the market in 2017;
- and that the redesign of low helium MRI devices takes around seven to ten years,

renewing the exemption would be justified by Art. 5(1)(a) and recommend the renewal for five years only until 2026. If at all, new design low helium MRI scanners may not necessarily be placed on the market in 2024 already since older models can still be sold. Nine years from 2017 to 2026 leave time for the redesign, and it should be clearer by then whether new design low helium MRI scanners that do not use exemption 26 have been or foreseeable will be placed on the market.

The exemption can expire for new models of conventional MRI scanners on 30 June 2024. The time until then is needed for the redesign to enable reliable lead-free solutions.

To avoid overlapping scopes for the use of lead in MRI scanners, the scope of exemption 11 should be excluded from the scope of exemption 26.

Overall, the renewal of the exemption can be justified by Art. 5(1)(a) with the need to ensure the reliability of lead-free substitutes in the MRI scanners.

Lake Shore (2019) request the renewal of the exemption for the cryogenic temperature sensors which are also covered by exemption IV-26. In cryogenic temperature sensors, lead is still required to enable reliable contacts to these sensors. Neither the applicant nor other manufacturers contacted are able to achieve RoHS compliance for their sensors without exemption 26. The applicant has been undertaking efforts towards lead-free solutions, but the tests in the past years and the current status of the applicant's research and development program cannot be foreseen to enable the substitution or elimination of lead within the next seven years. Art. 5(1)(a) would hence justify the renewal of this part of exemption 26 as well.

15.4. Recommendation

The accessible information suggests that substitution and elimination of lead in MRI scanners are scientifically and technically practicable but need time for redesigning the devices so that the reliability of lead-free solutions is ensured. Art. 5(1)(a) would therefore allow renewing the exemption.

In cryogenic temperature sensors, substitution or elimination of lead are scientifically and technically not yet practicable and not foreseeable for the coming seven years. It is therefore recommended to renew the exemption with the below wording and expiry dates:

	Exemption	Scope and dates of applicability
26(a)	*Lead in the following applications that are used durably at a temperature below – 20 °C under normal operating and storage conditions in MRI devices:* *(I) solders on printed circuit boards;* *(II) termination coatings of electrical and electronic components and coatings of printed circuit boards;* *(III) solders for connecting wires and cables;* *(IV) solders connecting transducers and sensors.*	*Expires on* - *30 June 2026 for cat. 8 medical devices others than in-vitro diagnostic medical devices, i.e. low helium content MRI scanners (< 10 kg/device));* - *30 June 2027 for cat. 8 medical devices others than in-vitro diagnostic medical devices [,i.e. MRI scanners for which the Declaration of Conformity is issued for the first time before 30 June 2024].* *This exemption does not cover the use of lead in the scope of exemption 11 of Annex IV.*
26(b)	*Lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C*	*Expires on 30 June 2028 for cat. 8 and cat. 9*

In case the COM decides not to adopt the reference to the first Declaration of Conformity for cat. 8 medical devices others than in vitro diagnostic medical devices, the text in [brackets] should be omitted.

The validity date of the exemption for low helium MRI devices was reduced to five years since it could not be clarified that new models of these devices do not depend on exemption 26 for RoHS compliance would not be placed on the market before 2028.

The expiry date for the other scanners in 2027 is aligned with the recommended expiry date of exemption IV-27. The redesign of these devices enables lead-free solutions for exemption 26 and 27 at the same time. Since it is expected that the exemption would no longer be needed after 2027, the expiry date for the low helium and the other MRI devices were not aligned.

To avoid overlapping scopes, exemption IV-11 is recommended to be excluded from the scope of exemption IV-26(a). Overlaps with exemption IV-27 should be eliminated in the next review of exemption 27 by excluding the scope of exemption 26(a) from the scope of exemption 27, or by introducing the core technical justification for the use of lead, the use of nickel-free components, into the wording of exemption 27. For details c.f. section 15.3.2 on page 353.

15.5. References

COCIR (2011): Application for granting new Exemption: Lead in solder for electrical circuitry that is used at temperatures below -20°C. Online verfügbar unter https://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_8/8_COCIR_-_Exemption_request_-_Lead_in_solders_low_temperature.pdf.

COCIR (2020): Answers to questionnaire 1 (clarification questionnaire) for RoHS exemption IV-26. Online verfügbar unter http://rohs.biois.eu/Ex_26-IV_COCIR_Questionnaire-1_Clarification_Answers.pdf.

COCIR (2021a): Answers to questionnaire 2, sent via E-Mail by Emily Thyrwitt-Jones, RINA, to Dr. Otmar Deubzer, Fraunhofer IZM.

COCIR (2021b): Answers to questionnaire 3, sent via e-mail by Emily Thyrwitt-Jones, RINA, on behalf of COCIR, to Dr. Otmar Deubzer, Fraunhofer IZM.

COCIR (2021c): Answers to questionnaire 5, sent via e-mail by Emily Tyrwhitt-Jones, RINA, on behalf of COCIR, to Dr. Otmar Deubzer, UNITAR.

COCIR (2021d): Answers to questionnaire 6, sent via e-mail by Emily Tyrwhitt-Jones, RINA, on behalf of COCIR, to Dr. Otmar Deubzer, UNITAR.

COCIR et al. (2019): Request for renewal of exemption 26 of RoHS Annex IV. Unter Mitarbeit von Lakeshore COCIR. Online verfügbar unter http://rohs.biois.eu/Ex_26-IV_COCIR_Renewal-Request.pdf.

Gensch et al. (2012): Assistance to the Commission on technological, socio-economic and cost-benefit assessment related to exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive). RoHS V. Unter Mitarbeit von Carl-Otto Gensch, Yifaat Baron, Markus Blepp, Andreas Manhart und Dr. Deubzer, Otmar, Fraunhofer IZM. Öko-Institut e. V. und Fraunhofer IZM. Freiburg (Adaptation to Scientific and Technical Progress of Annex II Directive 2011/65/EU). Online verfügbar unter https://circabc.europa.eu/sd/a/42ccb088-4c26-4e3a-8a0c-218ea738964c/RoHS_V_Final_report_12_Dec_2012_Final.pdf.

Gensch et al. (2015): Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance restrictions in Electrical and Electronic Equipment (RoHS Directive). Final Report -Pack 6. RoHS 11, Pack 6. Unter Mitarbeit von Carl-Otto Gensch, Yifaat Baron, Moch, Katja, Öko-Institut e. V. und

Dr. Deubzer, Otmar, Fraunhofer IZM. Online verfügbar unter https://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/20150624_RoHS_Ex_Pack6_Final_Report.pdf.

Gensch et al. (2020): Study to assess seven (7) exemption requests relating to Annex III and IV to Directive 2011/65/EU: request for renewal of exemptions 6(a), 6(b), 6(c), 7(a) and 7(c)-I of Annex III; request for renewal of exemption 27 of Annex IV; and request for a new exemption for lead in bismuth lead strontium calcium copper oxide superconductor cables and wire and lead in electrical connections to these wires to be added to Annex IV (Pack 18) – 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. RoHS 23, Pack 18. Unter Mitarbeit von Carl-Otto Gensch, Yifaat Baron, Moch, Katja, Öko-Institut e. V. und Dr. Deubzer, Otmar, Fraunhofer IZM. Online verfügbar unter https://circabc.europa.eu/sd/a/9eaaeae6-6dd2-4ab1-9715-d3a4a69fed1b/RoHS_Pack18_final.pdf.

Lake Shore (2014): Request for a new exemption of RoHS Annex IV for “Lead in solders used to make electrical connections to temperature measurement sensors designed to be used periodically at temperature below -150 °C”. Online verfügbar unter https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_6/2014-2/Lake_Shore_Submission.pdf.

Lake Shore (2019): Request for renewal of exemption 26 of RoHS Annex IV. Online verfügbar unter http://rohs.biois.eu/Ex_26-IV_LakeShore_Renewal-Request.pdf.

Lake Shore (2021): Answers to questionnaire 2, sent by Scott Ayer, Lake Shore, via e-mail to Dr. Otmar Deubzer, UNITAR.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

Scientific Instruments (2021): E-Mail communication with Dr. Otmar Deubzer, Fraunhofer IZM.

16. Exemption 29 of Annex IV: Lead in alloys in cryo-cooler cold heads

The complete current wording of the exemption is:

Lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments.

The exemption expires on 30 June 2021 for cat. 8 medical devices and 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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text.

Acronyms and Definitions

Ag	silver
Cu	copper
Pb	lead
Sn	tin

16.1. Background and Technical Information

COCIR (2020a) request the renewal of the above exemption for the maximum validity period of seven years with a modified wording that restricts the exemption scope compared to the current exemption:

"Lead in alloys as a thermal conductor in cryo-cooled cold probes in medical devices"

The applicant requests the exemption renewal for cat. 8 medical devices others than in-vitro diagnostic medical devices.

16.1.1. History of the Exemption

Exemption 29 in its current wording goes back to an exemption request submitted by TMC in 2012. Gensch et al. (2012) recommended the COM to grant the exemption, and the COM added it to Annex IV as exemption 29 in the Directive 2011/65/EU (2011). It is now reviewed for the first time to adapt it to scientific and technical progress following COCIR's request to renew this exemption.

16.1.2. Summary of the requested exemption

COCIR (2020a) summarize their exemption request as follows:

"Cryo-cooled cold probes are used in cryoablation therapy to generate local low temperatures in medical therapy to destroy abnormal or diseased tissue. The interface between the components of the cryo-cooled cold probe are joined together using lead-tin-silver solder. The solder wicks in between the components, joining them mechanically and thermally. The cryo-cooled cold probe functionality depends directly on its ability to cool (freeze) and heat (thaw) rapidly during a cryoablation procedure and so a high thermal conductivity of the solder is essential. In turn this is dependent upon the ability of the internal components including the cryostat (machined heat exchanger) to reach the desired temperatures rapidly and uniformly. The lead alloy solder joints are required to withstand large stress (mechanical, shock and temperature) while having suitable ductility. Due to the substrates the solder has to join (stainless steel, copper, and brass) and wick between the manufacturability of the joint is technically challenging. Lead free solders of tin-silver and tin-copper have been trialled and deemed unsuitable, with current testing on tin-copper-silver solder being undertaken. Alternative technologies have been considered, including the use of brazing/welding, adhesives, mechanical bonds and additive manufacturing; all of which are unable to demonstrate the technical performance required for cryo-cooled cold probes."

No contributions were submitted to the stakeholder consultation.

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

COCIR (2020a) indicate around 2.8 kg of lead entering the EU market annually in cryo-cooled probes. The applicant did not provide a substantiated calculation in a publicly available document.

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

COCIR (2020a) explain that *the exemption is relevant for cryo-cooled cold probes that are used in cryoablation therapy to generate locally low temperatures to destroy abnormal or diseased tissue. They indicate the following examples of applications in which cryo-cooled cold probes are used:*

- *Prostate cryosurgery;*
- *Renal cryosurgery offering lower rates of local tumour progression versus Radiofrequency ablation;*
- *Pulmonary (lungs and thoracic (chest) tumours);*
- *Liver metastases (secondary malignant cancer growths);*
- *Gynaecological tumours;*
- *Dermatological (skin) tumours;*
- *Otorhinolaryngology (ear, nose and throat surgery);*
- *Proctology (rectum, anus, and colon); and*

- *Tissue in pain management.*

COCIR (2020a) point out that cryo-cooled cold probes are crucial for medical treatment and offer advantages over other methods in cancer treatment:

- *They are less invasive than surgery, reducing pain, bleeding and other complications;*
- *Shorter recovery time of patients, therefore reducing the need for prolonged or any hospital stay, reducing procedure costs to the healthcare systems;*
- *Reduction of damage on nearby healthy tissue due to the focused nature of the treatment;*
- *Can be used in combination with standard treatments such as surgery, chemotherapy, hormone therapy and radiation; and*
- *May offer an alternative to treating cancers that are considered inoperable, due to other medical factors or are not responding to standard treatments.*

COCIR (2020a) explain that the cold probe technology is based on the Joule-Thomson effect where high-pressure argon gas, generally at 3,100 psi (pounds per square inch, equivalent to around ~ 214 bar, 21,374 kPa), is circulated through cryo-cooled cold probes to induce tissue freezing at the distal end (far end) of the probe, creating an ice ball. A cryostat is used to maintain a low temperature within the shaft and allow for rapid cooling and heating during the procedure. Once the freezing is complete, active tissue thawing is achieved by circulating helium gas under pressure (generally 1,700 psi) through the cryo-cooled cold probes creating a warming effect to melt the ice ball. The freezing and thawing are repeated until the ablation (tissue destruction) of targeted tissue is complete, which typically requires at least two cycles.

Figure 16-1: Cryo-cooled cold probe with integrated ice length slider allowing users to vary size and shape of the ice ball depending on clinical requirements

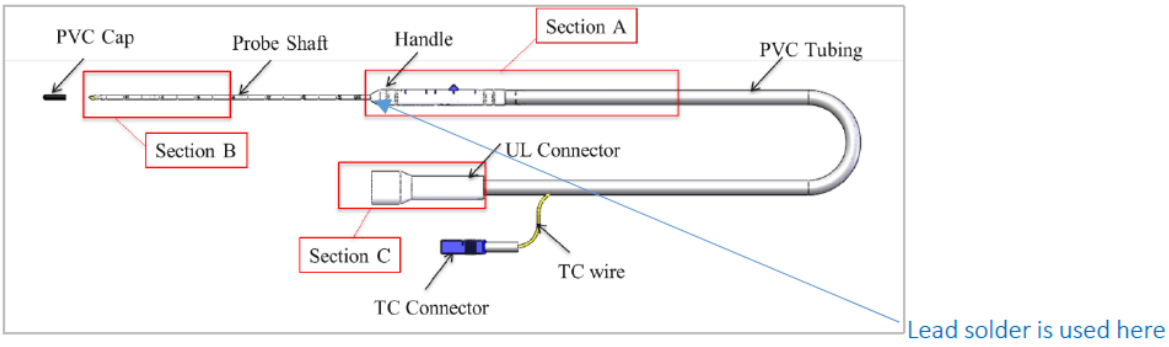
Source: COCIR (2020a)

COCIR (2020a) inform that cryo-cooled cold probes are assembled from several components formed from stainless steel, copper, and brass, connected to the sharp tipped probe shaft that is inserted into the body. At the distal end of the shaft is the expansion chamber where argon gas under pressure - greater than 3,000 psi - expands and causes the tip and a controlled length of the shaft, to reach -180 °C to allow the rapid freezing of the surrounding tissue. As the cold argon gas travels away from the active freezing area, COCIR (2020a) continue, it passes into a vacuum sleeve that protects the rest of the shaft from the freezing temperatures. After reaching the handle area of the cryo-cooled cold probe, the released cold argon gas travels through a cryostat which serves as a heat exchanger to allow the incoming argon gas to be pre-cooled. A thermocouple is used to verify the freezing and thawing cycles by measuring the temperature of the return gas, with

the thermocouple and lead solder experiencing temperatures of at least as low as -80 °C during freezing application.

COCIR (2020a) further explain that the interface between the components of the cryo-cooled cold probe are joined together using lead-tin-silver (54 % Pb, 45 % Sn, 1 % Ag w/w) solder, with each probe having between 8 – 10 connections. The solder wicks in between the components, joining them mechanically and thermally. Figure 16-2 illustrates the location where the lead solder is applied.

Figure 16-2: Use of lead solder in cold probe



Source: COCIR (2020b)

According to COCIR (2020a), the cryo-cooled cold probe functionality depends directly on its ability to cool (freeze) and heat (thaw) rapidly during a cryoablation procedure and so a high thermal conductivity of the solder is essential. In turn this is dependent upon the ability of the internal components including the cryostat (machined heat exchanger) to reach the desired temperatures rapidly and uniformly. The lead alloy solder joints allow this to occur during a procedure. The reliability of the solder joint is crucial for patient safety, as if it were to fail, the shaft which normally would be at non-freezing temperature may become extremely cold causing damage to non-targeted tissues including arteries, veins, or nerves and the skin at the insertion site. Lead based solder joints in cryo-cooled cold probes have had a very long and successful history of use for cryogenic medical procedures for over 20 years and have proven to be very safe and reliable.

The lead solder has to have the following functionality according to COCIR (2020a):

- *The ability to withstand large amounts of stress from the following factors and maintain a reliable bond:*
    - *Cryo-cooled cold probe use involves manual manipulation of the probe during use and thus mechanical stresses are induced which could lead to brittle joint failure;*
    - *Ability to withstand mechanical shock which the probe may experience during transportation and in service use due to being dropped;*
    - *The use of high-pressure gas (argon - typically at 3,100 psi) is introduced into the cryo-cooled cold probe (for at least two ten-minute cycles) during routine one-time use (treatment procedure) which places stress on the solder joints;*
    - *Very large temperature changes including very low temperatures;*

- *The lead solder must have high thermal conductivity and thermal capacity at cryogenic temperatures. The thermal properties of materials at ambient temperatures are very different to those at cryogenic temperatures and so the commonly used metals used in domestic refrigerators are not suitable at such low temperatures. Research has shown that lead is a particularly good material in this application and has 20 years of data supporting its use due to its high thermal conductivity and thermal capacity;*
- *Ductility: Lead / tin solder is relatively ductile at low temperatures and able to withstand the thermal shock that occurs when cryo-cooling begins (freeze cycle) and ends (thaw cycle);*
- *Lead provides a strong flexible bond between components of different materials (stainless steel, brass, and copper) that have differing coefficients of thermal expansion (the material distorts to accommodate movement between adjacent materials due to differential thermal expansion and contraction when temperatures change);*
- *Resistance to oxidation and corrosion in conditions of use; and*
- *Ability to form very small and well defined, continuous circumferential solder joints, requiring good flow and wetting properties of the bond on difficult-to-solder metals.*

COCIR (2020a) explain that wetting refers to the capacity of molten solder to interact with a substrate, at the interface of solder and substrate, to form a certain amount of intermetallic compound that acts as an adhesion layer to join the solder and the substrate. The reaction between the solder and substrate is important as it may affect the micro-structure and eventually the mechanical strength of the solder joint.

16.2. Applicant's justification for the requested exemption

16.2.1. Substitution of lead

Lacking wettability of lead-free solders

COCIR (2020a) reports a manufacturer to have trialled both a lead-free tin-silver alloy (96 % Sn, 4 % Ag w/w) and a lead-free tin-copper alloy (97 % Sn, 3 % Cu w/w) on 10 and 4 (including two different designs) cryo-cooled cold probes respectively. The trial showed manufacturability issues where the very small and continuous circumferential solder joints in the cryo-cooled cold probe were unable to be formed to the required standard as is achieved using lead solder due to inferior flow and wetting properties of the lead-free alternatives. It is well known that wetting of lead-free solder alloys, such as tin-silver-copper, on copper and other metal surfaces is inferior to tin-lead solder due to many variables which include the composition of the metal being soldered, the type of flux, the solder composition and the temperature. These variables affect the "wetting force" which allows solder to spread across a metal surface. This is important in cryo-cooled cold probes as the solder has to spread such that it flows across metal surfaces and between two adjacent metal parts to form a strong bond.

