Study to assess eight (8) exemption requests in Annexes III and IV to Directive 2011/65/EU: "Renewal of exemptions III.41, IV.37, IV.41, and requests for new exemptions for lead and DEHP in certain NRMM engines applications, lead in solder and hexavalent chromium to be used in mass spectrometers, lead in certain thermal cutoff fuses and lead in solders of certain applications used to identify radiation"

(Pack 14) –Final

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

October 2018

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05 October 2018

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Acknowledgements

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

Disclaimer

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

EUROPEAN COMMISSION

Directorate-General for Environment

Directorate B - Circular Economy & Green Growth

Unit B3 - Waste Management & Secondary Materials

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1. Executive summary – English

Under Framework Contract no. ENV.A.2/FRA/2015/0008, a consortium led by Oeko-Institut was requested by DG Environment of the European Commission to provide technical and scientific support for the evaluation of exemption requests under the new RoHS 2 regime. The work has been undertaken by the Oeko-Institut and Fraunhofer Institute IZM, and has been peer reviewed by the two institutes.

1.1. Background and objectives

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

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

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

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

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

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

1.2. Key findings – Overview of the evaluation results

The exemption requests covered in this project and the applicants concerned, as well as the final recommendations and proposed expiry dates are summarised in Table 1-1. Three requests for the renewal of existing exemption and five requests for new exemptions were included in the scope of this project. The reader is referred to the corresponding sections of this report for more details on the evaluation results.

The – not legally binding – recommendations for the exemption requests (Annex III, Ex. 41, Annex IV, Ex. 37, Annex IV, Ex. 41, Ex. Re. 2017–3, Request 2017-5, Ex. Re. 2017-6 and Ex. Re. 2017-7) were submitted to the EU Commission by Oeko-Institut and have already been published at the EU CIRCA website on 22 October 2018. So far, the Commission has not adopted any revision of the Annex to Directive 2011/65/EU based on these recommendations.

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

Ex. Req. No.	Requested exemption wording	Applicant	Recommendation	Expiry date and scope
Existing exemptions				
Annex III, Ex. 41	Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council	Stihl	Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council	Expires on 30 June 2021
Annex IV, Ex. 37	Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies: (a) wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0,1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations; (b) measurements of solutions where an accuracy of +/− 1 % of the sample range and where high corrosion resistance of the electrode are required for any of the following: (i) solutions with an acidity < pH 1;	Japanese Business Council in Europe (JBCE)	Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies: (a) wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0,1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations; (b) measurements of solutions where an accuracy of +/− 1 % of the sample range and where high corrosion resistance of the electrode are required for any of the following: (i) solutions with an acidity < pH 1;	7 years. However, if the Commission views the lack of involvement of producers in the research of alternatives as a point of concern, a shorter period could be granted, such as three or five years.

Ex. Req. No.	Requested exemption wording	Applicant	Recommendation	Expiry date and scope
	(ii) solutions with an alkalinity > pH 13; (iii) corrosive solutions containing halogen gas; (c) measurements of conductivities above 100 mS/m that must be performed with portable instruments.		(ii) solutions with an alkalinity > pH 13; (iii) corrosive solutions containing halogen gas; (c) measurements of conductivities above 100 mS/m that must be performed with portable instruments.	
Annex IV, Ex. 41	Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.	Instrumentation Laboratories (represented by Intertek)	Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases	Renewal until 1 April 2023 , if the Commission agrees that environmental impacts of substitution justify an exemption, or 18 month transition period
Requests for new exemption				
2017-3	Lead in solders of alpha spectrometers, pulse-processing electronics, scintillation detectors and spectroscopy systems used in equipment to identify radiation, expiring on 23 July 2024	Ametek	Exemption request denied	
2017-4	Lead in solder and hexavalent chromium in parts used to make RF detectors in Mass Spectrometers, to be added to Annex IV	Sciex	Exemption request withdrawn	
2017-5	Lead in thermal cut-off fuses overmolded into solenoid coils used in industrial monitoring and control instruments (Category 9) and EEE falling under Category 11.	Asco Numatics	Exemption request withdrawn	

Ex. Req. No.	Requested exemption wording	Applicant	Recommendation	Expiry date and scope
2017-6	Bis (2-ethylhexyl) phthalate in rubber parts such as O-rings, seals, vibration dampers, gaskets, hoses, grommets and cap-plugs that are used in engine systems including exhausts and turbochargers that are designed for use in equipment that is not designed solely for consumer use.	The European Association of Internal Combustion Engine Manufacturers (EUROMOT)	Bis (2-ethylhexyl) phthalate in rubber components in engine systems, designed for use in equipment that is not intended solely for consumer use i. Not exceeding 30% by weight for • gasket coatings; • solid-rubber gaskets; or • rubber components included in complex sub-assemblies. A complex sub-assembly is defined as an assembly of at least three components using electrical, mechanical or hydraulic energy to do work, and is attached to the engine. ii. Not exceeding 10% by weight of rubber, for rubber-containing components not in the scope of item i	5 years
2017-7	Lead in solders of sensors, actuators and engine control units (ECUs) that are used to monitor and control engine systems including turbochargers and exhaust emission controls of internal combustion engines used in equipment that are not intended to be used solely by consumers.	The European Association of Internal Combustion Engine Manufacturers (EUROMOT)	Lead in sensors, actuators and ECUs of combustion engines installed in equipment used at fixed positions while in operation, which is designed for professionals, but also used by non-professional users and which is in the scope of Regulation (EU) 2016/1628 for internal combustion engines for non-road mobile machinery. Equipment benefiting from Ex. 41 of Annex III of this Directive shall be excluded from this exemption	5 years