COCIR (2020a) states that in the cryo-cooled cold probes, soldering is to copper, brass and stainless steel. Due to the complex geometric arrangement of the components in the cryo-cooled cold probe the solder is required to wick between components, requiring good

wettability. Although with careful pre-treatment and selection of alloy composition and a suitable flux, soldering is possible, there will always be differences in the wetting properties of lead-free solders compared with lead-solders due to differences in surface tension forces.

COCIR (2020a) points out that solder wetting of brass is more difficult than to copper because the zinc content of brass is readily oxidised and so more aggressive fluxes are required to achieve wetting. Soldering to stainless steel is very difficult as its air-formed oxide is very inert requiring very aggressive fluxes. Solder wetting by solder on stainless steel can be very poor and the solder spread will be minimal if not all oxide is removed. The known difference in solder spread of tin/lead solders compared with lead-free solders can be exacerbated on metals such as brass and stainless steel that have air-formed oxides that are difficult to remove. A feasibility study including the review of currently available data is under way on a tin-copper-silver alloy (97 % Sn, 0.25 % Ag w/w, 2.75 % Cu).

Reliability at low temperatures

COCIR (2020a) put forward that reliability at low temperatures is important to substitute lead in solders. All solders become harder and much more brittle as temperature decreases and most lead-free solders are harder than tin-lead. Lead-free solders are less ductile than tin lead at room temperature, examples of hardness values for un-annealed alloys are (with a lower hardness value indicating a softer more ductile material):

- *Eutectic tin 37 % lead: Vickers hardness = 12.9*
- *Tin 4.7 % silver 0.7 % copper: Vickers hardness = 21.9*

COCIR (2020a) states that harder solders are likely to induce higher stress levels that would be more likely to cause damage to the solder (e.g. cracks or de-bonding). Relatively soft and ductile materials can deform to relieve any stresses occurring as a result of differential thermal expansion when temperature changes. Brittle materials will not deform so high stress forces will be induced, potentially leading to bond failure.

COCIR (2020a) further put forward that solder is not routinely tested down to the temperatures experienced in the cryo-cooled cold probe and therefore there is limited data available. Lead-free solders have been shown to have very sharp transition from ductile to brittle behaviour at cold temperatures whereas lead alloy solders do not, with sources demonstrating the transition temperature for many lead-free solders to be in the range of -50 °C to -150 °C which correlates with the expected cryo-cooled probe solder joint temperatures.[185] The lack of substitutes with proven reliability is a concern to users of these devices as they require high reliability.

16.2.2. Elimination of lead

COCIR (2020a) provide a review of common alternative bonding methods outlined below analysing their potential applicability for use in cryo-probes.

- *Brazing or welding*
  The advantage of this would be its ability to form strong, thermally conductive joining

[185] Lupinacci, A., Shapiro, AA. Et al. A study of solder alloy ductility for cryogenic applications, IEEE Interational Symposium on Advanced Packaging Materials (2013), and Ratchev, P., Loccufier, T., Vandevelde, B. Et al. A Study of Brittle to Ductile Fracture Transition Temperatures in Bulk Pb-Free Solders, EMPC, 12-15 (2005); sources as referenced by COCIR 2020a.

of the components. However high temperatures are required (500 °C for brazing and >1000 °C for welding) would damage other components in the cryo-cooled cold probe. Also, braze alloys do not flow into gaps like solder and so will not form good gas-tight seals.
Automated micro-welding equipment may overcome the damage to surrounding material however; the weld bead produced by this method is less desirable for leak prevention under high pressure than the smooth and uniform soldered joint and so will not form good gas-tight seals.

- *Thermally conductive adhesives*
  Such adhesives are commercially available however when they are cooled to very low temperatures, the adhesive has the propensity to become extremely brittle and therefore is likely to cause bond failure due the stresses imposed. Commercial thermal conducting adhesives are not specified for use at very low temperatures. Also, they have inferior thermal conductivity when compared with metals such as solder.

- *Mechanical connections*
  Mechanical connections are used to make electrical connections such as with connectors but these cannot be gas-tight and so are unsuitable in cryo-cooled probes.

- *Additive manufacturing process (3D printing)*
  Although state of the art of additive manufacturing has been raised to a high level within the last few years, it is not possible to accurately deposit structures that form gas-tight bonds in the internal small diameter structures that are required inside the cryo-cooled probes. Due to the design of the cryo-cooled cold probe utilising multiple materials it is unlikely that additively produced structures would meet all of the technical requirements. Furthermore, additive manufacturing may introduce micro-porosity which could jeopardize the integrity of the vacuum sleeve, thereby endangering the user and patient during use.

16.2.3. Roadmap towards substitution or elimination of lead (COCIR (2020a))

COCIR (2020a) want to continue working with SnAgCu (the most commonly used lead-free solder) but if unsuitable, alternative alloys that are uncommon in electrical equipment could be assessed. At present, no alternative alloy with wetting and flow properties that are similar or better than SnPb on the metals used in the probes has been found.

When a new lead-free connection design has been developed, extensive testing, often followed by clinical trials are needed before approval requests can be submitted. COCIR (2020a) indicate the typical timescales in the below table.

Table 16-1: Predicted timescales for the development of lead-free connections

Phase	Elapsed time
Research to identify potential alternatives	1-2 years
Testing of alternative materials in cryo-probes	1-2 years (if successful)
Design control documentation of design change	3 months
Process Development for new material	3-6 months
Fabrication and sterilization of test articles	3 months
Reliability assessment, aging trials, sterilization testing	1-2 years
Accelerated Aging (3-year shelf life	4 months
Real-Time Aging (3-Year shelf life)	3 years
Functional testing after aging	2 months
Submission for global approvals	1-2 years
Total Cumulative Time	Over 8 years to 12.5 years

Source: COCIR (2020a)

COCIR (2020a) base the above timescales on the assumption that a potential alternative with the required performance is found.

16.2.4. Environmental arguments and socioeconomic impacts (COCIR (2020a))

COCIR (2020a) state that without this exemption cryo-cooled cold probes could not be sold in the EU. Patients would be required to seek alternative therapy, likely more expensive and possibly more invasive surgery.

According to COCIR (2020a), 2.45 million EU citizens were diagnosed with cancer in 2008, and 1.23 million died because of cancer. Cancer cost the EU €126 billion in 2009 with healthcare accounting for €51 billion. Cryo-cooled cold probes offer unique functionality and cost-effective treatment in cancer treatment in areas such as lung cancer which costs the EU €18.8 billion and prostate cancer which costs the EU €8.43 billion.

COCIR (2020a) claim that environmental impacts and an LCA are not applicable as there are no technically suitable substitute materials or designs that are known to be sufficiently reliable.

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 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.

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by"* the REACH Regulation if the requested exemption would be granted/renewed.

REACH Annex XIV (2021)[186] lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- *Lead chromate (entry 10);*
- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

The applications in the scope of the exemption at hand do not use any of the above lead compounds.

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16*[187] *and entry 17*[188] *restrict the use of lead carbonates and lead sulphates in paints;*

[186] ECHA, https://echa.europa.eu/authorisation-list?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

[187] 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

[188] 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

- *Entry 19 refers to arsenic compounds but includes a few lead compounds*[189] *such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*

The above applications are not applicable to the use of lead in the scope of the exemption at hand.

- *Entry 28*[190] *addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30*[191] *addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they 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 above restrictions are not applicable to the use of lead in the scope of the exemption. Further on, lead is part of an article and thus is not placed on the market or used as substances, constituents of other substances or mixtures supplied to the general public, the more as it is used in professional medical equipment.

- *Entry 63*[192] *restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72*[193] *stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

Lead is not used in jewellery, nor in articles or accessible parts thereof that might be placed in the mouth by children. It can also be excluded that lead in the applications in the scope of the exemption at hand is used in textiles, clothing or shoes in the scope of entry 72, e.g. in the context of medical monitoring of patients. Additionally, EEE as such is excluded from the scope of entry 72.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status (October 2021) of these Annexes, the requested exemption would not weaken the environmental and health

[189] 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

[190] 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

[191] 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

[192] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[193] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

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. Scientific and technical practicability of substitution or elimination of lead

Substitution of lead

Design changes to accommodate requirements of lead-free solder alloys

The applicant argues that the quick change from normal to low temperatures and back causes stress in the probe due to the differences in the coefficients of thermal expansion (CTE) and the related thermal mismatch of the three different metals (brass, copper, steel) which are joined by soldering. The consultants raised the question whether other metals with a smaller thermal mismatch and/or less materials could be used to reduce the mismatch.

COCIR (2020b) replied that brass tubing is used to carry the high pressure argon gas at around 21.4 MPa over a length of at least 2.4 meters from the control console to the cold probe while allowing flexibility such that the cold probe can be precisely placed during the treatment. COCIR (2021a) explain that the brass tubing has an outer diameter of 1.6 mm and a wall thickness of 0.25 mm and as such is ductile allowing for flexibility of the high-pressure argon gas connection line between the console and the cold probe. According to COCIR (2020b), the brass tubing still provides for the critical parameters of high-pressure conveyance (strength) while being more flexible than stainless steel. Most of the other components of the cold probe are manufactured from stainless steel alloys 303, 304, and 316L. These alloys are able to be readily machined or drawn into tubing having good diametrical dimensional tolerance along with excellent corrosion resistance (protective from the flux used to solder the components together). The strength of the stainless steel is also critical for its ability to withstand high pressure and significant temperature induced stress during use. The outer shaft component utilizes stainless steel as its surface is required to be biocompatible and sterile during patient treatment. The copper component used in the cold probe is a very small machined finned-tube heat exchanger. Copper is used for its machineability and excellent heat transfer characteristics.

COCIR (2020b) further explain that the stainless steel, brass and copper parts are used because they are all very satisfactory for use in creating strong soldered assemblies. Given the use of flux and proper soldering procedure, these materials allow for the solder joints to be formed with a very uniform and strong bond around the entire circumference of the tube-to-tube connections that are required. COCIR (2020b) highlight that any material changes would require testing to ensure that the performance of the alternative parts meet the same demanding criteria as the current design meets, which includes mechanical stresses due to the probes' manual manipulation, high pressure gas and cold temperatures.

The consultants understand that the three different materials steel, copper and brass were selected for their specific properties which are required to make the system operational and allow their medical use, and for the manufacturability with lead solders. Since COCIR (2021a) explain that lead-free solder is currently being trialled in an effort to identify an alternative solution with first successes, the consultants focused on assessing the status of this solution.

Lead-free solder alloys

COCIR (2020a) report about recent trials with tin-silver-copper (SnAgCu) solder whose results COCIR (2020b) estimated to be available in November 2020. COCIR were therefore asked to provide insights into the status of these trials.

COCIR (2021a) explicate that initial feasibility testing was accomplished whereby four probes from each of three different designs (chosen to be a representative design sample) were manufactured using the SnAgCu solder. This test was passed. Initial evaluation testing of the strength of the lead-free solder was also undertaken. This test was passed. A low volume pilot build was completed. Accelerated aging testing was completed and passed with certain failures not attributed to the use of lead-free solder. Real time aging of the cold probes manufactured with SnAgCu solder is underway with results of functional testing expected to be available approximately two to three months after the end of the aging test period in May 2023.

COCIR (2021a) further state that, if real time aging of the cold probes built using lead-free solder passes, further work will be required to allow the methodical changeover to lead-free solder. Based on the new situation due to the progress with the SnAgCu solder, COCIR (2021a) upon request provide the below updated and specified for the SnAgCu solder time plan for substitution of lead since the roadmap in section 0 on page 258 does not yet reflect the latest results of the SnAgCu solder testing. Table 16-2 below illustrates these and the steps following after May 2023.

Table 16-2: Steps specifically foreseen for the ongoing SnAgCu test program

Step	Required time
Successfully passed tests: • Initial feasibility testing • Initial evaluation testing of lead-free solder strength • Low volume pilot build completed. • Accelerated aging testing completed Real time aging of the cold probes ongoing until May 2023	Until May 2023
Functional testing after real time ageing	2-3 months
Training in the production areas	3 months
Manufacturing systems, including material purchasing and incoming inspection	6 months
Manufacturing equipment may need to be upgraded to handle higher temperature and decreased tip life for lead-free solder, and qualification of the equipment	9 months
Clinical trials are currently being considered	2 years
Alternative to clinical trials: Summative usability testing	1 year
Global approvals	1-2 years
Total time required after May 2023:	Minimum ~3.7 years
	Maximum ~5.8 years

Source: Table prepared by the consultants based on information submitted by COCIR (2021a)

If the above tests and steps can be successfully passed, according to the above plan, the applicant could achieve RoHS compliance earliest end of January 2027, latest after the maximum validity period of seven years starting on 30 June 2021 and ending on 30 June 2028, which would be five years after May 2023.

The above test program deviates from the one presented in the applicant's renewal request presented in Table 16-1 on page 372 even though the overall time required remains the same. Real time ageing and functional testing thereafter are the last steps in this plan prior to approval while they are among the first steps in the above plan. *COCIR (2021b) explain that some of these activities had not been fully thought out when the application for renewal of the exemption was applied for in December 2019 and the presented plan is typical of medical devices in general, while the above plan is specific to cryoprobes and so is more applicable to this exemption.*

The consultants wondered whether some of the above steps could not be processed in parallel, e.g. design control documentation and process development, or training in production areas, manufacturing systems and manufacturing equipment upgrades. Also the

time planned for approval could not be shorter taking into account that only the approval for the EU is required, not a global approval, to place cold probes on the EU/EEA market. *COCIR (2021b) admit that these steps and others can and would be performed in parallel. They agree that the EU approval would in principle require less time than global approval, but due to the increased burden required by the new MDR - all medical devices are having to be re-approved – the regulatory staff would require additional time for International Submissions Dossier and MDR certification audit.*

The applicant did not indicate how far parallel processing of steps outlined in the above implementation plan could reduce the time required to finalize the testing program. The consultants assume that it is at least one year. Since the exact time required for the testing turned out to be not decisive for the recommendation (see next section), the consultants did not follow up this discussion.

Activities since 2011

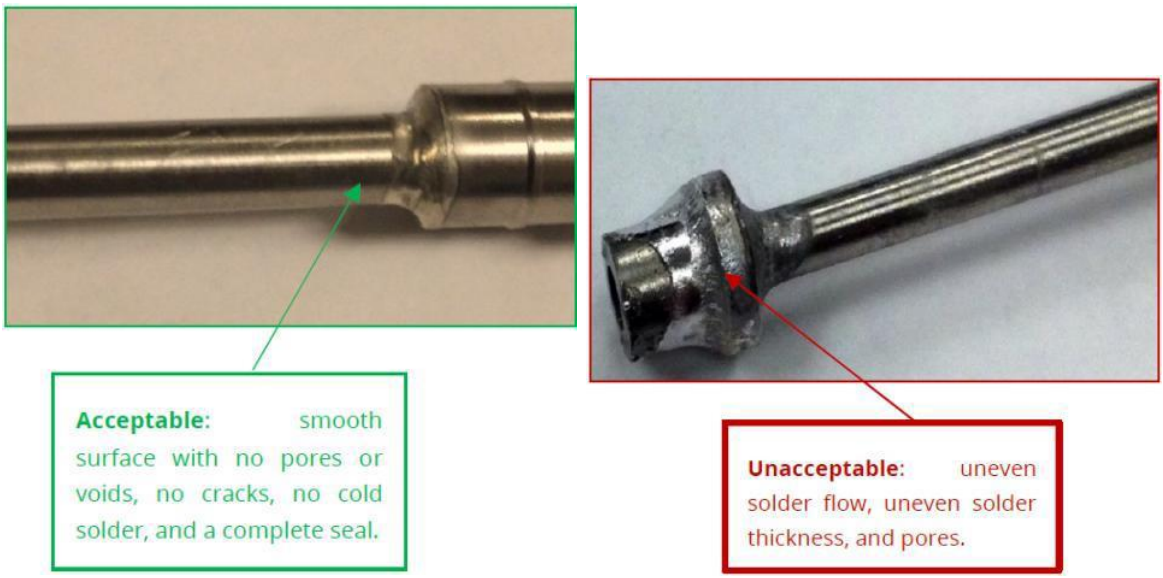
COCIR claim to have started working with the above common quasi-standard SnAgCu solder only recently and was therefore asked why they had not tried this earlier in the last around 10 years since the official publication of the recast RoHS Directive 2011/65/EU with EEE of cat. 8 included into the exemption scope.

COCIR (2021a) put forward that historically, at least two significant attempts with respect to resources and cost were made prior to the current work. COCIR (2020a) describe trials with a lead-free tin-silver alloy (96 % Sn, 4 % Ag w/w) and a lead-free tin-copper alloy (97 % Sn, 3 % Cu w/w) on ten and four (including two different designs) cryo-cooled cold probes respectively. The trials failed mainly due to insufficient wetting of the lead-free solders resulting in sub-standard solder joints. Wetting of solders among others depends on the soldering temperature. COCIR (2020b) report that the temperatures at which the trialled alloys were tested was not captured by the reports generated at that time. Therefore, they unfortunately cannot share this information.

COCIR (2020b) put this missing information into perspective, claiming that increasing soldering temperatures can improve wettability only to a limited extent. Solder wetting is mainly affected by the effectiveness of the flux used to remove surface oxides. As bonding temperatures increase, so do the oxidation rates of solder metals and substrate metals. Solders require fluxes that function by removing surface oxides to allow liquid solder to interact with an oxide-free substrate. The ability of the flux to remove oxides depends on its composition and various solder fluxes formulations with differing reactivity are used. Fluxes for soldering to stainless steel need to be very aggressive as the oxide on stainless steel is very inert. When brass is heated, the zinc content rapidly oxidises to form zinc oxide and this needs to be dissolved in the flux. At higher temperature, much more oxide is formed and will overwhelm the fluxes ability to maintain an oxide-free surface.

COCIR (2021a) provide the below photos from the tests which show the insufficient wetting of the lead-free test sample.

Figure 16-3: Failed lead-free solder trial



Source: COCIR (2021a)

The applicant states that the tested lead-free solders already failed in the wettability testing. This test can be assumed to be an early stage of the solder test program. The related efforts would have been limited and disproportionate to the already ten years that have passed since the enactment of Directive 2011/65/EU (2011), which included cat. 8 equipment into its scope. *COCIR (2021b) justify this situation stating that the development of lead-free cryoprobes did not start in 2011 as sales in the EU were very limited. It was not until 2019 that EU sales became significant to justify research and development of lead-free substitutes.*

There were thus no activities to substitute lead in the eight years between 2011 and 2019.