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

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

Conformément aux termes du contrat-cadre ENV.A.2/FRA/2015/0008, un consortium mené par l'Oeko-Institut a été chargé par la direction générale (DG) de l'environnement de la Commission européenne afin d'apporter son concours technique et scientifique à l'évaluation des demandes d'exemption suivant le nouveau régime de la directive RoHS 2. Les travaux ont été réalisés par l'Oeko-Institut et le Fraunhofer IZM (Institut Fraunhofer pour la fiabilité et la microintégration), et fait l'objet d'un examen par des pairs des deux instituts.

2.1. Contexte et objectifs

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

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

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

- Le premier critère est susceptible d'être perçu comme un critère de seuil et renvoie au règlement REACH (1907/2006/CE). Une exemption peut uniquement être accordée si elle ne fragilise pas la protection environnementale et sanitaire offerte par le règlement REACH;
- De plus, une demande d'exemption doit être déclarée légitime selon l'une des trois conditions suivantes :
  - Une substitution est irréalisable d'un point de vue scientifique ou technique. Autrement dit, un matériau de substitution ou un substitut pour l'application dans laquelle la substance faisant l'objet d'une restriction est utilisée, doit encore être découvert, développé et, dans certains cas, jugé apte à une utilisation dans l'application spécifique;
  - La fiabilité d'un substitut n'est pas garantie. En d'autres termes, la probabilité que les EEE recourant à un substitut assurent la fonction requise sans connaître de défaillance pendant une durée comparable à celle de l'application dans laquelle la substance d'origine est incluse, est inférieure à celle de l'application;
  - Les impacts négatifs de la substitution sur l'environnement, la santé, et la sécurité des consommateurs l'emportent sur ses avantages.
- Dès lors que l'une de ces conditions est remplie, l'évaluation des exemptions, estimation de la durée nécessaire comprise, devra tenir compte de la disponibilité des substituts et de l'impact socio-économique de la substitution, ainsi que les effets néfastes sur l'innovation et une analyse du cycle de vie concernant les impacts globaux de l'exemption; et
- Le fait que toutes les exemptions doivent désormais présenter une date d'expiration et qu'elles peuvent uniquement être renouvelées après soumission d'une nouvelle demande, constitue un aspect inédit.

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

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

Les demandes d'exemption couvertes dans le présent projet et les demandeurs concernés, de même que les recommandations finales et les dates d'expiration proposées, sont résumées dans le Tableau 2-1 ci-après. Trois demandes de renouvellement d'exemptions existantes, ainsi que cinq demandes de nouvelles exemptions, ont été incluses dans le cadre du présent projet. Le lecteur est invité à se référer aux sections correspondantes du présent rapport pour plus de détails sur les résultats de l'évaluation.

Les recommandations – non contraignantes d'un point de vue juridique– faites en relation avec les demandes de renouvellement d'exemptions (Annexe III - Exemption 41 ; Annexe IV- Exemption 37 ; Annexe IV - Exemption 41 ; renouvellement d'exemption 2017–3, demande 2017-5, renouvellement d'exemption 2017-6 et renouvellement d'exemption 2017-7) ont été soumises à la Commission européenne par l'Oeko-Institut et ont déjà fait l'objet d'une publication le 22 octobre 2018 sur la plateforme Internet « CIRCA » de l'UE. A ce jour, la Commission n'a pas procédé à de quelconque révision de l'Annexe à la Directive 2011/65/UE sur la base de ces recommandations.

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

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

Dem. ex. n°	Termes de l'exemption demandée	Demandeur	Recommandation	Date d'expiration et champ d'application
Exemptions en vigueur				
Annexe III, Ex. 41	Le plomb dans les soudures et finitions des raccordements des composants électriques ou électroniques et les finitions des cartes de circuit imprimé utilisés dans les modules d'allumage et autres systèmes de commande électrique ou électronique des moteurs, qui, pour des raisons techniques, doivent être montés directement sur ou dans le carter ou le cylindre des moteurs à combustion portatifs [classes SH:1, SH:2, SH:3 de la directive 97/68/CE du Parlement européen et du Conseil	Stihl	Le plomb dans les soudures et finitions des raccordements des composants électriques ou électroniques et les finitions des cartes de circuit imprimé utilisés dans les modules d'allumage et autres systèmes de commande électrique ou électronique des moteurs, qui, pour des raisons techniques, doivent être montés directement sur ou dans le carter ou le cylindre des moteurs à combustion portatifs [classes SH:1, SH:2, SH:3 de la directive 97/68/CE du Parlement européen et du Conseil	Expire le 30 juin 2021.
Annexe IV, Ex. 37	Le plomb dans les électrodes en platine platiné utilisées pour des mesures de conductivité,	Conseil aux entreprises japonaises en Europe	Le plomb dans les électrodes en platine platiné utilisées pour des mesures de	7 ans. Néanmoins, si la Commission estime

Dem. ex. n°	Termes de l'exemption demandée	Demandeur	Recommandation	Date d'expiration et champ d'application
	lorsqu'au moins une des conditions suivantes est remplie: a) mesures de conductivité sur une plage étendue, couvrant plus d'un ordre de grandeur (par exemple, entre 0,1 mS/m et 5 mS/m), dans des applications de laboratoire pour des concentrations inconnues; b) mesures des solutions nécessitant une précision de ± 1 % de la plage des échantillons et une résistance élevée de l'électrode à la corrosion, dans les cas suivants: i) solutions acides de pH < 1; ii) solutions basiques de pH > 13; iii) solutions corrosives contenant un halogène. c) mesures de la conductivité au-delà de 100 mS/m devant être effectuées au moyen d'instruments portables.	(JBCE)	conductivité, lorsqu'au moins une des conditions suivantes est remplie: a) mesures de conductivité sur une plage étendue, couvrant plus d'un ordre de grandeur (par exemple, entre 0,1 mS/m et 5 mS/m), dans des applications de laboratoire pour des concentrations inconnues; b) mesures des solutions nécessitant une précision de ± 1 % de la plage des échantillons et une résistance élevée de l'électrode à la corrosion, dans les cas suivants: i) solutions acides de pH < 1; ii) solutions basiques de pH > 13; iii) solutions corrosives contenant un halogène. c) mesures de la conductivité au-delà de 100 mS/m devant être effectuées au moyen d'instruments portables.	problématique le manque d'implication de la part des fabricants en vue d'une recherche d'alternatives, une période d'application plus courte, par exemple de trois ou de cinq ans, pourrait être accordée.
Annexe IV, Ex. 41	Le plomb en tant que stabilisateur thermique dans le polychlorure de vinyle (PVC) employé comme matériau de base dans les capteurs électrochimiques ampérométriques, potentiométriques et conductométriques qui sont utilisés dans les dispositifs médicaux de diagnostic in vitro pour	Instrumen-tation Laboratories (représenté par Intertek)	Le plomb en tant que stabilisateur thermique dans le polychlorure de vinyle (PVC) employé comme matériau de base dans les capteurs électrochimiques ampérométriques, potentiométriques et conductométriques qui sont utilisés dans les dispositifs médicaux de diagnostic in vitro pour	Renouvellement de l'exemption jusqu'au 1er avril 2023 si la Commission accepte que les impacts environnementaux de la substitution justifient une exemption ou

Dem. ex. n°	Termes de l'exemption demandée	Demandeur	Recommandation	Date d'expiration et champ d'application
	les analyses de sang et autres liquides et gaz organiques.		les analyses de sang et autres liquides et gaz organiques.	une période de transition de 18 mois.
Demandes de nouvelles exemptions				
2017-3	Le plomb présent dans les soudures des spectromètres à particules alpha, des équipements électroniques de traitement des impulsions, des détecteurs à scintillation et des systèmes de spectroscopie utilisés dans les équipements pour identifier des radiations ; expire le 23 juillet 2024.	Ametek	Demande d'exemption rejetée	
2017-4	Le plomb présent dans les soudures et le chrome hexavalent qui se trouvent dans les composants utilisés pour la fabrication des détecteurs RF (de signaux radiofréquence) des spectromètres de masse, à rajouter dans l'annexe IV.	Sciex	Demande d'exemption retirée	
2017-5	Le plomb présent dans les fusibles thermiques surmoulés qui se trouvent dans les bobines solénoïdes utilisées dans les instruments industriels de monitoring et contrôle (Catégorie 9) and EEE relevant de la Catégorie 11.	Asco Numatics	Demande d'exemption retirée	
2017-6	Le phthalate de bis (2-éthylhexyle) présent dans les composants en caoutchouc tels que : les joints toriques, sceaux, amortisseurs de vibrations, joints, tuyaux, passes-fils et bouchons	L'Association européenne des fabricants de moteurs à combustion interne (EUROMOT)	Le phthalate de bis (2-éthylhexyle) présent dans les composants en caoutchouc des systèmes de moteurs conçus pour un usage qui n'est pas destiné uniquement à une	5 ans