Elimination of lead

COCIR describe several alternative bonding techniques and one alternative manufacturing process:

- Brazing or welding
- Thermally conductive adhesives
- Mechanical connections
- Additive manufacturing process (3D printing)

The applicant's arguments why the above alternative techniques cannot eliminate the use of lead in cold probes explain plausibly that the elimination of lead in cold probes is scientifically and technically not practicable now and in the foreseeable future.

16.3.3. Environmental arguments and socioeconomic impacts

The applicant did not provide information as to environmental impacts of substitution/elimination of lead stating that substitution or elimination are scientifically and technically impracticable.

The applicant's data as to patients suffering from cancer and the related costs are from 2008 and 2009 and are thus outdated. It is nevertheless plausible that, should cryo-cooled cold probes no longer be placed on the EU/EEA market if the exemption is not renewed, there would be adverse impacts on human health and life since cold probe ablation is an applied and established therapy.

From 2011 to 2019 the applicant did not undertake any efforts to avoid the use of lead in the solders used in the cold probes. The activities were started in 2019 when the sales of cryo-cooled cold probes had reached a level which the applicant deemed adequate to justify the efforts and resources required for research and development of lead-free solutions. Sales of small numbers of devices in the applicant's understanding of Art. 5(1)(a) cannot justify lacking efforts to achieve RoHS compliance.

16.3.4. 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.

COCIR request the renewal of exemption IV-29 for the maximum validity period and a modified scope that includes cryo-cooled cold probe medical devices only. During the stakeholder consultation, no contributions were received supporting or objecting the requested renewal. A possible explanation would be that the applicant already covers most of the market for these applications. Further stakeholders could not be found during the evaluation. The applicant claims that neither substitution nor elimination are scientifically and technically practicable at the time being and are not foreseeable within the next seven years. COCIR members have started testing lead-free tin-silver-copper solder to substitute lead solders in cryo cold probes. The tests are ongoing and would allow the substitution of lead if successfully completed. COCIR indicate a minimum of 5.5 years and up to 7.5 years after the current expiry date of the exemption on 30 June 2021 to complete the testing including the obligatory approval for the new lead-free cryo-cooled cold probes.

Prior to the current tests, the applicant had tested two other lead-free solders that failed already in the wetting test phase, which is an early stage in the test program so that the required effort for these activities were limited. Asked about other activities in the past ten years since 2011, when the new RoHS Directive was enacted, the applicant stated that the efforts to achieve RoHS compliance were started in 2019 only when the sales of cryo-cooled cold probes had increased to a level that justified the expenses to substitute lead.

This means that for eight years there were no activities to achieve RoHS compliance without depending on exemption 29. By 2011, lead-free soldering had already been standard in the electrical and electronics industry, tin-silver-copper solder had been established as a quasi-standard solder next to other lead-free solders that were available. There is thus no technical justification for eight years of inactivity delaying tests of lead-free soldering

solutions until 2019. Given the current time scale of around 9 years from 2019 to 2028 for the applicant's current test program, RoHS compliance either could have been achieved already or it would otherwise be clear that lead cannot yet be substituted if the applicant had started the test program in 2011 already, which is the latest date that can be expected for such activities.

Sales of too small numbers of devices to justify eight years of lacking compliance efforts and, in consequence thereof, still lacking substitution or elimination solutions, in the consultants' understanding of Art. 5(1)(a) does not allow granting an exemption based on the current status that substitution of lead is still impracticable since this status or the uncertainty about the practicability are a consequence of the applicant's inactivity. If COCIR had started their activities in 2011 already, they would be through with their nine years of testing program which they describe for their ongoing efforts. The consultants do not see the applicant's explanation as a socioeconomic reason either that could be considered with view to the renewal of exemption 29, the more as socioeconomic reasons alone can hardly justify an exemption by Art. 5(1)(a).

In the consultants' view and in the light of the review practices that have been established in the past years of exemption reviews in alignment with the Commission policies, the consultants would recommend not to renew the exemption. It needs to be taken into account, however, that cryo-cooled cold heads are important therapeutic medical tools. In the case that they could no longer be placed on the EU/EEA market due to the revocation of exemption 29 for cat. 8 medical devices other than in-vitro diagnostic medical devices, it is highly probable that it would have adverse impacts on health care.

Art. 5(1)(a), third dash, justifies granting exemptions among others if the total negative **health impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof. If the exemption is not granted, either a forced substitution may become necessary with probes whose reliability would not be ensured, or no cryo-cooled cold probes could be placed on the EU market for the next years thus reducing the quality of health care and, in worst case, endangering patients' lives. In the light of these considerations, it can be argued that the substitution of lead would have negative health impacts that are likely to outweigh the positive health impacts of substitution.

The consultants therefore recommend renewing the exemption to avoid negative impacts on EU health care if the COM considers this to be justifiable by Art. 5(1)(a), but for three years only instead of the requested seven years. This leaves time for COCIR to prove continued compliance efforts and to monitor their efforts, and, if needed, to request the renewal of the exemptions with more insights already as to the status and feasibility of lead-free soldering in cryo-cooled cold probes.

16.4. Recommendation

The substitution or elimination of lead cryo-cooled cold probes is not yet achieved. COCIR neglected their legal compliance obligations and did not undertake any efforts to substitute or eliminate lead before 2019 stating that the low number of cryo-cooled cold probes sold in the EU during this period did not justify the efforts and resources required to achieve compliance. The applicant indicates a maximum of nine years to finalize the lead-free soldering tests started in 2019. If COCIR had started these compliance efforts in 2011, when the current RoHS Directive was enacted with cat. 8 EEE included in its scope, the tests

would be finalized by now and it would be clear whether lead-free solders can avoid the use of lead, and if so, the exemption could expire on 30 June 2021 as regularly foreseen.

In the consultants' view and in the light of the review practices that have been established in the past years of exemption reviews in alignment with the Commission policies, the consultants would recommend not to renew the exemption. At the same time, the applicant has induced a situation that cryo-cooled cold probes could no longer be placed on the EU/EEA market latest from 30 December 2022 on (30 June 2021 + maximum possible 18 months transition period) if the exemption is not granted. A forced substitution may become necessary with probes whose reliability would not be ensured, or no cryo-cooled cold probes could be placed on the EU market for the next years thus endangering patients' lives. In the light of these considerations, it can be argued that forcing either substitution of lead or withdrawal from the market due to non-substitution would have negative impacts on the EU health care and danger patients' health and lives that are likely to outweigh the positive health impacts of the lead substitution in the cryo-cooled cold probes.

The consultants therefore recommend renewing the exemption for three years to avoid the above negative health impacts if the COM agrees that this is justifiable by Art. 5(1)(a). Three years leave time for the applicant to prove their continued compliance efforts and for documenting their efforts. Three years are also sufficient time to request the renewal of the exemptions 18 months prior to its expiry with more insights already as to the status and feasibility of lead-free soldering in cryo-cooled cold probes.

The consultants recommend the below wording if the COM decides to renew the exemption.

	Exemption	Scope and dates of applicability
29	*Lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems.*	Expiry on - 30 June 2021 for cat. 9 industrial monitoring and control instruments - 30 June 2021 for cat. 8 in-vitro diagnostic medical devices
29(a)	*Lead in alloys as a thermal conductor in cryo-cooled cold probes in medical devices*	Expiry on 30 June 2024 for cat. 8 medical devices other than in-vitro diagnostic medical devices

16.5. References

COCIR (2020a): Request for renewal of exemption 29 of RoHS Annex IV. Online verfügbar unter http://rohs.biois.eu/RoHS_V_Application_Form_29_COCIR.pdf.

COCIR (2020b): Answers to questionnaire 1 (clarification questionnaire). Online verfügbar unter http://rohs.biois.eu/Exe29-IV_COCIR_Questionnaire-1_Clarification.pdf.

COCIR (2021a): Answers to questionnaire 2 received from Emily Thyrwitt-Jones, RINA, to Dr. Otmar Deubzer, Fraunhofer IZM, via e-mail on behalf of COCIR.

COCIR (2021b): Answers to questionnaire 3 sent via e-mail by Emily Tyrwhitt-Jones, RINA,on behalf of COCIR to Dr. Otmar Deubzer, Fraunhofer IZM, on behalf of COCIR.

Directive 2011/65/EU (2011): 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 (recast). RoHS 2. European Union. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065, zuletzt aktualisiert am 01.07.2011, zuletzt geprüft am 05.10.2012.

Gensch et al. (2012): Assistance to the Commission on technological, socio-economic and cost-benefit assessment related to exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive). RoHS V. Unter Mitarbeit von Carl-Otto Gensch, Yifaat Baron, Markus Blepp, Andreas Manhart und Dr. Deubzer, Otmar, Fraunhofer IZM. Öko-Institut e. V. und Fraunhofer IZM. Freiburg (Adaptation to Scientific and Technical Progress of Annex II Directive 2011/65/EU). Online verfügbar unter https://circabc.europa.eu/sd/a/42ccb088-4c26-4e3a-8a0c-218ea738964c/RoHS_V_Final_report_12_Dec_2012_Final.pdf.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

17. Exemption 31(a) of Annex IV: Pb, Cd, Cr6+ and deca-BDE in spare parts

The current wording of exemption 31(a) is as follows:

"Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in-vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer."

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date was scheduled for 21 July 2023, and for IMCIs for 21 July 2024.

Declaration

In the sections preceding section 17.4 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. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and definitions

Cd	Cadmium
CR6+	Hexavalent chromium
CT-scan	Computed tomography scan
Deca-BDE	Deca-brominated diphenyl ethers
IVD	In-vitro Diagnostics
JBCE	Japan Business Council in Europe
MRI	Magnetic Resonance Imaging
LCA	Life Cycle Assessment
Octa-BDE	Octa-brominated diphenyl ethers
OEM	Original Equipment Manufacturer
PET	Positron emission tomography
Penta-BDE	Penta-brominated diphenyl ethers
PB	Lead

PBDE	Poly-brominated diphenyl ethers
PCB	Printed Circuit Board
RoHS 1	Directive 2002/95/EC
RoHS 2, RoHS	Directive 2011/65/EU
X-ray system	Medical devices as CT and PET

17.1. Background

COCIR (2020) submitted a request for the renewal of the exemption 31(a) of Annex IV (category 8) for the maximum validity period. No consultation responses were received.

The requested wording of exemption 31(a) includes an amendment to the current wording under Annex IV of RoHS Directive 2011/65/EU (2011) (RoHS 2): "polybrominated diphenyl ethers (PBDE)" are replaced by "deca brominated diphenyl ethers (deca-BDE)". COCIR (2020) explained that *penta-BDE and octa-BDE were used in electrical equipment until these substances were banned by the REACH Regulation in 2004 and so will no longer occur in recovered parts. The only PBDE flame retardant that has been used in medical devices until 2014 was deca-BDE.* The proposed new wording is:

"Lead, cadmium, hexavalent chromium, and deca-brominated diphenyl ethers (deca-BDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in-vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.

Expires on:

(a) 21 July 2028 for the use in medical devices other than in-vitro diagnostic medical devices;

(b) 21 July 2030 for the use in-vitro diagnostic medical devices"

The maximum term for an exemption is 7 years from the date of renewal approval. Accordingly, IVDs can also only be applied for until 2028. The 7-year maximum validity is not added to the current expiration date.

In the original exemption renewal form under item 4b "Please specify if application is in use in other categories to which the exemption request does not refer" category 9 was checked, but the application itself refers to category 8. The consultant was informed by a JBCE representative[194] that *a new exemption application for this is scheduled for January 2023, if their members continue to need this Exemption 31(a).*

[194] Personal email from Takuro Koide (JBCE) to Jana Rückschloss (Fraunhofer IZM) on September 14, 2021

17.1.1. History of the exemption

Applications for renewal were submitted in time, and exemption 31(a) will be reviewed for the second time to adapt it to scientific and technical progress.

Exemption 31(a) of Annex IV was not part of RoHS Directive 2002/95/EC (2003). COCIR requested[195] the predecessor of this exemption in 2011 for medical devices. FEI Company[196] requested an amendment in 2013 to include electron microscopes (cat. 9 industrial monitoring and control instruments), supported by COCIR. Gensch et al. (30 September 2013b) reviewed the request. As a result of earlier reviews, the Commission (COM) granted the exemption whereupon it was added to RoHS Annex IV in its current wording in 2016 amending the previous exemption 31.

In 2014, (Gensch und Baron 2014) conducted the evaluation for exemption request 2013-6, which was related to one exemption on lead and hexavalent chromium in reused spare parts, recovered from industrial monitoring and control instruments. This exemption was originally requested for category 9 applications, but was also deemed to be relevant for medical devices of cat. 8.

The recommendations resulting from (Gensch und Baron 2014) evaluation served as input for the Commission Delegated Directive (EU) 2016/585 of 12 February 2016[197]. The point 31(a) added through this amendment to Annex IV of the RoHS Directive reads: *"Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in-vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer".*

In 2020, prior to the expiry of the exemption for cat. 8 medical devices other than in-vitro diagnostic medical devices COCIR requested the amendment and renewal of the exemption in 2020, and Gensch et al. (2020) recommended either granting this modified exemption as a separate exemption besides exemption 31(a) for seven years for cat. 8 medical devices other than in-vitro diagnostic medical devices (option 1 below), or to merge it with exemption 31(a) (option 2)

Option 1:

> *Bis (ethylhexyl) phthalate, dibutyl phthalate, diisobutyl phthalate and benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in-vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.*

Option 2:

> *Bis (ethylhexyl) phthalate, dibutyl phthalate, diisobutyl phthalate, benzyl butyl phthalate, lead, cadmium, hexavalent chromium, and polybrominated diphenyl*

[195] C. f. https://rohs.exemptions.oeko.info/index.php?id=132

[196] For details see https://rohs.exemptions.oeko.info/index.php?id=206

[197] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016L0585

ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in-vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.

The COM's decision concerning the adoption of the above exemption is still pending. To avoid that exemption 31(a) in its current form expires in July 2021 for cat. 8 EEE other than in-vitro diagnostic medical devices, COCIR (2020) requested the renewal of this exemption.

17.1.2. Summary of the renewal request

COCIR (2020) summarized their exemption request as follows:

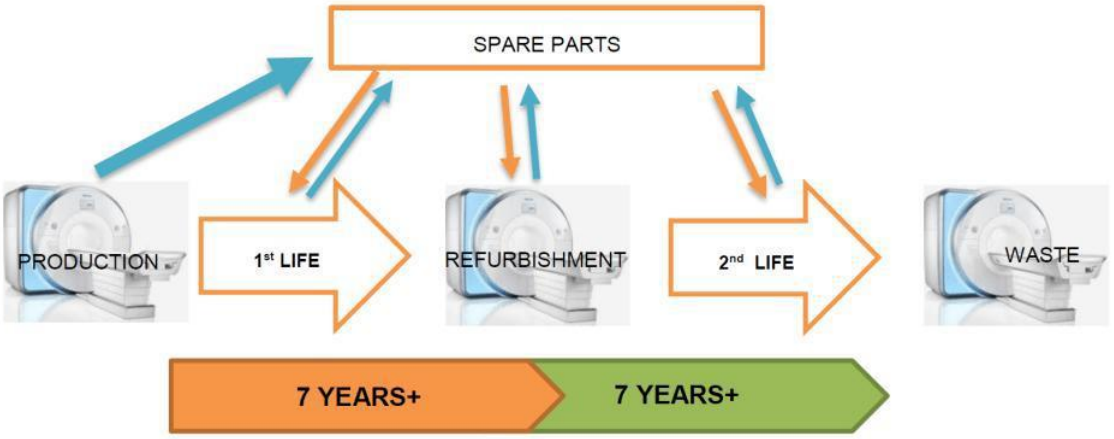
"Medical devices are frequently refurbished by the original manufacturer for reuse after they have been used by first users. Many refurbished medical devices are sold in the EU as EU hospitals have limited budgets and refurbished equipment provides the capability that they need and the lower prices allows hospitals to buy additional medical equipment and therefore offer a better healthcare to patients. Refurbishment uses recovered spare parts (which have also been refurbished themselves) as using new parts is not an option because they are no longer produced. Recovered and refurbished parts are also reused as spare parts for repair and maintenance of the installed base in the EU. Reuse of only some parts is permitted by RoHS without exemption 31(a) so that without this exemption, reused parts cannot be used in the EU as it is not possible to know if the part is covered by an exclusion or not.

Reuse of parts is always preferable to disposal as waste and manufacture of a replacement part. The overall health and environmental impact of reuse is shown, using life cycle assessments, to be significantly smaller than the overall impacts from disposal of parts as waste and manufacture of a replacement parts. There are also qualitative human health impacts, if limitations occur for the refurbishment market. Delays in hospitals being not able to afford new replacement equipment mean that old less reliable equipment has to be used for a longer time, or delays to treatment would be caused, if bigger upgrades (including making new replacement parts) would need to be performed, because adequate spare parts are not available."

17.2. Technical description of the requested exemption

COCIR (2020) described the principle of medical device refurbishment illustrated in Table 17-1 stating that recovered spare parts may be used for a period of at least as long as twice the life of a medical imaging device because some parts are reused more than once. Therefore, spare parts need to be available to repair the equipment during its first life, and then during its second life after refurbishment. Some parts are reused many times, such as X-ray tube housings, which can have technical lifetimes of up to 25 years. COCIR (2020) stated that the requested exemption is relevant for medical imaging devices (e.g. MRI, CT, PET, SPECT, ultrasound imaging, X-Ray systems, dialysis pumps) and in-vitro diagnostic (IVD) medical devices. Over time, the percentage of spare parts with critical substances will decrease as new RoHS compliant spare parts become available from newer medical devices. Figure 17-1 shows the lifetime extension through reuse of spare parts.

Figure 17-1: Lifetime extension through reuse of spare parts



Source: COCIR (2020)

Table 17-1: Effect of source of equipment and parts on whether they can be reused without exemption 31(a)

Source of recovered part	Identity of medical device in which the recovered part is used for repair/ maintenance	RoHS compliance status of recovered part without exemption 31(a)	Could this part be used in a medical device placed on the EU market after exemption 31(a) expires?
From a medical device regardless of whether it was originally sold before July 2014, which may contain RoHS-restricted substances	Medical device placed on the EU market before 21 July 2014 (yes 6 substances, yes 4 phthalates)	May contain RoHS substances	Yes, thanks to RoHS article 4.4
	Medical device placed on the EU market between July 2014 and July 2021 (original 6 substances restricted, 4 phthalates not yet banned)	May contain RoHS substances	Yes, permitted by actual exemption 31(a) and Article 4.4(f)
	Medical device placed on the EU market after 21 July 2021 (no 6 substances, no 4 phthalates)	May contain RoHS substances	No, cannot be used unless exemption 31(a) is renewed with the same original wording

Source of recovered part	Identity of medical device in which the recovered part is used for repair/ maintenance	RoHS compliance status of recovered part without exemption 31(a)	Could this part be used in a medical device placed on the EU market after exemption 31(a) expires?
From a medical device regardless of where it was originally sold between July 2014 and July 2021 which may contain RoHS substances due to an expired exemption	Medical device placed on the EU market before 21 July 2014 (yes 6 substances, yes 4 phthalates)	May still contain original 6 RoHS substances not covered anymore by existing exemptions + phthalates	Yes, due to article 4.4
	Medical device placed on the EU market between July 2014 and July 2021 (contains no original 6 restricted substances except	May still contain original 6 RoHS substances but not covered anymore	Yes, due to article 4.4(f)
	Medical device placed on the EU market after 21 July 2021 (no 6 substances and no 4 phthalates unless covered by exemption)	May still contain original 6 RoHS substances not covered anymore by existing exemptions + phthalates	No, cannot be used unless exemption 31(a) is renewed with the same original wording

Source: COCIR (2020)

Exemption 31(a), allows the use of recovered spare parts from medical devices to be reused for the repair, refurbishment, servicing or maintenance operations regardless of when and where the medical devices from which the parts originated was previously placed on the market. *COCIR (2020)* emphasized that *"about one third of new medical devices are sold in the EU. This means that two thirds of recovered parts could not be used to refurbish, repair, service or maintain medical devices that have been placed on the EU market after 21 July 2021 without this exemption maintaining its exact wording. […] To ensure full compliance, without this exemption, with RoHS, it would be necessary for manufacturers to halt any refurbishment operation (or to sell refurbished equipment outside of the EU only) and to stop using all recovered spare part for refurbishment, repair, servicing or maintenance in the EU to avoid the risk of unintentional non-compliance."*

Determining whether RoHS-restricted substances are present in recovered parts

COCIR (2020) stated that *without this exemption, the OEM would have to analyse each spare part for prohibited substances because the parts will probably contain RoHS substances if manufactured before 2014, or they may contain RoHS substances not covered anymore by an expired exemption, if manufactured after 2014. COCIR (2020)* explained that *"some RoHS substance uses can be determined by analysis using non-destructive X-ray Fluorescence (XRF) screening analysis. However, this is not always definitive and can give incorrect*

results. It is also unsuitable for hexavalent chromium and PBDEs which can be analysed only by destructive analysis methods. Also, larger or more complex parts need to be opened to analyse internal materials and this is usually destructive. It is therefore usually impossible to determine compliance without destroying the part."

Another issue are the additional costs that would be incurred by such investigations. The economic viability for companies that refurbish medical equipment may no longer be given.

17.2.1. Amount of lead used under the exemption

In the exemption renewal form, *COCIR (2020)* stated that *no additional lead will enter the European market because there is no net change in quantity within the EU.* They explain further *"All parts that have been produced for medical devices after 21 July 2014 and after 21 July 2016 for In-Vitro-Diagnostic Medical Devices (IVD MD) will not contain RoHS restricted substances, except in applications which had previously been exempted under RoHS Annex III and IV. However, recovered parts from older equipment may contain these substances. Some non-EU parts (recovered from pre-2014 medical devices /from pre-2016 in-Vitro-Diagnostic devices that were originally sold outside of the EU) will contain RoHS substances and with this exemption will enter the EU market in the future, but also, a similar quantity of parts recovered from medical devices placed on the EU market before 21 July 2014 will also leave the EU. Overall, there will be no net change in the amounts of these substances present within the EU as the amounts entering will be similar to the amounts leaving."*

As typical examples of approximate concentrations, COCIR (2020) point out:

- *Pb in solder and in solder-able coatings ca. 2 – 40 %,*
- *Lead in alloys: 4 – 10 % in copper alloys and 0.4 – 2 % in aluminium alloys, e.g. used as bearings (e.g. in motors) and in gearboxes,*
- *CrVI in passivation coatings 1 – 30 %,*
- *Cd pigments (in applications excluded from REACH) 1 – 50 %,*
- *Deca-BDE flame retardant 3 – 8 %*

17.2.2. Use and function of the restricted substance

Since the components from a wide variety of end-of-life devices are recycled for reuse, the technical functions of these components are broadly diversified. *COCIR (2020) provided an illustrative non-exhaustive list of application fields and functions.*

Fields of RoHS-regulated substances include:

- *Lead in solders and solderable coatings of components;*
- *Lead in ceramic capacitors;*
- *Lead in pigments (mainly used in paints and polymers);*
- *Lead in copper and aluminium alloys at concentrations higher than permitted by exemptions 6c and 6b of Annex III, e.g. used for bearings, to make gears for gearboxes, in fasteners, etc.;*

- *Lead in electroplated coatings used on plugs and sockets;*
- *Lead stabilisers in PVC cables and other PVC parts;*
- *Cadmium in pigments used in applications that are exempt from the REACH Regulation;*
- *Cadmium in brazed parts such as to attach pipes used for cooling equipment;*
- *Hexavalent chromium in passivation coatings on metals;*
- *Hexavalent chromium in pigments, e.g. used in labels, etc.;*
- *Deca-BDEs in plastic parts and in coatings;*
- *RoHS substances in applications that had been previously exempted under RoHS Annex III and IV;*

Functions of RoHS-regulated substances include:

- *Lead in solders and in terminal coatings for making electrical connections with high reliability or magnetic requirements*
- *Lead compounds as PVC stabilisers*
- *Lead in ceramics of ceramic capacitors that was permitted by exemption 7cIII (expired Jan 2013 so may occur in medical devices made before 2013)*
- *Hexavalent chromium compounds in passivation coatings for its corrosion properties*
- *Deca-BDE as flame retardants used in various polymers*

Types of recovered parts that are reused

Medical device manufacturers recover many types of parts from used equipment for reuse. COCIR (2020) gives the example of a manufacturer that collects and reuses 3,500 different parts. According to the applicants the most commonly recovered and reused types of parts are:

- *MRI coils*
- *Printed circuit boards from many different types of equipment*
- *Detectors and components of detectors (e.g. radiation detectors)*
- *X-ray tubes*

Some old printed circuit boards were made with lead solders before July 2014. Pre-2014 electric motors and cables may contain lead stabilisers in the PVC insulation. (COCIR 2020) added that *"plastic components and mouldings may have been made using PBDE flame retardants before July 2014. Now in 2019, it is impossible to determine from the plastic manufacturer, which flame retardant was used at least five years ago. The only way to determine if the plastic contains PBDE is by destructive chemical analysis and this would make the part unusable, so would be pointless."*

COCIR (2020) further explained that *X-ray imaging equipment consists of many sub-assemblies: parts for patient positioning, for holding and moving the X-ray tube and detector into the required positions, and the X-ray tube and detector assembly. New assemblies built*

from reused parts are used as replacements for existing X-ray systems and may also be used to construct new systems. This systems typically have very long lives often exceeding 25 years but the X-ray tubes have shorter lives, which can be as short as 6 months or as long as 15 years depending on the frequency and intensity of use. X-ray tube assemblies have to be periodically replaced because of bearing wear or erosion of the anode. The average period for all tubes is estimated by COCIR to be about 5 years. The X-ray assembly housing can be used at least 25 years before recycling of materials is the best option.

COCIR (2020) stated that *"one of the largest parts of the assembly that is reused is the external housing. This is constructed from aluminium alloys or sometimes brass, some steel parts, lead sheet as radiation shielding and a few other materials. The aluminium alloys and the brass in some cases are also alloyed with lead which acts as radiation shielding. The X-ray tube assembly housing has a number of small inserts which have in the past been, treated with chromate passivation coatings to prevent corrosion and so the coatings contain a very small quantity of hexavalent chromium. Chromate passivation treatment has been replaced by all medical device manufacturers, so only recovered parts from equipment placed on the market before July 2014 will contain these coatings, but these parts could potentially be reused for 25 years until 2039 if allowed by exemption 31(a)."*

17.3. Justification for the requested exemption

As justification for this exemption, COCIR (2020) contend that *the overall negative health, safety and environmental impacts of manufacturing relevant parts and equipment anew are higher than using refurbished parts and equipment.* This is further detailed in section 17.3.3 on page 393.

According to COCIR (2020) manufacturers do not collect medical devices made by other manufacturers and typically around 95 % of assemblies are returned to the original manufacturer. The manufacturers therefore almost close the loop. Nevertheless it is usually not possible to reliably determine whether a spare part had been removed from a medical device originally sold in the EU before 21st July 2014 or it is from equipment that had previously been sold to a user outside of the EU. JBCE (2021) primarily cite logistical hurdles that make such tracking impossible: *"In practice, it is not possible to mark each and every spare part with the required information and keep it updated throughout the whole life cycle. Spare parts cannot be marked as there are up to 50,000-100,000 spare parts per manufacturer, used in different markets and repaired multiple times over their whole life-cycle. […] Spare parts, in the hundreds of thousands to millions, are recovered during maintenance by field engineers, during repair in repair centres and operations in refurbishment facilities. The flow of parts is redirected to refurbishment facilities or directly to storage for regional repair and service centres."*

17.3.1. Substitution and elimination of Pb, Cd, Cr6+ and deca-BDE

Since the last application for this exemption, "PBDE" in the wording of the current exemption 31(a) can be confined to deca-BDE. COCIR (2020) explained that *"penta-BDE and octa-BDE were used in electrical equipment until these substances were banned by the REACH Regulation in 2004 and so will no longer occur in recovered parts. The only PBDE flame retardant that has been used in medical devices until 2014 was deca-BDE."*

Avoidance of the substances is not envisaged under the requested application. COCIR (2020) summarized that *"this exemption will no longer be needed when all parts that are*

recovered from used medical devices are made on July 2014 and after this date. Some parts have lifetimes of at least 25 years when reused several times. In the future, the number of pre-2014 parts that contain RoHS restricted substances will gradually decrease as they are reused and eventually reach end of life in a state where they are no longer suitable for reuse. Although the quantity of reused parts will continue at about the same level or slightly increase into the foreseeable future, the quantities of RoHS substances present (except where exempt) will gradually decrease, eventually to zero."

17.3.2. Roadmap towards substitution or elimination of Pb, Cd, Cr6+ and deca-BDE

Over time, replacement parts containing RoHS substances will decrease as new equipment approvals are subject to RoHS legislation and any exemptions are also phased out in incremental steps. End-of-life parts and devices will treated appropriately as the system is almost a "closed-loop". COCIR (2020) explained that *"Medical equipment manufacturers make great effort to collect their own brand of used equipment from their clients and occasionally from brokers when their equipment is not sold back to them directly (there is no obligation for hospitals to sell it back to the OEM). Manufacturers do no collect medical devices made by other manufactures. The equipment that cannot be refurbished are treated as waste according to the WEEE Directive, the others are refurbished. Parts recovered from devices during refurbishment (or repair/maintenance) are used to repair, maintain, service or refurbish other equipment, so that parts remain within a "closed-loop"."*

17.3.3. Environmental arguments and socioeconomic impacts

The justification for this exemption is that the overall health, safety and environmental impact without this exemption is more negative than the overall health, safety and environmental impact with this exemption.

COCIR (2020) stated that the *"environmental benefits of reusing a part are always greater than manufacturing a new part and destroying the old one. It is a basic principle of the EU Circular Economy, reconfirmed in the Waste Framework Directive in 2018, that reuse and life extension are always far better options than waste recycling and manufacturing of replacement new products."* A more in-depth study of environmental impacts was provided in the exemption application. COCIR (2020) used the following environmental assessments to support their exemption request:

(A) Comparison of impacts from equipment refurbishment versus new parts manufacture (qualitative evaluation)

(B) LCA for printed circuit board parts reuse versus new parts manufacture by Van Holsteijn en Kemna using EC Ecodesign methodology (qualitative evaluation)

(C) LCA for MRI and X-ray system refurbishment versus new parts manufacture by Gabriel I Zlamparet[198]

(D) LCA for X-ray tube assemblies

[198] Energy savings and environmental impacts of refurbishing medical devices approaching end-of-life: A case study of MRI and X-Ray scanners, Gabriel I Zlamparet et.al. Unpublished work, provided to the consultant

(E) Third-party verified assessment from RINA Consulting (Goodman et al. 2019)

The items on the list are each summarized below with their main contents.

Qualitative environmental assessments

(A) Comparison of impacts from equipment refurbishment versus new parts manufacture

According to COCIR (2020) *this exemption request relates only to pre-existing components and therefore the impacts of two scenarios should be compared:*

- *exemption 31(a) being renewed, versus*
- *exemption 31(a) expiry without renewal*

Table 17-2 describes the different aspects in more detail.

Table 17-2: Comparison of impacts from scenarios of exemption 31(a) being renewed compared to exemption 31(a) expiry without renewal

With exemption renewal	Without exemption
100 % of recovered parts can potentially be reused	Most of the recovered spare parts cannot be used as the presence of RoHS restricted substances or the origins of the device from which they were recovered are often not known.
Fewer new components will be manufactured and more medical devices will be refurbished.	Refurbishment of medical devices will have to use newly manufactured parts. However, this may not be possible for older parts that have been discontinued. Therefore, fewer medical devices will be refurbished for reuse in the EU. Making small numbers of specially made new parts will be considerably more expensive than use of recovered parts and this will make refurbishment costs too high to be viable as an alternative to new equipment.
Less waste as 100 % of undamaged, recovered parts can potentially be reused.	Recovered parts will become waste if they cannot be used outside of the EU as they cannot be used in the EU.
All refurbished equipment can be sold in the EU or elsewhere.	Unless new parts can be made, refurbished equipment will not be available in the EU, which will impact on EU hospitals.
Greater availability of spare parts for repair, servicing and maintenance which will ensure shorter downtime of essential medical devices for EU citizens and avoid delays in urgent medical treatment	Much lower availability of spare parts for repair of EU medical devices ensuring longer downtime of essential medical devices and delays in provision of urgent medical treatment to EU citizens.

With exemption renewal	Without exemption
	When medical devices are out of warranty, new spare parts may not be available (if production is discontinued) and so it could take up to 8 months to manufacture replacement parts, if this is feasible)

Source: COCIR (2020)

The arguments of this qualitative assessment were purely descriptive and no further scientific and quantitative evidence was provided in the relevant chapter of the exemption request. The following paragraphs summarize the applicant's statements COCIR (2020).

COCIR (2020) explained further that *longer downtimes for healthcare providers occurs as a result of lower availability of parts for repair and maintenance, which in turn leads to a negative health and* ***safety impact*** *on patients.* They stated that *"The reliability and diagnostic and treatment performance is usually proportional to the age of the equipment. If an old medical device develops a fault, the resultant non-availability due to either the medical device age or availability of reused parts, can pose a serious safety risk to patients if they cannot be treated and if delays occur."*

Environmental impacts *of newly produced parts include more emissions (greenhouse gases and hazardous substances), higher resource consumption and more waste according to* COCIR (2020)*. In comparison, refurbishment consumes significantly less resources and energy and generates usually no waste according to* COCIR (2020). *If the parts cannot be reused, they will reach end of life prematurely. New parts will have to be manufactured as replacements, which results in a negative environmental and health impact. Another argument put forward is the technological progress in recycling and the increase of environmental efficiency in the production of new parts. Therefore, it is better to keep parts in the loop as long as possible.*

COCIR (2020) *raises two arguments on the topic of* ***health impacts****: first, disadvantages due to the production of new parts (related to the entire life cycle) and second, risks for patients due to outdated or missing medical equipment. They state that substitutions of the regulated RoHS substances do not necessarily result in a better environmental assessment because the substitutes may also be harmful. Regarding the second argument, COCIR (2020) states that hospitals have limited funds for new equipment and frequently buy refurbished medical devices, which have lower prices and are still better than their outdated device in use.* COCIR (2020) *explained that "Today we already see that the demand for refurbished equipment exceeds the numbers that are available. As a result, the ability to buy refurbished medical devices reduces the average age of the hospital's medical equipment, because a refurbished device usually replaces an older device. […] If refurbished medical devices are not available, the hospital would eventually have to buy a new device, but this is likely to be delayed until sufficient funds become available, which could be several years or more."* COCIR (2020) *provided the following list as possible results for patients if Exemption 31(a) is removed:*

- *There may be no medical device available at the nearest hospital and so they may need to travel a long distance (this would be case when a hospital buys its first MRI, CT, etc. although this would be less common today). Travelling longer distances is difficult for people with ill health or elderly or patients with reduced mobility. As this*

also increases the demand at other hospitals, which in turn can result in delays to treatment due to increased waiting lists for treatment.