Dem. ex. n°	Termes de l'exemption demandée	Demandeur	Recommandation	Date d'expiration et champ d'application
	et fiches qui sont utilisés dans les systèmes de moteurs, y compris les échappements et les turbocompresseurs conçus pour un usage dans des équipements qui ne sont pas conçus uniquement pour un usage par des consommateurs.		utilisation par les consommateurs. **i.** n'excédant pas 30% en poids pour : • les revêtements d'étanchéité; • les joints en caoutchouc plein; ou • les composants en caoutchouc inclus dans des sous- ensembles complexes. Un sous-ensemble complexe est défini comme étant un ensemble d'au moins trois composants recourant à de l'énergie électrique, mécanique ou hydraulique pour le fonctionnement des composants, et qui est attaché au moteur. **ii.** n'excédant pas 10% en poids de caoutchouc, pour les composants contenant du caoutchouc qui n'entrent pas dans le champ d'application du point « i ».	
2017-7	Le plomb présent dans les soudures de détecteurs, actionneurs et dans les unités de contrôle de moteur (ECUs) qui sont utilisés pour surveiller et contrôler les systèmes de moteurs, y inclus les turbocompresseurs et les contrôles d'émission d'échappements des moteurs à combustion internes, utilisé dans des équipements qui ne sont pas destinés à être utilisés uniquement par des consommateurs.	L'Association européenne des fabricants de moteurs à combustion interne (EUROMOT)	Le plomb présent dans les soudures de détecteurs, actionneurs et dans les unités de contrôle de moteur (ECUs) des moteurs à combustion installés dans des équipements utilisés dans des positions fixes lors de leur fonctionnement, qui sont conçus pour les professionnels, mais également utilisés par des utilisateurs non-professionnels et qui entrent dans le champ d'application du	5 ans

Dem. ex. n°	Termes de l'exemption demandée	Demandeur	Recommandation	Date d'expiration et champ d'application
			règlement (EU) 2016/1628 pour les moteurs à combustion interne pour les engins mobiles non routiers. Les équipements jouissant de l'Exemption 41 de l'Annexe III de cette Directive doivent être exclus de cette exemption.	

3. Introduction

3.1. Project scope and methodology

The scope of the project covers the evaluation of three existing exemptions and five requests for new exemptions. An overview of the exemption requests is given in Table 1-1 in the Executive Summary.

In the course of the project, a stakeholder consultation was conducted. The stakeholder consultation was launched on 20 October 2017 and held for a duration of six weeks, thus concluding on 1 December 2017.

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

Information concerning the consultation was provided on the project website, including a general guidance document, the applicants' documents for each of the exemption requests, results of earlier evaluations where relevant, a specific questionnaire and a link to the EU CIRCA website. Contributions were not made to either of the exemptions.

Following the stakeholder consultation, an in depth evaluation of the exemptions began. The requests were evaluated according to the relevant criteria laid down in the RoHS 2 Directive, as shown in the Executive Summary in Section 1.

Within this period, the applicant of Ex. Re. 2017-4 withdrew its requests. The evaluation of this request was therefore discontinued.

The evaluations of the other exemptions evaluated in the course of the project appear in chapters 5 through 10. The information provided by the applicants and by stakeholders is summarised in the first sections. This includes a general description of the application and requested exemption, a summary of the arguments made for justifying the exemption, information provided concerning possible alternatives and additional aspects raised by the applicants and other stakeholders. The Critical Review follows these sections, in which the submitted information is discussed, to clarify how the consultants evaluate the various information and what conclusions and recommendations have been made. For more detail, the general requirements for the evaluation of exemption requests may be found in the technical specifications of the project.[1]

[1] Cf. http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_pack_14/Technical_Specification_RoHS14.pdf

3.2. Project set-up

Assignment of project tasks to Oeko-Institut, started 4 September 2017. The overall project has been led by Yifaat Baron. At Fraunhofer IZM the contact person is Otmar Deubzer.

4. Links from the Directive to the REACH Regulation

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

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

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

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

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

The approach adopted in this report is that once a substance has been included into the regulation related to authorisation or restriction of substances and articles under REACH, the environmental and health protection afforded by REACH may be weakened in cases where, an exemption would be granted for these uses under the provisions of RoHS. This is essentially the same approach as has already been adopted for the re-evaluation of some existing RoHS exemptions 7(c)-IV, 30, 31 and 40,[2] as well as for

[2] See Zangl, S.; Blepp, M.; Deubzer, O. (2012) Adaptation to Scientific and Technical Progress under Directive 2011/65/EU - Transferability of previously reviewed exemptions to Annex III of Directive

the evaluation of a range of requests assessed through previous projects in respect of RoHS 2.[3] 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.

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).

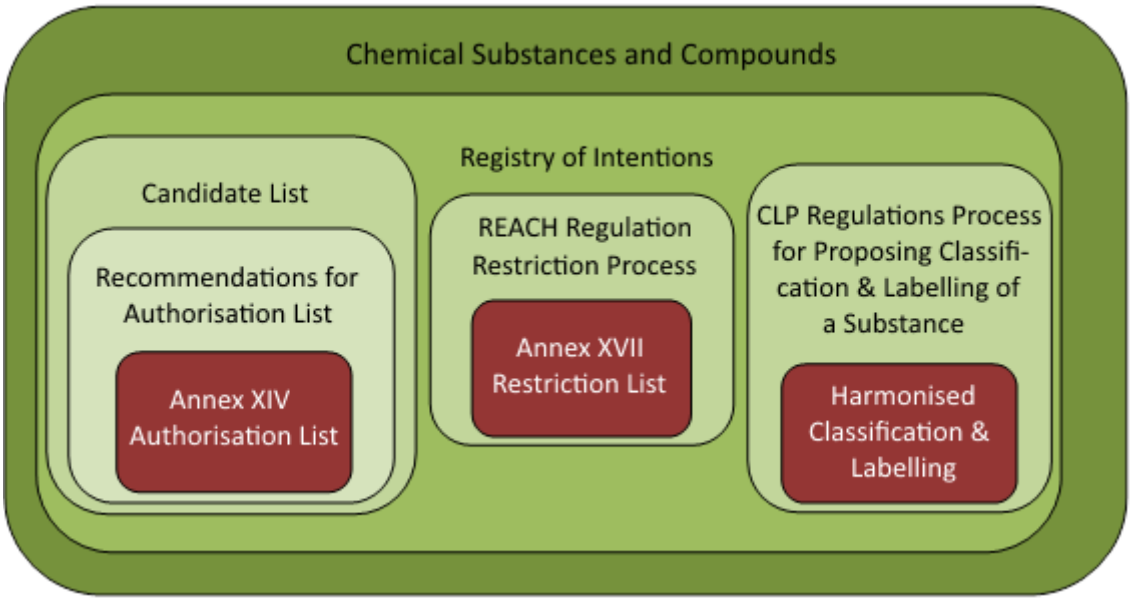
As ECHA is the driving force among regulatory authorities in implementing the EU's chemicals legislation, the ECHA website has been used as the reference point for the aforementioned lists, as well as for the exhaustive register of the amendments to the REACH Legal Text.

Figure 4-1 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.

2011/65/EU, Final Report, Öko-Institut e.V. and Fraunhofer IZM, February 17, 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Re-evaluations_transfer_RoHS_I_RoHS_II_final.pdf

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

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



Source: Own illustration

In beforehand of the Registry of Intentions shown in the figure above, there are additional activities and processes in order to identify substances of potential concern conducted by the ECHA together with the Member States and different ECHA Expert Groups.[4] If a Member State evaluates a certain substances to clarify whether its use poses a risk to human health or the environment the substance is subject to a Substance Evaluation. The objective is to request further information from the registrants of the substance to verify the suspected concern. Those selected substances are listed by ECHA in the community rolling action plan (CoRAP).[5] If the Substance Evaluation concludes that the risks are not sufficiently under control with the measures already in place and if a Risk Management Option (RMO) 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) / the European Chemicals Agency (ECHA), on request by the Commission, may prepare Annex XV dossiers for identification of Substances of Very High Concern (SVHC), Annex XV dossiers for proposing a harmonised Classification and Labelling, or Annex XV dossiers proposing restrictions. The aim of the public Registry of Intentions is to allow interested parties to be aware of the substances for which the authorities intend to

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

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

submit Annex XV dossiers and, therefore, facilitates timely preparation of the interested parties for commenting later in the process. It is also important to avoid duplication of work and encourage co-operation between Member States when preparing dossiers. Note that the Registry of Intentions is divided into three separate sections: listing new intentions; intentions still subject to the decision making process; and withdrawn intentions. The registry of intentions is available at the ECHA website at: 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 (see below);
- In parallel, if a decision is made concerning the Restriction on the use of a substance in a specific article, or concerning the restriction of its provision on the European market, then a restriction is formulated to address the specific terms, and this shall be added to Annex XVII of the REACH Regulation. The Annex can be found in the consolidated version of the REACH Legal Text (see below); and
- As of 14 September 2018, the last amendment of the REACH Legal Text was dated from 18 April 2018 (Commission Regulation (EU) No 2018/589) and so the updated consolidated version of the REACH Legal Text, dated 09.05.2018, was used to check Annex XIV and XVII: The consolidated version is presented at the EUR-Lex website: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20180509.

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

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

In this respect, restrictions and authorisations as well as processes that may lead to their initiation, have been reviewed, in respect of where RoHS Annex II substances are

mentioned (i.e. lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE).[6]

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

The information has further been cross-checked in relation to the various exemptions evaluated in the course of this project. This has been done to clarify that the Article 5(1)(a) pg.1 threshold-criteria quoted above is complied with in cases where an exemption is to be granted / its duration renewed/ its formulation amended/ or where it is to be revoked and subsequently to expire as an exemption. The considerations in this regard are addressed in each of the separate chapters in which the exemption evaluations are documented (Chapter 5 through 10) under the relevant section titled "REACH compliance – Relation to the REACH Regulation" (Section 6.5.1 through Section 10.5.1).

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

5. Annex III, Ex. 41

"Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council (2))"

Declaration

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

Acronyms and definitions

EoL	End of life
Pb	Lead
Sn	Tin
STIHL	Andreas Stihl AG & Co. KG
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment

5.1. Background

Exemption 41 in RoHS Annex III expires on 31 December 2018:

> "*Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council*"

STIHL has requested the renewal of the exemption for the maximum validity period of five years.

In 2013, Stihl requested an exemption, which was reviewed and recommended to be granted. Thereupon the Commission adopted the requested exemption to RoHS Annex

III as exemption no. 41 with the expiry on 31 December 2018, which is the maximum five years duration.