- *Older equipment tends to be less reliable than newer devices due to wear and tear. While the device is not functioning and awaiting repair, patients cannot be treated. Not being able to treat patients can have serious implications and as a worst case lead to death, but at best longer recovery times. As an illustrative example, stroke victims can be effectively treated if the hospital staff can quickly determine if the cause is a blocked artery or a burst artery. Treatments for each are different and it dangerous to use the wrong treatment. Stroke victims are diagnosed by either CT or MRI and this must be carried out within a few hours of the stroke for the patient to have any chance of a full recovery. If the CT or MRI is not available then the patient's likelihood of recovery is greatly reduced.*
- *If recovered and refurbished spare parts are not available to repair medical devices, new parts have to be made or a higher level component (i.e. a whole module rather than a small PCB used inside the module) needs to be replaced. The resultant delay can have serious negative implications for patients.*
- *Older equipment may not have the same performance as newer refurbished equipment. For example, magnet power of MRI has increased in the last decades and increased magnet power gives superior image quality that could allow medical staff to detect tumours earlier or see smaller blood clots, etc. Earlier diagnosis results in improved likelihood of recovery and gives faster recovery. It can also allow simpler medical procedures to be used such as keyhole surgery rather than more invasive treatments when for example, tumours become larger. Earlier diagnosis therefore can shorten time in hospital, give quicker recovery and give cost savings to hospitals.*

COCIR (2020) *described further a range of* ***socioeconomic impacts*** *related to increase in direct production costs and possible social impacts within the EU for a scenario where this exemption is not granted. They explain that these implications result from the impossibility to use recovered spare parts which would lead to use newly manufactured spared parts. The following aspects are listed by the applicant:*

- *Increasing costs: If refurbished medical devices are not available, hospitals would eventually have to buy a new device, but this is likely to be delayed until sufficient funds become available, which could be several years or more.*
- *Safety risks for patients: Hospitals that cannot afford new equipment are often able to buy refurbished equipment that is considerably newer than the old equipment that it will replace. The reliability and diagnostic and treatment performance are usually proportional to the age of the equipment. A "new" refurbished device is still better than the absence or delay of medical treatment due to lack of equipment. Delays can lead to death, but more often the patient suffers for longer and their illness worsen.*
- *Longer downtimes for healthcare providers due to lower availability of parts for repair and maintenance on a global scale.*
- *Health impact: manufacturing new replacement parts will cause larger emissions of greenhouse gases and hazardous substances, consume more resources and produce more wastes than refurbishment of parts.*

COCIR (2020) summarized that *"It is not possible to quantify the benefit of a hospital being able to buy refurbished medical devices or repair equipment more quickly, as so many unquantified variables affect patients' recovery and treatment costs, but […] the ability to reuse recovered parts has clear health, safety and environmental benefits."*

(B) LCA for printed circuit board parts reuse versus new parts manufacture by Van Holsteijn en Kemna using EC Ecodesign methodology

As a further qualitative evaluation, COCIR (2020) used the method of the MEErP ecodesign study (Kemna et al. 2011) to compare reuse and new parts manufacture for PCBs. COCIR stressed that *most of the life cycle impact is related to the production phase for most impacts.*

Table 17-3: Selected whole life cycle environmental and health impact data extracted from the EcoReport Calculations' template[199]

Type of electronics	Global warming potential Related to 1 kg of electronic parts	Heavy metals emissions to air Related to 1 kg of electronic parts	Waste, hazardous/ incinerated and non-haz. landfill Related to 1 kg of electronic parts
PWB 1/2 layer 3.75 kg/m^2	20 kg CO_2eq	37 mg Ni equivalent	1.74 kg haz. waste plus 2.7 kg non-hazardous waste landfilled
PWB 6 layer 4.5 kg/m^2	25 kg CO_2eq	70 mg Ni equivalent	1.9 kg haz. waste plus 4.2 kg non-hazardous waste landfilled
Surface mount devices	176 kg CO_2eq	423 mg Ni eq	135 grams haz waste plus 2.9 kg non-hazardous waste landfilled
IC's avg., 5 % Si, Au	514 kg CO_2eq	448 mg Ni eq	241 grams haz. waste plus 8.9 kg non-hazardous waste landfilled
Controller board	125 kg CO_2eq	427 mg Ni eq	97 grams haz. waste plus 2.1 kg non-hazardous waste landfilled

Source: COCIR (2020)

[199] Support tools for experts, Ecoreport calculations' template (unprotected) https://ec.europa.eu/growth/industry/sustainability/product-policy-and-ecodesign_en

Following this approach COCIR (2020) roughly estimated the EU impacts without this exemption for printed circuit boards used for repair, maintenance and servicing of medical devices using the EcoReport Tool. There was a calculation error in the original exemption request, which COCIR (2021) corrected. They calculated the numbers shown in Table 17-4 as yearly impacts.

Table 17-4: Estimated EU impacts from replacement printed circuit boards used for repair, maintenance and servicing of medical devices in the EU that would arise without this exemption.

Impact **Quantity: 2,220,000 kg**	**Laminate**	**SM compo-nents**	**ICs**	**Impact per tonne**	**Total EU impact per year**
Global warming potential	20 CO_2 eq / kg	176 CO_2 eq / kg	514 CO_2 eq / kg	230,6 CO_2 eq / t	511,932,000 kg CO_2 eq
Heavy metals emissions to air	37 mg Ni eq / kg	423 mg Ni eq / kg	514 mg Ni eq / kg	334,5 mg Ni eq / t	742,590,000 mg Ni eq
Waste, hazardous/ incinerated	1,74 kg / kg	0,135 kg / kg	0,241 kg / kg	0,6483 t	1,439,226 kg
Non-hazardous waste landfilled	2,7 kg / kg	2,9 kg / kg	8,9 kg / kg	4,64 t	10,300,800 kg
Share of total mass	30 %	40 %	30 %		

Source: COCIR (2020) and COCIR (2021)

Quantitative environmental assessments

(C) LCA for MRI and X-ray system refurbishment versus new parts manufacture

COCIR used a “full life cycle assessment produced by Tsinghua University” (Zlamparet und Li) as source for the overall quantitative environmental assessment. The paper compares the building of new medical devices to refurbished ones for X-ray systems (PET and CT) *and MRI. The LCA results of the paper show for all 18 environmental and human life cycle impacts that these are significantly lower for refurbished systems. Three illustrative impact examples for MRI and for X-ray systems are listed in the exemption renewal form and can be found in Table 17-5. Other contents of the unpublished paper are not cited. Accordingly, they are not used to justify this exemption.*

Table 17-5: Example results of life cycle assessment comparison of new and refurbished MRI and X-ray systems

Impact	**Size of impact of refurbished system compared with a new system (which is 100 %)**	
	MRI	X-ray system
Climate change	27 %	3 %
Human toxicity	32 %	6 %
Terrestrial ecotoxicity	28 %	5 %

Source: COCIR (2020)

(D) LCA for X-ray tube assemblies

A "comparative LCA" for X-ray tubes is provided in Annex I of the exemption renewal form. Like before COCIR (2020) used two alternative scenarios for the comparison:

- *With exemption allowing reuse, and;*
- *Without exemption so that parts become waste and have to be replaced*

A qualitative description of the two scenarios is followed by an estimate from two manufacturers on the energy consumption for the production of an aluminium housing and in the second example for all reusable parts for a typical design. The figures in the calculation were scaled up to annual energy consumption. The following Table 17-6 shows the results of this calculation. The energy and new materials consumption without an exemption with option (ii) is nearly six times larger than option (i) when calculated over a ten years period.

Table 17-6: Total impacts for 2020 to 2029 with and without exemption 31(a)

Option	10 year totals 2020 to 2029		
	Numbers	Total energy consumption (72 to 307 kWh / new housing)	Total new materials needed (assumes 10 kg / new housing)
i) Reuse of parts permitted		1.7 - 7.4 GWh	240 tonnes
Number of new parts	24,000		
Number reused	136,000		
ii) Reuse of non-EU non-compliant parts not permitted after 31(a) expires		10 - 42 GWh	1,396 tonnes
Number of new parts	139,600		
Number reused	20,400		

Source: COCIR (2020)

Using the MEErp tool, the applicant calculates from this the environmental impacts shown in Table 17-7. COCIR (2020) summarized that *"The data […] shows the size of some of the impacts that are avoided by reuse of just one type of part that is recovered for reuse. In fact, all impacts are higher if new parts need to be made than in parts can be reused. The overall health and environmental benefit from all recovered and reused parts will be significantly larger."*

Table 17-7: Selection of impacts from mining, refining and manufacture of materials used for X-ray tube housings calculated using the MEErP Tool

Impact	Quantity/kg Al produced	Impact for 1,156 tonnes[200]
Greenhouse gas emissions	11 kg CO_2 eq	12,716 kg CO_2 eq
Heavy metals emission to air	10 mg Ni eq	11.56 kg Ni eq
Heavy metals emissions to water	25 mg Hg/20	28.9 kg Hg/20
PAH emissions to air	97 mg Ni eq	112 kg Ni eq
Non-hazardous waste to landfill	452 grams	522.5 tonnes waste

Source: COCIR (2020)

(E) Third-party verified assessment from RINA Consulting

A third-party review report of the environmental assessments was performed by RINA Consulting Ltd. (Goodman et al. 2019). This report explains that *"Comparative LCAs are usually carried out using proprietary software for specific materials or a type of equipment for which all of the materials and quantities are known. Due to the very large variety of recovered parts and the fact that the quantities of each type of part reuse each year will not be known, it is reasonable that the usual approach cannot be used, therefore COCIR has carried out two qualitative LCA and two quantitative LCAs for specific types of equipment and parts as illustrative examples." The quantitative LCAs include a large proportion of the parts that are refurbished – X-ray tubes and PCBs being two of the more commonly refurbished types of part.* (Goodman et al. 2019) concludes that *"COCIR has used multiple LCAs to justify the application for renewal of exemption 31(a). Each show that the overall health and environmental impacts of reuse of recovered parts is significantly less than the overall impacts from disposal of usable parts and manufacture of new replacement parts. […] The wide variety of types of parts and their uncertain composition has prevented the use of formal LCA calculations (e.g. by using commercial LCA software) except for the MRI*

[200] 1,156 tonnes is the additional aluminium required if this exemption is not renewed following on from calculations in the Table above (i.e. 1,396 – 240 tonnes)

and X-ray system refurbishment LCA, but the difference in impacts arising from the two scenarios is so large that this conclusion would be the same irrespective of data accuracy."

17.4. Critical review

17.4.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the 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.

Lead

REACH Annex XIV (2021)[201] *lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:*

- *Lead chromate;*
- *Lead chromate molybdate sulphate red;*
- *Lead sulfochromate yellow;*

The applicant lists the below uses of lead in the scope of the exemption, which are, however, not exhaustive:

- *Lead in solders and solderable coatings of components;*
- *Lead in ceramic capacitors;*
- *Lead in pigments (mainly used in paints and polymers);*
- *Lead in copper and aluminium alloys at concentrations higher than permitted by exemptions 6c and 6b of Annex III, e.g. used for bearings, to make gears for gearboxes, in fasteners, etc.;*
- *Lead in electroplated coatings used on plugs and sockets;*
- *Lead stabilisers in PVC cables and other PVC parts;*

Given the above lead uses and taking into account that this list is not exhaustive, the consultants cannot exclude that certain substances listed on Annex XIV may be used in the in applications in scope of the requested exemption. This would, however, not weaken the

[201] ECHA, https://echa.europa.eu/authorisation-list?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

protection afforded by REACH as only articles that wereplaced on the market before 21 July 2014 are reused in the EU, which is not related to the placing on the market or the use of lead which would require authorization under REACH.

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16[202] and entry 17[203] restrict the use of lead carbonates and lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds[204] such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*

The above applications are not applicable to the use of lead in the scope of the exemption at hand.

- *Entry 28[205] addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30[206] addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they 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 above restrictions are not applicable to the use of lead in the scope of the exemption at hand. Further on, the substances are part of an article and thus are not placed on the market or used as substances, constituents of other substances or mixtures supplied to the general public, the more as they are used in professional medical equipment.

- *Entry 63[207] restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or*

[202] 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

[203] 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

[204] 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

[205] 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

[206] 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

[207] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).

- *Entry 72[208] stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

Lead and lead compounds are contained in parts of medical equipment. In the scope of the exemption at hand, lead is not used in wristwatches or any other jewellery in the scope of entry 63, nor are conditions foreseeable where these parts would be placed in the mouth by children. Finally, EEE in the scope of RoHS Directive 2011/65/EU are excluded from the scope of this entry.

No entries of relevance for the use of lead in the requested exemption could be identified in Annex XVII based on the product and component examples and information provided by the applicant. The exemption would thus not weaken the protection afforded by Annex XVII.

Cadmium

With regards to **Annex XIV of the REACH Regulation**, cadmium is not mentioned in the list of substances that require an **authorisation** for use.

*With regards to **Annex XVII of the REACH Regulation**, cadmium is mentioned in a few of the listed restrictions.*

Paragraph 1 of entry 23[209] of Annex XVII refers to cadmium and several of its compounds. Under this entry, several restrictions are mentioned for cadmium and the compounds, among others:

- *A list of various polymers in which Cd may not be used unless required in colour for safety reasons.*
- *Shall not be used for cadmium plating[210] metallic articles or components of articles used in equipment and machinery in certain branches and applications, e.g. cooling and freezing, food production, etc.*
- *Brazing fillers unless used for safety reasons*
- *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.*

The restriction in braze alloys does not cover articles that have already been brazed or are made by brazing outside of the EU. The applicant states that cadmium in pigments is used in applications only that are exempt from the REACH Regulation. Due to the multitude of possible uses in the scope of the exemption at hand, it cannot be guaranteed that no restrictions may apply. The applicant argues that restrictions for cadmium have been in

[208] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

[209] C.f. ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e2518

[210] 'Cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface

force for over 40 years and so no medical devices that are refurbished or parts that are recovered will contain cadmium in restricted forms.

Due to their carcinogenicity, entry 28[211] 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 exemption at hand does not imply their placing on the market or as constituents of other substances or mixtures. They are contained in articles (professional medical equipment).

Entry 72[212] lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It refers among others to cadmium and its compounds as listed under entry 28, 29 and 30 (germ cell mutagenic substances) and restricts their use in clothing and textiles. The entries list several cadmium compounds, among others cadmium sulphide and cadmium nitrate.

The use of cadmium does not imply use in clothing and textiles.

No entries of Annexes XIV and XVII could be identified that address the use of cadmium in the requested exemption based on the product and component examples and information provided by the applicant. The exemption would thus not weaken the protection afforded by Annex XVII.

Deca-BDE

Deca-BDE may occur but only in parts from medical devices. Manufacturers, importers or downstream users shall not place a substance listed on Annex XIV on the market for a use or use it themselves.[213] Deca-BDE is not listed on Annex XIV yet, but it is proposed for inclusion into Annex XIV. This inclusion would, however, not affect the uses of deca-BDE in the scope of the requested exemption. Only articles placed on the market before 21 July 2014 are reused in the EU, which is not related to the placing on the market or the use of deca-BDE.

Entry 67 of Annex XVII stipulates that deca-BDE[214] shall not be used in the production of, or placed on the market in, among others, articles and parts thereof in concentrations higher than 0.1 % by weight after 2 March 2019. This would in principle be applicable to the use of deca-BDE in the scope of this exemption. Paragraph 4(d) of entry 67 excludes, however, the placing on the market of deca-BDE in electrical and electronic equipment and parts thereof regulated under the RoHS Directive from the above stipulation. Entry 67 is thus not applicable to the exemption request at hand.

[211] 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

[212] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

[213] REACH Art. 56(1)

[214] C.f. EUR-Lex, https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1487145528686&uri=CELEX:32017R0227

No use of deca-BDE in the scope of the requested exemption could be identified in Annexes XIV and Annex XVII based on the product and component examples and information provided by the applicant. The exemption would thus not weaken the protection afforded by Annex XVII.

Hexavalent Chromium

According to COCIR (2020), hexavalent chromium is used in passivation coatings on metals and in pigments, e.g. in labels, etc. Annex XIV addresses hexavalent chromium in some compounds. Like for deca-BDE, these entries are not applicable to the uses in the scope of the requested exemptions as only previously made articles are reused in the EU. Entry 47 of REACH Annex XVII addresses chromium VI compounds, however, in cement and leather. This entry is thus not applicable to the uses of Cr-VI in the scope of the requested exemption.

No use of hexavalent chromium in the scope of the requested exemption could be identified in Annexes XIV and Annex XVII based on the product and component examples and information provided by the applicant. The exemption would thus not weaken the protection afforded by Annex XVII.

Conclusion

No cases could be identified where the exemption, if granted, would weaken the protection provided by the REACH regulation. Entries of Annex XIV were found not to be applicable due to the fact that no new parts are produced, but used parts are reused. Some entries of Annex XVII apply to the restricted substances in the scope of this requested exemption, but not to the specific uses of these substances in the requested exemption. This confirms the evaluation of former reviews of reuse-related requests by Gensch et al. (2013) and by (Gensch und Baron 2014).

Given the multitude of substances and compounds in the scope of the exemption, the large number and not exclusively defined different parts, and the fact that the REACH regulation may be amended in the coming years, it cannot be excluded that the protection provided by the REACH regulation might be weakened nevertheless in individual cases. The applicant then would have to address this situation with compliance measures. Overall, the exemption could be renewed under this condition.

17.4.2. Exemption 31(a) and RoHS Art. 4

RoHS Art. 4(4) provides that paragraph 1 – the substance restrictions - of that same Article *does not apply [215] to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:*

- *4(4)(b) medical devices placed on the market before 22 July 2014;*
- *4(4)(c) in-vitro diagnostic medical devices placed on the market before 22 July 2016;*

EEE of cat. 8 - which is in the scope of the requested exemption - placed on the market before 22 July 2014 and 22 July 2016 respectively can thus be repaired, reused, updated

[215] Art. 4(1): Member States shall ensure 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 (list of restricted substances).

or upgraded using spare parts that contain restricted substances listed on Annex II. Vice versa, the RoHS Directive does not allow these operations for devices placed on the market after the above deadlines, which is why exemption 31(a) is required to continue the reuse of recovered parts containing restricted substancs as spare parts for these devices.

RoHS Art. 4(5) stipulates that, *provided the reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of spare parts is notified to the consumer, paragraph 1* – the substance restrictions - *shall not apply to reused spare parts:*

- *4(5)(b) recovered from medical devices […] placed on the market before 22 July 2014 and used in EEE placed on the market before 22 July 2024;*
- *4(5)(c) recovered from in vitro diagnostic medical devices placed on the market before 22 July 2016 and used in EEE placed on the market before 22 July 2026.*

Parts for reuse can thus not be recovered from medical devices placed on the market after the above deadlines, and they cannot be reused in medical devices placed on the market after the above deadlines even if all other conditions are fulfilled. Without the requested exemption, the supply with and the reuse of used parts would thus be interrupted.

17.4.3. Scientific and technical practicability of substitution or elimination of Pb, Cd, $Cr6^+$ and deca-BDE

This exemption renewal request shall enable that spare parts containing the above RoHS-restricted substances recovered from and used for the repair or refurbishment of medical devices, including in-vitro diagnostic medical devices, or electron microscopes and their accessories. Substitution or elimination of these substances in these parts are therefore not relevant.

None of the substances requested for this exemption are used in newly produced equipment but are potentially present in parts recovered from old equipment. Substitution and elimination will happen automatically over time under this exemption as ever less and less new equipment containing the listed critical substances is approved, reducing the need for spare parts in the long term.

When asked how they guarantee, that no newly produced parts will enter this system, which contain critical substances under RoHS Directive 2011/65/EU. JBCE (2021) answered that *"New spare parts for medical devices are all manufactured complying with RoHS since 2014. Spare parts are part of the certification of the equipment, so the RoHS compliance is ensured by the CE marking, the Notified Body, etc. No OEM would ever have a parallel production line for non-RoHS parts as well as RoHS compliant parts as this would be simply inefficient and extremely costly […] The only non-RoHS compliant parts available on the market are the ones that had been first integrated within old products, sold before 2014."*

Since this exemption has been in place for years without obvious issues as to new, non-compliant parts entering the system, the consultants assume that the system has been sufficient to ensure compliance.

17.4.4. Environmental arguments and socioeconomic impacts

The applicant has provided detailed information on the broad range of environmental arguments including environmental, health and safety impacts as well as on socioeconomic impacts in a scenario where the exemption is not granted.

The applicants used four environmental assessments and a review report of the assessments to substantiate their argumentation.