STIHL (2017c) now requests the renewal of exemption 41 until 2025. The time is needed for testing of the reliability of alternative materials, changeover and clearing of the supply chain. In the past years, alternatives have been found and showed sufficient reliability and durability in tests. The applicant nevertheless requests a renewal of the exemption to complete the changeover and clear the supply chain. Ignition modules have to be sealed with epoxy resin and therefore cannot be recycled. The renewal allows for the sell-off of units that have already been produced. STIHL (2017c) does not expect that another extension will be needed.

5.1.1. Amount of lead used under the exemption

STIHL (2017a) estimates the market volume for handheld petrol tools with around 4.6 Mio units in the EU in 2016. Each unit contains approx. 0.75 g of lead, if lead containing solder is used, resulting in a total of less than 3.5 t of lead in the EU.
History of the exemption

5.2. Technical description of the requested exemption

The exemption was reviewed by Gensch et al. in 2013. A detailed technical description of the exemption is available on page 71 of the 2013 review report.

5.3. Applicant's justification for the requested exemption

5.3.1. Substitution or Elimination of Lead

STIHL (2017a) explains that lead is a common alloying element in solder material to control the melting point. STIHL (2017c) has successfully tested alternative materials and will be able to replace the substance. STIHL (2017c) confirms that in production the change-over to lead-free solder can be done until mid-2019. Since Stihl has some very slow moving products, the applicant needs additional time to clear the supply chain. The additional time is also needed to confirm the reliability in the field with a sufficiently high number of products. STIHL (2017c) assures that the exemption renewal will not delay the start of production of the lead-free versions.

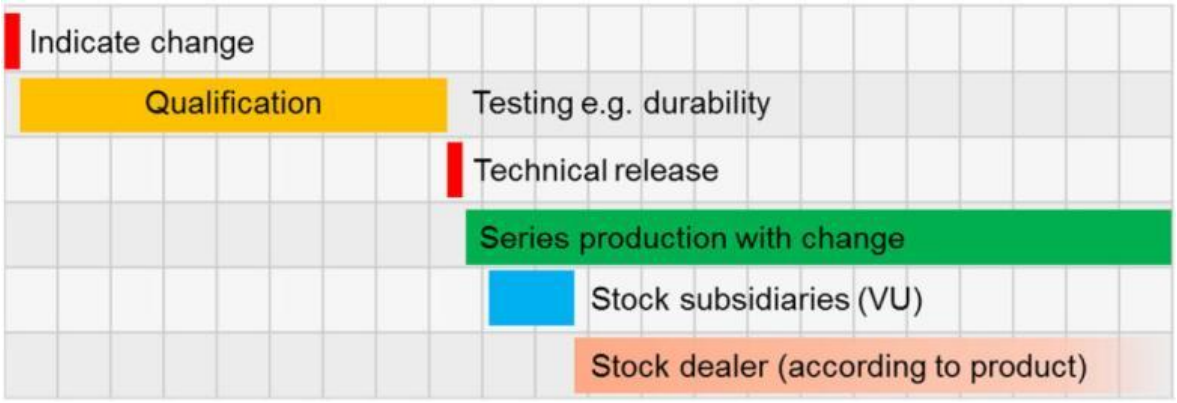
According to STIHL (2017b), any change of products or processes on the supplier side needs to follow the internal standard "STIHL Werknorm (SWN) SWN 39001". The verification of process and product quality follows "STIHL Advanced Product Quality Planning (APQP) procedure", which is structured into 3 phases:

1. First phase – Requirement consolidation:
   Drawing and specification review, definition of APQP profile per material number;

2. Second phase – Quality planning with supplier and test planning:
   Manufacturing feasibility, system/process FMEAs, definition of test-plans, purchase and installation of new test equipment
3. Third phase – Verification of product quality:
   Process audits, production trial - e.g. Run@Rate, measurement system comparisons, new part evaluation, update test plans, machine capability studies, process capability studies, alignment about documentation.

The duration of these 3 phases is linked to the project milestones and varies from one project to the other depending on the project's complexity.

Figure 5-1: Typical timeline for a technical change (STIHL 2017b)



STIHL (2018) is in the qualification stage doing tests with parts from series production and also has put a large number of pieces in the field for field testing. STIHL presented the below table in 2013 already for the initial exemption request resulting in the adoption of exemption 41 to RoHS Annex III.

Table 5-1: Steps and timelines for technical changes (STIHL 2018)

Task	Activity	Required Time
Step 1: Redesign	Selection of alternative components for lead-free solder and redesign	2 – 3 months
Step 2: Qualification and optimization based on lab tests	Production of samples, lab tests (temperature shock testing, up to 4 months), and optimization of design based on test results	1.5 years
Step 3: Supplier invests in new equipment	If tests from step 2 were successful: supplier invests in additional production equipment (planning, invest, construction and startup)	1 - 2 years
Step 4: Change to lead-free solder for one product	A worst-case product is identified and changed to lead-free solder	2 months
Step 5: Field testing	The performance of the lead-free products is observed in the field. Customer claims are evaluated and analyzed, if the failure is related to the new solder.	2 years
Step 6: Investment and changeover phase to lead-free	• Supplier invests in new equipment for a change to lead-free solder for all STIHL ignition systems • Change all 85 types (ca. 15 families) of ignition systems for STIHL products to lead-free soldering	2 years
Total time		~ 7 to 8 years

According to STIHL (2018), "Step 5: Field testing" reflects the current status of the transition to lead-free soldering.