(A) Comparison of impacts from equipment refurbishment versus new parts manufacture (qualitative evaluation)

(B) LCA for printed circuit board parts reuse versus new parts manufacture by Van Holsteijn en Kemna using EC Ecodesign methodology (qualitative evaluation)

(C) LCA for MRI and X-ray system refurbishment versus new parts manufacture by Gabriel I Zlamparet[216]

(D) LCA for X-ray tube assemblies

(E) Third-party verified assessment from RINA Consulting

The cited assessments are critically reviewed below.

(A)/(B) Qualitative environmental and socioeconomic assessments

The applicant explained in detail what impacts would occur in case of an expiry of exemption 31(a) without renewal. Negative impacts include additional environmental burdens from production of new parts, longer waiting times or poorer diagnostic capabilities for patients. The argumentation is well comprehensible.

The applicant has illustrated the additional environmental impacts with a rough calculation. *COCIR (2020) estimated that about 2,200 tonnes of parts and 1,000 tonnes of equipment (total 3,200 tonnes) are refurbished and then reused in the EU annually. In the next step, they assume that the 2,200 tons of parts consist entirely of PCBs, which they break down into 30 % of one or two layer boards, 40 % surface mount devices and 30 % ICs.* This assumption is simplified. COCIR themselves state that *the diversity of reused components is enormous and medical devices are made up of a wide variety of components. Most common recovered parts are MRI coils, printed circuit boards, (components of) detectors and X-ray tubes.* The estimated results of the calculation for CO_2 equivalents saved, heavy metals and waste are therefore purely hypothetical in order to get a feel for the order of magnitude. Additionally, as the EcoReport Tool uses the same data sets for re-used spare parts with potentially RoHS-restricted substances and new spare parts without these materials, the resulting impacts regarding toxicity potentials and amounts of hazardous waste is not reliable and neglecting the core change here.

COCIR (2020) summarized the environmental impacts of the exemption as follows: *"Since 2015, Europe has accepted the concept that reuse is always the best form of materials management. Reuse is number one in the waste hierarchy and so there is no need to prove the very basic concept of circular economy*[217]*."* The cited concept also demands additional measures to achieve a carbon-neutral, environmentally sustainable and toxic-free circular economy. There is no ranking of required actions. Toxic-free products are therefore also part of the EU circular economy and the RoHS Directive is a component of the

[216] Energy savings and environmental impacts of refurbishing medical devices approaching end-of-life: A case study of MRI and X-Ray scanners, Gabriel I Zlamparet et.al. Unpublished work, provided to the consultant

[217] European Parliament website on circular economy: http://www.europarl.europa.eu/news/en/headlines/economy/20151201STO05603/circular-economy-definition-importance-and-benefits

implementation. In the context of reuse in the scope of the requested exemption, the use of parts containing toxic substances may be justified also in the light of the Circular Economy. The parts are already produced and alternatively would become waste while their reuse enables another useful life without increasing the total environmental burden from these toxic substances.

COCIR (2020) raise the argument that *substitutions of the regulated RoHS substances do not necessarily result in a better environmental assessment because the substitutes may also be harmful.* No evidence is provided for this statement.

COCIR (2020) cite safety risks from outdated medical equipment as argument. This can also be considered a general argument against medical device repair, as *"the reliability and diagnostic and treatment performance is usually proportional to the age of the equipment".*

(C), (D) Quantitative environmental assessments

The "comparative LCA" for X-ray tubes illustrates the savings potentials exploited through the reuse of used parts. Two manufacturers have calculated the energy consumption for manufacture of:

- *new housings made of aluminium alloy and*
- *new X-ray tube assemblies that include the same size of aluminium housing.*

Table 17-6 shows the results of a calculation for the energy and new materials consumption with and without an exemption. In addition, the data and calculations of the two manufacturers are subject to confidentiality and cannot be verified in detail. Efficiency gains from new technologies are not considered here. Production of virgin aluminium from bauxite ore is very energy intensive. However, the use of secondary raw materials from recycling would also require significantly more resources than the direct reuse of aluminium housings. In the view of the consultant, the facts are clear and sufficiently substantiated despite the lack of described background data.

The LCA performed in (Zlamparet und Li) is comprehensive and well reasoned, but only a few excerpts of the unpublished paper were cited in the public exemption request. Accordingly, they cannot be used to justify this exemption.

17.4.5. 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.

This exemption renewal request shall enable that spare parts containing the above RoHS-restricted substances recovered from and used for the repair or refurbishment of medical devices, including in-vitro diagnostic medical devices, or electron microscopes and their

accessories. Substitution or elimination of these substances and the reliability of substitutes in these parts are therefore not relevant. RoHS Art. 4 provides for the use of spare parts containing restricted substances for *medical devices placed on the market before 22 July 2014 and in-vitro diagnostic medical devices placed on the market before 22 July 2016. The requested exemption at hands enables the continued use of such spare parts in medical devices placed on the market after the above deadlines.*

COCIR's arguments are considered valid and well supported, but there are some notable technical weaknesses in the environmental assessments submitted.

The third party evaluation report (Goodman et al. 2019) is based on the statement that a comprehensive LCA for the exemption is impossible because of the very large variety of recovered parts and missing numbers of quantities of each type of part. Instead, illustrative examples shall demonstrate the fundamental advantages. (Goodman et al. 2019) conclude that *"the difference in impacts arising from the two scenarios is so large that this conclusion would be the same irrespective of data accuracy."* The consultants can follow this line of argument, but nevertheless point out the technical weaknesses of individual environmental assessments. The qualitative argumentation in the original exemption renewal form is conclusive, but the rough calculation used has little significance. The assumptions made are arbitrary and probably too high. The quantitative environmental assessments are understandable and support the justification for the requested exemption.

The studies listed do not comply with ISO 14040 and 14044. In particular, the information and calculations in the renewal form are more akin to a mitigation of potential environmental impacts than an LCA. Additionally, all presented environmental assessment only compare repair with re-used spare parts compared to new spare parts. They neglect to analyse if repair is beneficial in all cases as extending the use time might delay the implementation of more energy efficient technologies and therefore increase the overall energy consumption of the overall product stock.

COCIR (2020) described in detail that *"Parts collected from used equipment have already been manufactured and so any health or environmental impacts have already occurred* [as long as there are no health risk during the use of the products, which is not the case for the addressed products, the consultants]. *If the parts cannot be reused, they will reach end of life prematurely and new parts will have to be manufactured as replacements and this will have a negative environmental and health impact. Manufacture of new parts will consume energy, use natural resources and create emissions and waste."*

Supporting environmental arguments of this request, the information provided by the applicant referring to environmental impacts and data comparing LCA of new and refurbished equipment are comprehensive and detailed. From the consultants' perspective, the reasons why not granting the exemption would lead to negative environmental impacts have been well clarified and supported with robust evidence. As for the socioeconomic impacts in a scenario without the exemption, the applicant described the negative impacts derived from longer downtimes on treatments due to delays in availability of spare parts. The consultants understand that the reuse and refurbishment of parts adds to the availability of spare parts in particular in the current – and maybe future - situations where due to the global pandemic and geopolitical situation global supply chains were not as reliable as they used to be. Reuse of recoved parts may contribute under such conditions to avoid or bridging the time to purchases of new equipment whose delivery may be delayed for longer periods of time.

The electron microscopes were removed from the text of the exemption wording with the applicant's agreement. The renewal of the exemption with the modified scope was only requested for cat. 8 medical devices including in-vitro diagnostic medical devices. Electron microscopes fall into cat. 9 EEE and thus are not in the scope of the renewed exemption.

Overall, from the consultant's perspective, it can be followed that the use of recovered parts in medical devices can be deemed as a beneficial practice. Therefore, in the light of the information presented in this report, the consultants conclude that the renewal of this exemption request with the modified scope is justified as the total negative environmental impacts caused by substitution of newly produced spare parts are likely to outweigh the total environmental, health and consumer safety benefits thereof (third point, Article 5(1)(a)).

17.5. Recommendation

COCIR's arguments are considered relevant and well supported, the requested exemption would be justified by Art. 5(1)(a) because the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

In the absence of a renewal request for cat. 9 electron microscopes and their accessories, the current exemption 31(a) remains valid for these devices. For cat. 8 medical devices incl. in-vitro diagnostic medical devices, the consultants recommend renewing the exemption for the maximum validity period as requested with the following wording:

	Exemption	Scope and dates of applicability
31(a)	*Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer*	Expires on - 21 July 2021 for cat. 8 medical devices including in-vitro diagnostic medical devices - 21 July 2024 in cat. 9 industrial monitoring and control instruments, i.e. electron microscopes and their accessories.
31(b)	*Lead, cadmium, hexavalent chromium, and deca-brominated diphenyl ethers (deca-BDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in-vitro diagnostic medical devices, provided that* - *the reuse takes place in auditable closed-loop business-to-business return systems;* - *that each reuse of parts is notified to the customer; and* - *that the reuse does not weaken the environmental and health protection afforded by regulation (EC) No 1907/2006.*	Expires on 21 July 2028 for cat. 8 medical devices including in-vitro diagnostic medical devices

The consultants recommend to add the section with reference to regulation (EC) No 1907/2006 (REACH regulation) although, based on the product and component examples and information provided by the applicant as to the applications in the scope of the requested exemption, the consultants could not identify any entries on Annexes XIV and XVII of this regulation that would weaken the protection provided by the REACH regulation. The list of product examples is, however, not exclusive, and the REACH regulation may be amended in the coming seven years. Given the large number of restricted substances and their compounds in the scope of the exemption, the consultants cannot exclude that the exemption might weaken the protection provided by the REACH regulation in individual cases.

17.6. References

COCIR (2020): Request for renewal of exemption 31a of RoHS Annex IV. Online verfügbar unter http://www.rohs.biois.eu/Ex_31a-IV_COCIR_Renewal-Request.pdf.

COCIR (2021): Answers to questionnaire 3 for ex. IV-31(a).

Gensch, C.; Baron, Y. (2014): Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance restrictions in Electrical and Electronic Equipment (RoHS Directive). Online verfügbar unter https://www.oeko.de//oekodoc/2131/2014-685-en.pdf.

Gensch et al. (30 September 2013b): Assistance to the Commission on Technological, Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance Restrictions in Electrical and Electronic Equipment (RoHS Directive). Report for the European Commission DG Environment under Framework Contract No ENV.C.2/FRA/2011/0020, 2013. Final Report. Unter Mitarbeit von Carl-Otto Gensch, Yifaat Baron, Markus Blepp, Andreas Manhart, Katja Moch (Öko-Institut) und Fraunhofer IZM (Otmar Deubzer). Hg. v. Öko-Institut Freiburg e.V. Freiburg (Adaptation to Scientific and Technical Progress of Annexes III and IV of Directive 2011/65/EU, RoHS VII).

Gensch et al. (2013): Assistance to the Commission on Technological, Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance Restrictions in Electrical and Electronic Equipment (RoHS Directive). Report for the European Commission DG Environment under Framework Contract No ENV.C.2/FRA/2011/0020, 2013. Final Report. Unter Mitarbeit von Carl-Otto Gensch, Yifaat Baron, Markus Blepp, Andreas Manhart, Katja Moch (Öko-Institut) und Fraunhofer IZM (Otmar Deubzer). Hg. v. Öko-Institut Freiburg e.V. Freiburg (Adaptation to Scientific and Technical Progress of Annexes III and IV of Directive 2011/65/EU, RoHS VI Pack1). Online verfügbar unter https://circabc.europa.eu/ui/group/4a348b1c-a501-42a5-a278-6954ef1d1855/library/367d39cc-3608-4af1-b89b-c46a507384b1/details.

Gensch et al. (2020): Study to assess three (3) exemption requests relating to Annex IV to Directive 2011/65/EU: request for amendment of existing exemption 31a; request for a new exemption for bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids; and request for a new exemption for DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils(Pack 17) – 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 22. Unter Mitarbeit von Carl-Otto Gensch, Yifaat Baron, Moch, Katja, Öko-Institut e. V. und Dr. Deubzer, Otmar,

Fraunhofer IZM. Online verfügbar unter https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/RoHS_Pack-17_final-final_May_2020.pdf.

Goodman, Paul; Tyrwhitt Jones, Emily; Robertson, Chris (2019): RoHS exemption 31a. Assessment of life cycle assessment on the reuse of recovered parts containing RoHS substances. Report No. 2019-0688, Project No. REG0364001. RINA Consulting Ltd.

JBCE (2021): Answers to questionnaire 1, ex. IV-39, received from Takuro Koide, JBCE, via e-mail by Dr. Otmar Deubzer, Fraunhofer IZM.

Kemna, René; Azaïs, Nelly; Elburg, Martijn van; Voort, Maaike van der; Li, William (2011): MEErP 2011. Methodology for Ecodesign of Energy-related Products (Part 1). Prepared for the European Commission, DG Enterprise and Industry, Unit B1 Sustainable Industrial Policy, under specific contract SI2.581529. COWI Belgium sprl, Van Holsteijn en Kemna B.V. (VHK).

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

RoHS Directive 2002/95/EC (2003): Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. RoHS 1. RoHS 1, zuletzt aktualisiert am 13.02.2003, zuletzt geprüft am 04.12.2013.

RoHS Directive 2011/65/EU (2011): 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 (recast). RoHS 2. European Union. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065.

Zlamparet, Gabriel I.; Li, Jinhui: Energy savings and environmental impacts of refurbishing medical devices approaching end-of-life: A case study of MRI and X-Ray scanners. unpublished manuscript draft. Tsinghua University. Beijing, China.

18. Exemption 39 of Annex IV: Lead in MCPs

Complete wording of the current exemption:

Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is present:

(a) a compact size of the detector for electrons or ions, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable;

(b) a two-dimensional spatial resolution for detecting electrons or ions, where at least one of the following applies:

(I) a response time shorter than 25 ns;

(II) a sample detection area larger than 149 mm^2;

(III) a multiplication factor larger than $1,3 \times 10^3$.

(c) a response time shorter than 5 ns for detecting electrons or ions;

(d) a sample detection area larger than 314 mm^2 for detecting electrons or ions;

(e) a multiplication factor larger than $4,0 \times 10^7$.

Expires on 21 July 2021 for medical devices of category 8 other than in-vitro diagnostics, and for category 9 other than industrial monitoring and control instruments; on 21 July 2023 for in-vitro diagnostic medical devices, and on 21 July 2024 for industrial monitoring and control instruments.

Declaration

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

Information taken from applicants’ documents is displayed in italics in all sections to enable its differentiation from the consultants’ comments and arguments.

Acronyms and Definitions

ALD	atomic layer deposition
COM	European Commission
MCP	microchannel plate
Pb	lead

18.1. Background and Technical Information

JBCE et al. (2020) submitted a request the renewal and amendment of the above exemption until the end of 2026 for EEE of cat. 8 medical devices including in-vitro diagnostic medical devices and 9 monitoring and control instruments including industrial monitoring and control instruments with the following wording (amendments underlined):

Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is present:

(a) a compact size of the detector for ionising radiations, *electrons or ions, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable;*

(b) a two-dimensional spatial resolution for detecting ionising radiations *electrons or ions, where at least one of the following applies:*

(I) a response time shorter than 25 ns;

(II) a sample detection area larger than 149 mm^2;

(III) a multiplication factor larger than $1,3 \times 10^3$.

(c) a response time shorter than 5 ns for detecting ionising radiations, *electrons or ions;*

(d) a sample detection area larger than 314 mm^2 for detecting ionising radiations, *electrons or ions;*

(e) a multiplication factor larger than $4,0 \times 10^7$ for detecting UV, ionising radiations, electrons, or ions*.*

JBCE et al. (2020) justify the amendment stating that Annex IV has two kinds of exemptions for MCPs, namely exemptions 3 and 39. Exemption 3 (Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate) is an exemption for detecting ionising radiation, exemption 39 for detecting electrons and ions. The MCPs used for applications under both exemptions are identical so that JBCE et al. (2020) believe that only one exemption is needed to cover all uses and proposes merging exemptions 3 and 39. JBCE (2021a) state that they do not require the exemption for capillary plates.

18.1.1. Summary of the requested exemption

JBCE et al. (2020) summarize their exemption request as follows:

"This exemption is required to enable the use of lead contained in micro-channel plates (MCP), which are devices that detect ionizing radiation, electrons, ions or Ultraviolet light. Microchannel plates are installed in equipment such as mass spectrometry, semiconductor inspection, surface analysis, etc., and the equipment are used in various fields such as medicine, measurement, analysis, and academic research.

Lead-free MCPs are currently in the stage of trial production / testing. JBCE predicts that the MCPs mentioned above can be replaced by lead-free MCPs by the end of 2026. We apply for renewal of the exemptions 3 and 39 for MCP to be valid until that time."

18.1.2. History of the Exemption

Goodman (2006) recommended an exemption for lead in MCPs for categories 8 and 9 with the following wording:

Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate

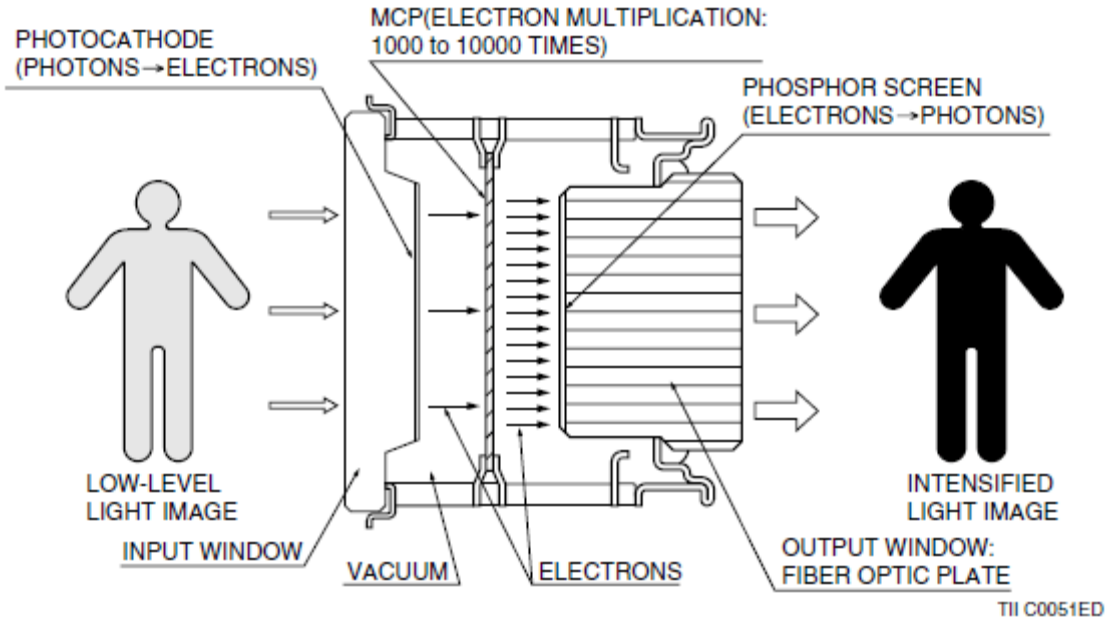
The European Commission (COM) adopted the exemption proposed above as no. 3 of Annex IV in the (Directive 2011/65/EU). The scope of the exemption is restricted to "Equipment utilising or detecting ionising radiation" of categories 8 and 9.