5.3.2. Environmental arguments

STIHL (2017b) claims that if the exemption will not be granted or only be granted for a shorter period of time, this will lead to a waste of precious resources (material, energy, work force) and to environmental pollution (exhaust fumes from transportation and waste burning, etc.).

- Waste:
  Ignition control modules and similar devices need to be sealed with epoxy resin and therefore cannot be recycled. STIHL (2017b) estimates 50 to 100 tonnes of complex waste containing several hundred kilograms of lead.
- Energy
  Energy will be wasted for transportation, waste scrapping, rework of machines, etc. The same steps will produce unnecessary environmental pollution (exhaust gases, waste residues in soil and water, etc.)
- Work force
  Work force is wasted for reworking machines.

STIHL (2018) says that the above impacts apply in particular to slow moving products, which need additional time beyond 2018 to clear the supply chain. STIHL (2018) defines "slow moving" products as products with low quantity and/or seasonal demands. Especially for the latter reason and the current unpredictability of the global

weather conditions, this effect is not restricted to a certain product type. They are produced, stocked at STIHL and at the dealers.

If the exemption is granted, STIHL (2017b) and other manufacturers can avoid these negative impacts.

5.3.3. Socioeconomic impacts

STIHL (2017b) claims that, should the exemption not be granted or only be granted for a shorter period of time, this would lead to considerable efforts and costs. Exact values strongly depend on the granted period of time. The main part of efforts and costs are produced in the first years after the current deadline of the exemption. Therefore, the applicant expects in any case a socio-economic impact, especially on the supply chain in the EU and beyond. STIHL (2017b) currently cannot reliably evaluate to which extent this will affect employment as boundary conditions, like the general market condition at the time, are not clear at the moment.

5.4. Stakeholder contributions

Contributions were not submitted regarding this exemption in the course of the stakeholder consultation.

5.5. Critical review

5.5.1. REACH compliance – Relation to the REACH Regulation

According to Article 5(1)(a) an exemption may "*not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006*". If granted, the exemption would allow the use of lead in solders used in certain ignition modules of hand-held devices with a combustion engine. The REACH Regulation has thus been consulted in this respect.

Annex XIV of the REACH Regulation lists a few substances, the use of which would require an authorisation in the EU:

- Lead chromate – used in printing inks, paints and to colour vinyl, rubber and paper[7];
- Lead sulfochromate yellow –used as a pigment, a dye and as a paint and coating additive[8];
- Lead chromate molybdate sulphate red –understood to be used as a pigment;

[7] Data on uses from Pubchem: https://pubchem.ncbi.nlm.nih.gov/compound/lead_chromate#section=Top

[8] Data on uses from Pubchem: https://pubchem.ncbi.nlm.nih.gov/compound/53488191#section=Use-and-Manufacturing

Seeing as the exemption for lead in solders used in certain ignition modules of hand-held devices with a combustion engine 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 contains several entries restricting the use of lead compounds:

- Entry 16 restricts the use of lead carbonates in paints;
- Entry 17 restricts the use of lead sulphates in paints;
- Entry 63 restricts the use of lead and its compounds in jewellery and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children.
- Entry 28 and entry 30 stipulate that various lead compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public.

The exemption for lead in solders used in certain ignition modules of hand-held devices with a combustion engine does not regard paints or jewelry, 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 used in certain ignition modules of hand-held devices with a combustion engine 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, entry 28 and entry 30 of Annex XVII of the REACH Regulation would not apply. It is concluded that a renewal of the exemption would not weaken the protection afforded by REACH through entries 16, 17, 28, 29 and 63.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status April 2018). Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

5.5.2. Scientific and technical practicability of substitution

STIHL was asked whether any of its competitors' might have a solution, or whether otherwise they would support the exemption request. STIHL (2017b) stated that as to their knowledge, many other competitors lead by the association EUROMOT[9] had meanwhile also placed a request for an exemption similar to exemption 41: „Lead in solders of sensors, actuators and engine control units (ECUs) that are used to monitor and control engine systems including turbochargers and exhaust emission controls of internal combustion engines used in equipment that are not intended to be used solely by consumers". The EUROMOT request actually technically has an overlapping scope with exemption 41. Further on, the European Garden Machinery Federation EGMF

[9] Cf. Request 2017-7 by EUROMOT: http://rohs.exemptions.oeko.info/index.php?id=284

(2018) and (Husqvarna 2018), a competitor of STIHL, sent letters to support STIHL's exemption request.

STIHL (2017c) stated that in production the change-over to lead-free solder can be done until mid-2019, and that the renewal of the exemption would not delay the placement of lead-free products on the market. At the same time, the applicant stated that full scale production would start after 2023 only. The applicant was asked to clarify these contradicting statements. STIHL (2018) confirmed that in production the change-over to lead-free solder can be done until mid-2019, provided, however, that the results from the final qualification steps (field testing) assure the reliability in the field with a sufficiently high number of products. However, this part of the qualification is still running, the applicant is doing tests with parts from series production and also has a large number of pieces in the field.