JBCE (2012) applied for a new exemption for the use of "Lead in microchannel plates" reasoning that exemption 3 does not cover MCPs used in equipment detecting ions and/or electrons. Such equipment, among others, are used in mass spectrometers, semiconductor inspections and surface analysis. Gensch et al. (2013) recommended to grant the exemption with a specified scope. The COM followed this recommendation and added exemption 39 to Annex IV with the current wording. JBCE et al. (2020) request the renewal of the exemption as described above.

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

JBCE et al. (2020) describe the functional principle of MCP in the below Figure 18-1.

Figure 18-1: Structure and operating principle of MCPs illustrated by an image intensifier example



Source: JBCE et al. (2020)

MCPs amplify signals generated by incoming ionizing radiation, ions and electrons so that low intensity radiations and particles in low concentration can be either detected or used to

generate amplified signals, e.g. for example with image intensifiers used in night vision devices as depicted in the above figure.

More detailed technical information is available in the exemption request of JBCE et al. (2020) and in the report prepared by Gensch et al. (2013)[218].

18.1.4. Amount of lead used under the exemption

According to JBCE et al. (2020), lead is used in glass of MCPs with a share of 45 % to 50 % (weight). The amount of lead used under the exemption is around 2.5 kg. JBCE et al. (2020) state that they provided data for the total amount of lead in the previous consultation, and the report prepared by Gensch et al. (2013) shows that it was 2.5k g per year from Hamamatsu photonics to EU market. JBCE et al. (2020) say that the amount of lead could be different because sales fluctuate every year, but that there are no big annual differences so that they think it is reasonable to expect the same quantity this time.

JBCE et al. (2020) did not provide data for the total lead use under exemption 39. In their 2012 exemption request, JBCE (2012) had indicated around 100 kg of lead worldwide, from which 19 kg would be placed on the EU market in devices applying MCPs. Following JBCE et al. (2020) that the volumes fluctuate but without big annual differences, it is assumed that these amounts still sufficiently reflect the current situation.

18.2. Applicant's justification for the requested exemption

18.2.1. Overlapping scopes of exemptions 3 and 39 for MCPs

JBCE et al. (2020) state that Annex IV has two exemptions for micro-channel plates, no.3 and no.39. No.3 is an exemption for detecting ionising radiation, no.39 for detecting electrons and ions. The original exemption list of Annex IV did not include exemption 39. Therefore, JBCE submitted a request for a new exemption of MCP in 2012 and as a result, exemption No.39 was granted. This is the reason why Annex IV has two kinds of MCP exemptions. As the MCP used for applications of both exemptions 3 and 39 are identical, JBCE believe that only one exemption is needed to cover all uses and propose to merge exemptions 3 and 39.

JBCE et al. (2020) summarise the details of their request:

- *Request for amendment of Annex IV-39*
- *Request for extension of scope of Annex IV-39*
- *Request for deletion of Annex IV-3 if included in Annex IV-39*

[218] P.145 ff. - 13.0 Exemption Request No. 10 "Lead in micro-channel plates"

18.2.2. Overlapping scopes of exemptions IV-39 and III-7(c)-I

JBCE et al. (2020) assert that 7(c)-I of Annex III does not cover lead-MCPs. They refer to Goodman (2006) who concluded that an exemption would not be required if MCPs are defined as electronic components using the exemption which is exemption 7(c)-I in the current RoHS Directive. Consequently, the COM established the exemption for lead-MCPs presumably as it agreed that 7(c)-I was not applicable to MCPs. Moreover, JBCE (2012), when applying for the new exemption for lead-MCPs (now exemption 39), had received the question why MCPs are not covered by 7(c)-I of Annex III whereupon JBCE (2012) explained the background and their assertion. Gensch et al. (2013) asked Photonis, a manufacturer of MCPs based in Europe, if the new exemption is necessary or not and Photonis supported the new exemption, c.f. Gensch et al. (2013). For these reasons, JBCE et al. (2020) understood that lead-MCPs are NOT covered by 7(c)-I of Annex III or other existing exemptions besides exemptions IV-3 and IV-39.

18.2.3. Other MCP manufacturers

JBCE et al. (2020) state that in the previous consultation report, it is written Gensch et al. (2013) mention other manufacturers of lead contained MCPs other than Hamamatsu Photonics, i.e. are Photonis (USA, France), Litton (USA), Baspik (Russia), and Great Wall (China). Currently, Incom（USA）is a manufacturer of lead-free MCPs. Their MCPs have potential to replace lead-based MCP but there is insufficient data to determine if it is able to be a substitute technology so far.

18.2.4. Elimination of lead

JBCE et al. (2020) present alternative technologies for the detection of ionising radiation, electrons and/or ions. These technologies were described in detail in the report of Gensch et al. (2013) for the review of the original 2012 exemption request. Additionally to the technical details of these detectors, JBCE et al. (2020) present a summary of their properties and compare them with MCPs in the scope of exemption 39 as illustrated in the below table.

Table 18-1: Comparison of MCPs in the scope of exemption 39 with potential alternative detectors7

Sections of Exemption 39	a	b-I and c (ns)	b-II mm²	b-III and e
Criteria in Sections of Exemption 39	≤3 mm/MCP	<25 < 5	>149 >314	>1.3x10^3 >4 x 10^7

Detector	Detectable input	Dimensions of spatial input signal resolu-tion	Thickness (mm)	Response time (ns) (*1)	Detection area (mm2)	Multiplica-tion factor per detector (*2)	Possi-bility of stacking
MCP	• Ionising radiation • UV light • Electrons • Ions	1 and 2	0.2–1.0 2.0 on special order	≥ 0.2	50–10,000	10^3–10^8	Up to 3 MCPs
EMT	• Electrons • Ions	1	60–150	≥ 5	48–314	5.0 x 10^5 to 4.0 x 10^7	no
PD	• UV light • Visible light • Near infrared light	1	≥ 1.5	≥ 0.2	0.01 - 1,000	≤ 50	no
PD	• Specified for UV light	1	1.65–4.9	≥ 0.4	0.03–100	≤ 50	no
PD-EBCCD [382]	• Electrons • UV light	1 and 2	16.8	≥ 25	63–149	7.0 x 10^2 to 1.3 x 10^3	no
PMT	• UV light	1	18.2–127	≥ 3.27	50–2,123	1.6 x 10^5 to 1.9 x 10^7	no

Source: JBCE et al. (2020) (Note: the correlations to the sections of exemption 39 on top of the table were added by the consultants)

JBCE et al. (2020) point out that in the previous consultation for MCPs by Gensch et al. (2013) the recommended wording adopted by the COM excluded certain properties which other detectors can cover. JBCE et al. (2020) conclude that MCPs have unique properties which other detectors cannot replicate.

18.2.5. Substitution of lead

JBCE et al. (2020) claim that lead glass, which contains PbO, is essential to produce MCPs. The PbO is chemically stable material in the glass and is not replaceable with other material. Such glass had been used as "crystal glass" in the past for craft products. Adding PbO to glass lowers the melting temperature and molding is easier compared to other glasses. These features are required for fine processing structures like MCP with capillary diameters between few and tens of micrometres. Quartz, which is another glass material (which does not contain lead), is unable to be used to manufacture MCP because it only allows a short time treatment at high temperatures which would not be long enough to allow the formation of fine capillaries required for MCP. The below table illustrates the situation.

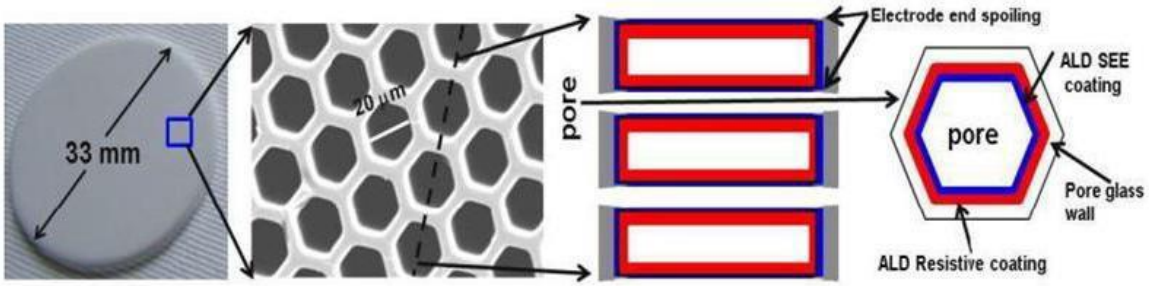
Table 18-2: Typical properties of Quartz glass and Lead glass

	Quartz glass	Lead glass
Softening temperature	1,580 °C	600 °C
Thermal expansion coefficient	0.55×10^{-6}	9.0×10^{-6}

Source: JBCE et al. (2020)

JBCE et al. (2020) say that atomic layer deposition (ALD) for coating channels with a conductive layer has been considered as a potential alternative method to manufacture lead-free MCPs. ALD is a thin-film deposition technique based on the sequential use of a gas phase chemical process; it is a subclass of chemical vapour deposition.219 The secondary emission electron layer applied in the glass micro-channels (pores) by atomic layer deposition takes over the function of generating electrons from ionizing inputs. Neither leaded glass nor any other RoHS-restricted substance is required. Figure 18-2 gives an overview on the production and the construction of an ALD-MCP.

Figure 18-2: ALD-MCP



Source: JBCE et al. (2020)

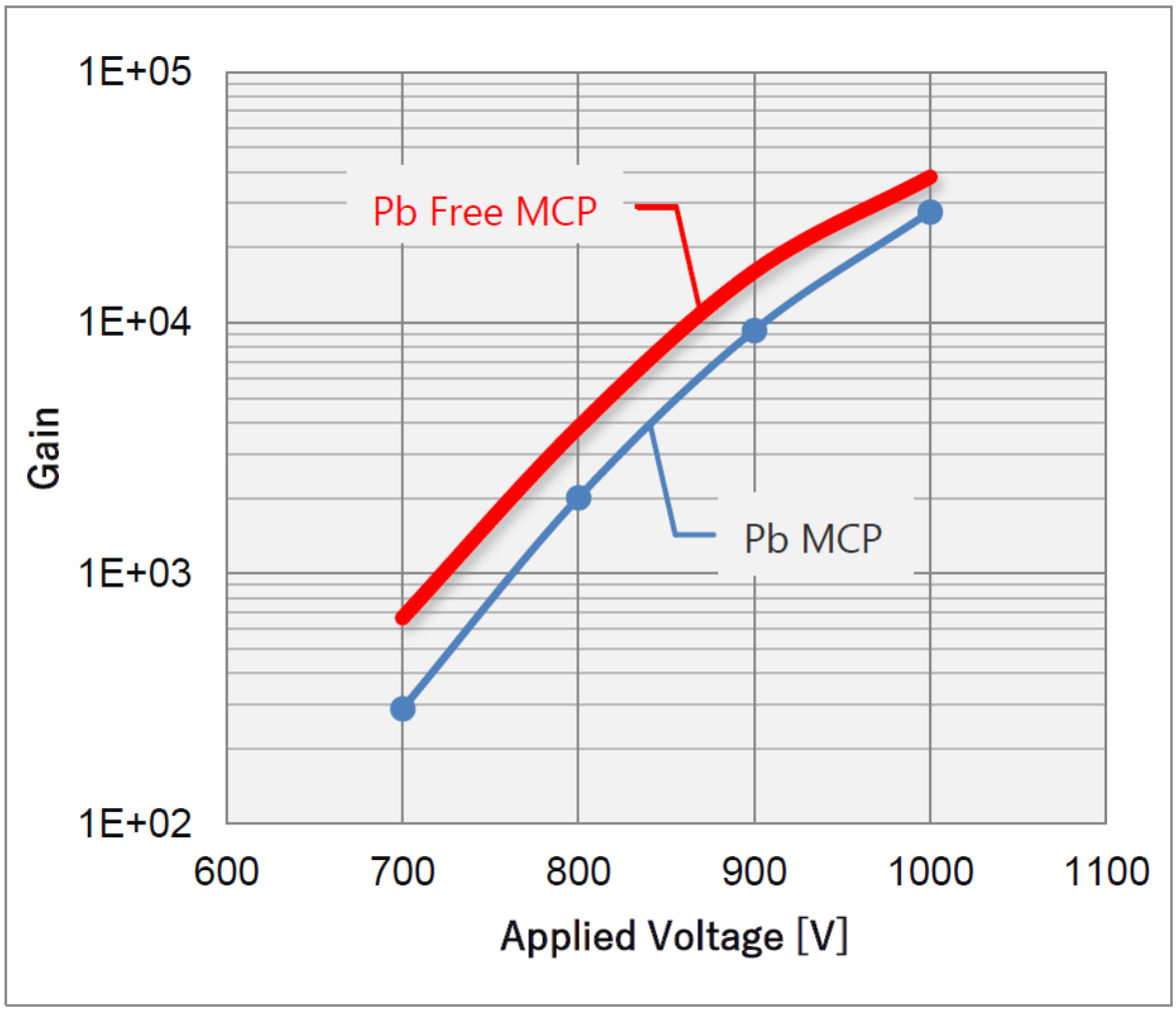
SEE: Secondary electron emission

JBCE et al. (2020) put forward that Gensch et al. (2013) agreed the claim of JBCE (2012) that ALD-MCP could not yet be considered as an alternative technology because channel diameters or detecting inputs were still very limited at that time.

JBCE et al. (2020) report that Hamamatsu Photonics produced a prototype ALD-MCP in 2018 with capillaries made from lead-free glass and without other RoHS-restricted substances. Figure 18-3 shows that lead-free MCP performance is better than lead-based MCP regarding the gain[220].

[219] Footage showing the basic form of ALD: https://www.youtube.com/watch?v=uCK7-lw4iHM; source as referenced by JBCE et al. 2020.
[220] Generally, the "gain" is the amplification of the input signal (JBCE et al. 2020).

Figure 18-3: Typical gain characteristic of a single MCP



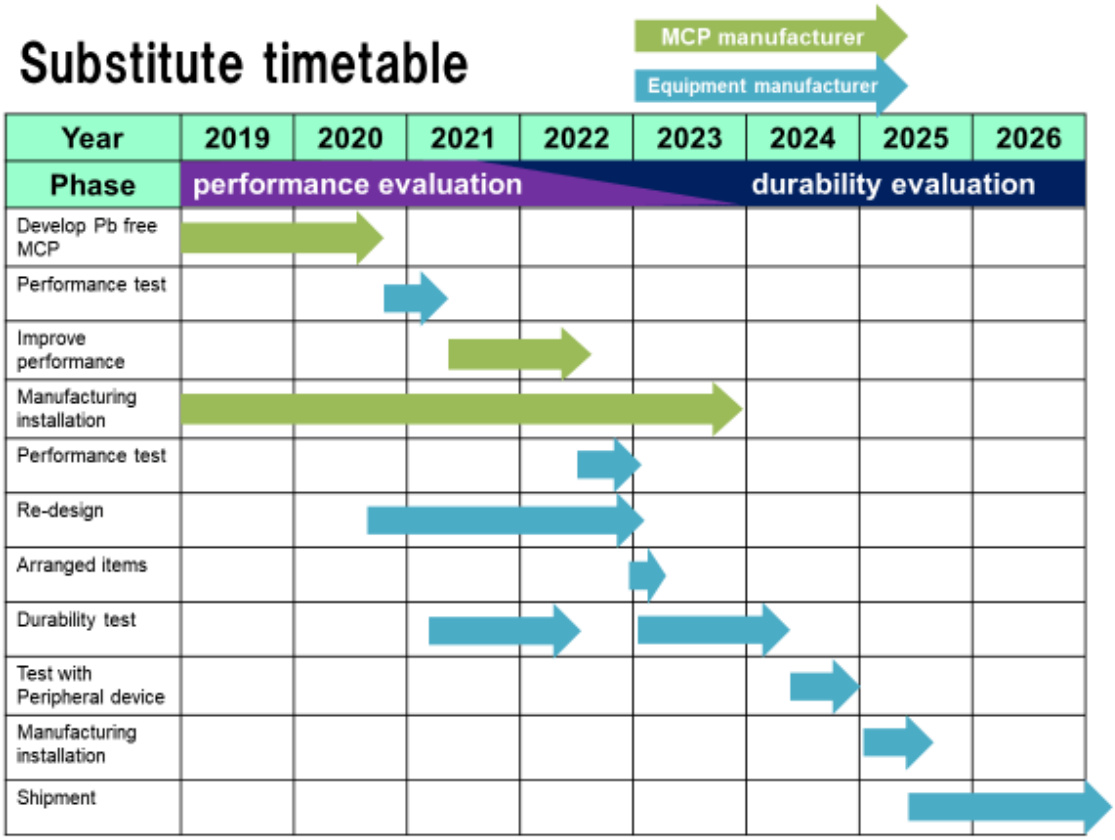
Source: JBCE et al. (2020)

JBCE et al. (2020) indicate that Hamamatsu photonics has provided prototypes of lead-free ALD-MCPs to equipment manufacturers since 2019 who have been testing their equipment with lead-free ALD-MCPs. The in-service data is currently being compiled by end-users and therefore is not yet available as further R&D is needed. This research is continuing and is expected to last until 2025, due to the requirement for additional testing.

18.2.6. Roadmap towards substitution or elimination lead in MCPs

Table 18-3 specifies the steps to be taken until 2026 when, according to JBCE et al. (2020), the amended exemption 39 could be revoked.

Table 18-3: Roadmap towards the substitution of lead in MCPs



Source: JBCE et al. (2020)

JBCE et al. (2020) provide further details and background of the above roadmap. MCP manufacturer Hamamatsu Photonics and equipment manufacturers plan the performance evaluation from 2019 to 2023 and durability evaluation from 2021 to 2026. The durability evaluation can only start after the results of the performance test have been evaluated due to the requirement to redesign the equipment using the ALD-MCPs before these reliability tests can start.

JBCE et al. (2020) explain that, after having developed a lead-free ALD-MCP, the MCP manufacturer improves the ALD-MCP based on the feedback from equipment manufacturers. MCPs have a variety of shapes and it is expected that it will take five years to establish the manufacturing installation for all kinds of MCPs. The equipment manufacturers will undertake the validation of their equipment twice before they complete the re-design of the equipment. Moreover, they test and collect data for the functioning of the equipment operating with ALD-MCPs in combination with peripheral equipment and establish the manufacturing installation for the new equipment. In parallel, they evaluate the durability of the equipment.

JBCE et al. (2020) conclude that the fastest shipment of equipment with ALD-MCPs could be in late 2025 as indicated in the above Table 18-3 if all tests are successful. The market launch may, however, be delayed due to the requirement to gain a suitable amount of reliability data before products can be updated. This depends on the results of the durability evaluation, which is particularly important for long life items of the equipment using ALD-MCPs. This substitute strategy is based on simple replacement of MCPs inside equipment.

It will take more years to complete the substitution if it is necessary to re-design entire equipment after thorough testing of the lead-free ALD-MCPs.

18.2.7. Environmental arguments and socioeconomic impacts

JBCE et al. (2020) are afraid that, if this exemption is not renewed, EU researchers, semiconductor manufacturers, etc., will not have access to the advanced instruments that rely upon MCP and so will be at a significant competitive disadvantage compared with their non-EU counterparts.

The applicant did not provide environmental or further socioeconomic arguments to justify the exemption request.

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 criteria: 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.

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV as an element. The fact that lead is a candidate substance therefore at the time being does not weaken the "*environmental and health protection afforded by*" the REACH Regulation.

REACH Annex XIV (2021) lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- *Lead chromate;*
- *Lead chromate molybdate sulphate red;*
- *Lead sulfochromate yellow;*

According to JBCE (2021c), none of the above substances are either added to MCPs or contained in MCPs. A renewal of the requested exemption would not weaken the protection afforded by the listing of substances on the REACH Authorisation list (Annex XIV).

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16[221] and entry 17[222] restrict the use of lead carbonates and lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds[223] such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*
- *Entry 28[224] addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 30[225] addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *Entry 63[226] restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72[227] stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

The exemption for lead in solders used 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, the use of lead in solders in the scope of the requested exemption is not a supply of lead compounds as a substance, mixture or constituent of other mixtures to the general public.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status September 2020). Based on the current status of

[221] 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

[222] 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

[223] 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

[224] 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

[225] 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

[226] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[227] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

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.

18.3.2. Scientific and technical practicability of substitution or elimination of lead

Substitution and elimination of lead

The use of lead in MCPs will become obsolete with the ALD-technology. A further reduction of lead in the current technology is technically not feasible since the glass composition defines the MCP properties in the scope of the new exemption 39. (INCOM 2021)already offer ALD-MCPs. Photonis (2021), another MCP manufacturer, confirm that the exemption is still required until end of 2026 as requested by JBCE mainly due to the need to integrate the ALD-MCPs into the various devices and to test their reliability as JBCE point out in their exemption request. Incom's lead-free microchannel plates with the performance and conditions of lead-containing MCPs in the scope of exemption 39 currently do not cover all the specifications of pore size and imaging quality that are available in the lead oxide MCP technology market and which are required for some applications. INCOM (2021) have a "baseline" MCP product available in 10 µm and 20 µm pores size, in various different sizes and shapes, ranging from 25 mm OD (20 mm dia. = 314 mm^2 active area) to 203 mm x 203 mm square (195 mm sq. = 38.025 mm^2 active area) size. They are currently working with early adopter customers to qualify and evaluate the ALD-MCP technology for a variety of applications, but the technology is not fully market-ready at this point in time. INCOM (2021) support the renewal of the exemption until 2026.

The elimination of lead by detectors others than MCPs was assessed in 2013 with the result that the scope of exemption 39 was restricted to those area where MCPs offer unique properties and combinations thereof which alternative detectors cannot offer due to their physical, geometric and electrical/electronic properties. Table 18-1 on page 418 provides the information which justifies the renewal of the exemption with the current scope concerning the properties listed under the subclauses 39 (a) to 39 (e).

The information presented by the stakeholders is plausible and coincides. The consultants therefore conclude that the substitution and elimination of lead are scientifically and technically practicable at least partially, but that further research is still required in some cases of MCPs, and finally more time is required until 2026 to ensure the reliability of the ALD-MCPs in the devices into which they are integrated.

18.3.3. Scope and wording of the exemption IV-39

One objective of the exemption request is that MCPs in future will only be covered by ex. 39, i.e. they should be removed from exemption 3 to the revised exemption 39. JBCE et al. (2020) therefore proposed the following amended wording for the renewed exemption 39 (the proposed changes are underlined):

Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is present:

(a) a compact size of the detector for <u>ionising radiations,</u> *electrons or ions, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative*

design yielding more space for the detector is scientifically and technically impracticable;

(b) a two-dimensional spatial resolution for detecting ionising radiations *electrons or ions, where at least one of the following applies:*

(i) a response time shorter than 25 ns;

(ii) a sample detection area larger than 149 mm^2;

(iii) a multiplication factor larger than 1,3 × 10^3.

(c) a response time shorter than 5 ns for detecting ionising radiations, *electrons or ions;*

(d) a sample detection area larger than 314 mm^2 for detecting ionising radiations, *electrons or ions;*

(e) a multiplication factor larger than 4,0 × 10^7 for detecting UV, ionising radiations, electrons, or ions.

JBCE (2021a) agreed to simplify the wording by adding the objects to be detected to the first paragraph (Lead in micro-channel plates …) and delete it in all subclauses. The UV radiation was removed completely since it is fully covered for the purpose of the MCPs by the term "ionising radiation".

To ensure that the exemption scope actually covers equipment for amplification as addressed in the current exemption 3, e.g. an image intensifier used in night vision devices (c.f. Figure 18-1 on page 415), as well as those for detection e.g. in analytical instruments, JBCE (2021b) agreed to integrate both functionalities into the exemption wording resulting in the following formulation for the amended exemption 39:

Lead in micro-channel plates (MCPs) used in equipment ***for the amplification or detection of ionising radiation, electrons or ions,*** *where at least one of the following properties is present:*

(a) a compact size of the detector, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable;

(b) a two-dimensional spatial resolution, where at least one of the following applies:

(i) a response time shorter than 25 ns;

(ii) a sample detection area larger than 149 mm^2;

(iii) a multiplication factor larger than 1,3 × 10^3.

(c) a response time shorter than 5 ns;

(d) a sample detection area larger than 314 mm^2;

(e) a multiplication factor larger than 4,0 × 10^7.

Exclusion of MCPs from the scope of exemption IV-3 and III-7(c)-I

As the above revised wording for exemption 39 includes the MCPs in the scope of exemption 3, the MCPs could be removed from the scope of exemption IV-3 as initiated by

JBCE et al. (2020). They say that the MCPs in the scopes of exemptions 3 and 39 are technically identical. The transfer of these MCPs from exemption 3 to exemption 39 thus technically does not include any scope restriction or partial revocation for MCPs compared to the current exemption 3, Art. 5(6) would not be applicable and a transition period would thus not be required. Purely formally, this shift could nevertheless be interpreted as a scope restriction since the restrictions of exemption 39 now also apply to the MCPs in the scope of the current exemption 3. Even though technically not required, the Commission might still consider to use this formal aspect to grant a certain transition period to give suppliers and producers sufficient time to adapt their documentation accordingly. As compensation for this initial additional administrative burden, suppliers and producers will only have to administrate one exemption for MCPs also beyond 2026, when the exemption would remain valid for recovered spare parts for MCPs placed on the market prior to 2027.

Concerning potential overlaps of exemption IV-39 with exemption III-7(c)-I, JBCE et al. (2020) claim that MCPs are not covered by exemption 7(c)-I. They base their statement on the following aspects:

- Goodman (2006) stated MCPs are electrical components which may be covered by exemption 5 – which is comparable to the current exemption III-7(c)-I - so that a specific exemption for lead in MCPs may not be required.
- The COM had adopted exemption IV-3 for MCPs when (Directive 2011/65/EU) was published, and the COM granted the additional exemption IV-39 for MCPs following the recommendation of Gensch et al. (2013)

Even though the applicants' above reasoning can be followed, it is not known on which grounds exactly the COM originally granted exemption 3 for MCPs. The COM might consider whether it is still appropriate to further clarify the situation and exclude the scope of exemption IV-39 from the scope of exemption III-7(c)-I, in particular with view to the expiry of exemption 39 in 2026 if the COM grants the exemption requested by JBCE et al. (2020). This would close a potential loophole and create definite clarity for the industry and its suppliers.

Impact of JBCE's exemption request on exemption IV-3

The exemption request of JBCE et al. (2020) also addresses exemption IV-3, but the exact intention was not completely clear. *They state that they apply for renewal of the exemptions 3 and 39 for MCP, but also "request the deletion of exemption IV-3". JBCE (2021b) clarified that they had applied for the deletion of exemption 3 because they want merge exemptions 3 and 39. Exemption 3 currently includes, however, also capillary plates besides MCPs, which are not addressed in JBCE's exemption request. JBCE (2021b) "[…] believes exemption for Capillary plate can end on schedule. […] JBCE member produce capillary plate but its market is small and specific so that its RoHS exemption isn't necessary.*"

JBCE was asked whether their members have a solution to substitute or eliminate lead so that they could provide at least a short explanation of the technical principle and its status of capillary plates. *JBCE (2021b) stated that they have no such example.* JBCE thus applied for the exemption revocation including capillary plates based on the fact their members produce such devices for uses that are excluded from the scope of the RoHS Directive and not because lead-free alternatives are already available. JBCE (2021b) *agree that exemption 3 remains valid until 2023 and 2024 respectively for cat. 8 in-vitro diagnostic medical devices and cat. 9 industrial monitoring and control instruments.*

The consultants understand from the above information that JBCE members' capillary plates are applied in specific products which are out of the scope of the RoHS Directive. and that substitution or elimination of lead are scientifically and technically still impracticable. This latter statement is underpinned by Photonis (2021) in which they explain that lead is still required for capillary plates. In the absence of a request for the renewal of exemption 3 for EEE other than in-vitro diagnostics (cat. 8) and industrial monitoring and control instruments (cat. 9), the exemption will expire in July 2021 for these categories of EEE. For in-vitro diagnostics and industrial monitoring and control instruments, the consultants recommend continuing exemption 3 until their foreseen expiry in July 2023 and July 2024 respectively.

18.3.4. Environmental arguments and socioeconomic impacts

JBCE et al. (2020) are afraid that *EU researchers, semiconductor manufacturers, etc., will no longer be able to use advanced instruments that rely on MCPs and so will be at a significant competitive disadvantage compared with their non-EU counterparts.*

The scope of exemption IV-39 was tailored to cover properties and combinations thereof which other detectors cannot offer. MCPs are thus crucial parts in many analytical and other instruments whose performance can hardly be replaced. The applicant's argument to the above adverse impacts of the premature revocation of the exemption can therefore be followed.

18.3.5. 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.

The available information suggests that the use of lead in MCPs in the scope of exemption IV-39 cannot be replaced by other detectors. The ALD-technology facilitates, however, the substitution of lead in MCPs and can even improve certain performance parameters. The technology is ready to be used in MCPs even though further research may still be required. Since MCPs are not standalone devices, further time is required for research, testing and qualification to implement ALD-MCPs reliably in all devices in which they are used.

The applicant requests the renewal of the exemption until end of 2026, which is plausible in the light of the remaining steps described above. Further, both the necessity to renew this exemption as well as the requested validity period are supported by Photonis and INCOM, two other MCP manufacturers who were asked to comment JBCE's exemption request. It is concluded that the renewal of the exemption in the consultants' view would be in line with the requirements of Art. 5(1)(a).

MCPs are currently covered by exemptions 3 and 39 of Annex IV even though the addressed MCPs are technically identical. The scope of exemption 39 is therefore adapted to cover the MCPs in the scope of exemption 3. The consultants therefore suggest to follow the applicant's proposal to remove MCPs from exemption 3 so that they are only covered by exemption 39. As the MCPs covered in exemption 3 and 9 are technically identical, the shift of MCPs from exemption 3 with its wide scope to exemption 39 with the more restricted scope technically is not a scope restriction. Purely formally, it could be interpreted in this sense, and the COM may consider to grant a transition period to allow the necessary administrative adaptations in the supply chain. Recommendation

In the consultants' view, the available information shows that the substitution of lead in MCPs in the scope of exemption 39 is scientifically and technically practicable at least partially, but that the reliability of the substitute is not yet ensured. The ALD-technology facilitates lead-free MCPs, but these need further research, testing and qualification to integrate them into reliable products. The renewal of the exemption until end of 2026 would therefore be in line with the stipulations of Art. 5(1)(a) until end of 2026.

18.4. Recommendation

It is recommended to renew the exemption with the below wording agreed with the applicant:

	Exemption	Scope and dates of applicability
39	*Lead in micro-channel plates (MCPs) used in equipment for the amplification or detection of ionising radiation, electrons or ions, where at least one of the following properties is present:* *(a) a compact size of the detector, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable;* *(b) a two-dimensional spatial resolution, where at least one of the following applies:* *(I) a response time shorter than 25 ns;* *(II) a sample detection area larger than 149 mm^2;* *(III) a multiplication factor larger than 1,3 × 10^3.* *(c) a response time shorter than 5 ns;* *(d) a sample detection area larger than 314 mm^2;* *(e) a multiplication factor larger than 4,0 × 10^7.*	Expires on 31 December 2026 for cat. 8 medical devices including in-vitro diagnostic medical devices and cat. 9 monitoringa and control instruments including industrial monitoring and control instruments

The scope of the above amended exemption IV-39 includes the MCP applications in the scope of the current exemption IV-3 to allow their integration into exemption 39 so that MCPs would be covered by one exemption only. In this context, the consultants recommend removing MCPs from the scope of exemption IV-3. Since no request for renewal was submitted, the expiry dates of the exemption should remain unchanged for the applications in the exemption scope as agreed with JBCE. Technically, shifting the MCPs in the scope

of exemption 3 to exemption 39 does not involve any scope restriction or partial revocation for MCPs compared to the current exemption 3. Purely formally, it may be interpreted as a restriction, and the COM might grant a transition period to allow the necessary administrative adaptations in the supply chain. In this case, the text in the brackets should be taken into account in the below scope description, while it could be neglected otherwise.

	Exemption	Scope and dates of applicability
3	*Lead in electromagnetic radiation amplification devices: [micro-channel plate and] capillary plate.*	Expires on - 21 July 2021 for cat. 8 medical devices others than in-vitro diagnostic medical devices, and for cat. 9 monitoring and control instruments others than industrial monitoring and control instruments - [21 July 2021 + transition period for micro-channel plates] - 21 July 2023 for [capillary plates used in] category 8 in-vitro diagnostic medical devices - 21 July 2024 for [capillary plates used in] category 9 industrial monitoring and control instruments

Finally, the MCPs in the scope of exemption IV-39 contain lead in glass and thus in principle could also be in the scope of exemption III-7(c)-I if they are considered as electrical and electronic components. With view to avoiding unnecessary use of lead due to the wide scope of the current exemption 7(c)(I) and the exemption expiry in 2026, the COM might consider adding a clause to exemption III-7(c)(I) which excludes applications under exemption IV-39 to avoid a potential loophole for the time after the expiry of the new exemption 39.

18.5. References

Directive 2011/65/EU: 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 (recast). RoHS 2. Fundstelle: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065.

Gensch et al. (2013): Assistance to the Commission on Technological, Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance Restrictions in Electrical and Electronic Equipment (RoHS Directive). Report for the European Commission DG Environment under Framework Contract No ENV.C.2/FRA/2011/0020, 2013. Final Report. Unter Mitarbeit von Carl-Otto Gensch, Yifaat Baron, Markus Blepp, Andreas Manhart, Katja Moch (Öko-Institut) und Fraunhofer IZM (Otmar Deubzer). Hg. v. Öko-Institut Freiburg e.V. Freiburg (Adaptation to Scientific and Technical Progress of Annexes III and IV of Directive 2011/65/EU, RoHS VI Pack1). Online verfügbar unter

https://circabc.europa.eu/ui/group/4a348b1c-a501-42a5-a278-6954ef1d1855/library/367d39cc-3608-4af1-b89b-c46a507384b1/details.

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. Unter Mitarbeit von Paul Goodman, ERA Technology Ltd. ERA Technology Ltd. Online verfügbar unter https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf.

INCOM (2021): Stakeholder contribution sent by Till Cremer, Incom Inc., via e-mail to Dr. Otmar Deubzer, Fraunhofer IZM, on 4 June 2021.

JBCE (2012): Request for a new exemption (IV-39). Online verfügbar unter https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_10/JBCE_exemption_request10_Lead_in_Micro_Channel_Plate_06Mar2012.pdf.

JBCE (2021a): Answers to questionnaire 1, ex. IV-39, received from Takuro Koide, JBCE, via e-mail by Dr. Otmar Deubzer, Fraunhofer IZM.

JBCE (2021b): Answers to questionnaire 2, IV-39, received from Takuro Koide, JBCE, via e-mail by Dr. Otmar Deubzer, Fraunhofer IZM, on 10 June 2021.

JBCE (2021c): Answers to questionnaire 3, ex. IV-39, received from Takuro Koide, JBCE, via e-mail by Dr. Otmar Deubzer, Fraunhofer IZM, on 10 June 2021.

JBCE et al. (2020): Application for renewal of exemption IV-39. Unter Mitarbeit von JEMIMA JAIMA. Online verfügbar unter http://rohs.biois.eu/Ex_3+39-IV_JBCE_Renewal-Request.pdf.

Photonis (2021): Stakeholder contribution to exemption IV-39, sent by Evert van Gelder, Photonis, via e-mail to rohs@biois.com on 27 November 2020.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

GETTING IN TOUCH WITH THE EU

In person

All over the European Union there are hundreds of Europe Direct information centres. You can find the address of the centre nearest you at: https://europa.eu/european-union/contact_en

On the phone or by email

Europe Direct is a service that answers your questions about the European Union. You can contact this service:

– by freephone: 00 800 6 7 8 9 10 11 (certain operators may charge for these calls),

– at the following standard number: +32 22999696 or

– by email via: https://europa.eu/european-union/contact_en

FINDING INFORMATION ABOUT THE EU

Online

Information about the European Union in all the official languages of the EU is available on the Europa website at: https://europa.eu/european-union/index_en

EU publications

You can download or order free and priced EU publications at: https://publications.europa.eu/en/publications. Multiple copies of free publications may be obtained by contacting Europe Direct or your local information centre (see https://europa.eu/european-union/contact_en).

EU law and related documents

For access to legal information from the EU, including all EU law since 1952 in all the official language versions, go to EUR-Lex at: http://eur-lex.europa.eu

Open data from the EU

The EU Open Data Portal (http://data.europa.eu/euodp/en) provides access to datasets from the EU. Data can be downloaded and reused for free, for both commercial and non-commercial purposes.