A changeover to lead-free soldering is thus technically practicable until mid-2019 under the above-mentioned conditions. From the technical point of view, STIHL (2018) needs the prolongation in case of issues with the reliability tests in order to start a second qualification phase of several years.

The available evidence including the time scales for testing submitted by the applicant in 2013 and now are consistent and plausibly show that the substitution of lead is scientifically and technically impracticable until the expiry of the exemption on 31 December 2018. RoHS Art. 5(1)(a) would hence justify the renewal of the exemption beyond 2018. The reliability of the lead substitution cannot be proved to be sufficient before the field testing period is finalized and the substitutes proven to be provide comparable performance.

From the technical point of view, the renewal until mid-2019 would be sufficient if the field tests are successful. In case the field tests reveal reliability issues, the applicant must, however, have the possibility to request another renewal of the exemption. According to RoHS Art. 5(5), an application for renewal of an exemption shall be made no later than 18 months before the exemption expires, which requires the renewal of the exemption until the end of 2020 plus a reasonable time for preparing the exemption request, for which the consultants believe 6 months to be a reasonable time.

5.5.3. Environmental arguments and socioeconomic impacts

Besides technical arguments, the applicant also puts forward negative environmental and socioeconomic impacts, in the case that the exemption is not granted or granted for a shorter period of time than 2025. The applicant claims to need more time to clean the supply chain of non-RoHS-compliant products in this case, which would cause waste of resources, energy and labour.

The applicant submitted the exemption request on 30 June 2017. The applicant's products in the scope of the exemption request are categorized as EEE that was outside the scope of Directive 2002/95/EC (RoHS 1), but which would not comply with this Directive (RoHS 2). The RoHS Directive in the status of June 2017 stipulated in Art. 2(2) that such products could only be made available on the market until 22 July 2019, which excludes any supply of an EEE for distribution, consumption or use on the

Union market in the course of a commercial activity, whether in return for payment or free of charge after July 2019. In the course of several amendments of the RoHS Directive in December 2017, Art. 2(2) was cancelled and Art. 4(3) amended[10] so that it now allows placing on the market of these devices until 22 July 2019. "Placing on the market" in this case only bans making available an EEE on the Union market for the first time after 22 July 2019, while EEE placed on the market before 22 July can be continued to be made available on the market after that date.

The applicant was asked whether this amendment changes the situation of the slow moving products. STIHL (2018) replied that "*it changes the situation in that way that we only have to consider production stock and not the complete quantity in stock up to the dealer. This would reduce the amount of waste the applicant does not have to scrap the stock parts at the dealers*".

5.5.4. Conclusions

The submitted information plausibly and consistently explains that lead substitution for the applications in the scope of exemption 41 scientifically and technically is impracticable until mid-2019 provided the field test period proves the reliability of the applicant's lead-free soldering solution. Art. 5(1)(a) would therefore justify the renewal of the exemption. In case the field test results are negative, a further renewal of the exemption may be necessary. The consultants therefore recommend granting the exemption until 30 June 2021, which allows sufficient time to prepare and submit another renewal request at least 18 months prior to the expiry of the exemption.

The above environmental and socioeconomic impacts would not justify granting the exemption beyond the technically justifiable deadline of June 2021. The amendment of RoHS Art. 4(3) together with the additional 2.5 years of time to clean the applicant's stocks of lead-soldered products will at least considerably mitigate, if not completely avoid the described negative environmental and socioeconomic impacts. Should the ongoing tests show that the currently aspired solutions are not sufficiently reliable, the expiry date in 2021 leaves enough time to request the continuation of the exemption beyond 2021, which would also avoid the socioeconomic and environmental impacts associated by the applicant with the exemption expiry.

5.6. Recommendation

It is recommended to renew the exemption until 30 June 2021 in its current wording:

Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council

Expires on 30 June 2021

[10] Cf. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017L2102

The available information shows that the use of lead-free solders for the applications in the scope of exemption 41 will still be scientifically and technically impracticable after the expiry of the exemption at the end of 2018 due to insufficient evidence as to the reliability of the lead-free solders. The renewal of exemption 41 would thus be justified on the basis of RoHS Art. 5(1)(a).

Solutions are expected to become available by mid-2019, but depend on the positive results of the applicant's currently still ongoing field testing. The consultants therefore recommend renewing the exemption until 30 June 2021 to allow the applicant sufficient time for preparing and submitting another renewal request should the case arise that the field tests do not prove that the substitution of lead provides an adequate performance.

The applicant's environmental and socioeconomic arguments in the consultant's opinion do not justify granting the exemption beyond 30 June 2021 in line with the requirements of Art. 5(1)(a).

6. Annex IV, Ex. 37

"Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies:
(a) wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0,1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations;
(b) measurements of solutions where an accuracy of +/– 1 % of the sample range and where high corrosion resistance of the electrode are required for any of the following:
(i) solutions with an acidity < pH 1;
(ii) solutions with an alkalinity > pH 13;
(iii) corrosive solutions containing halogen gas;
(c) measurements of conductivities above 100 mS/m that must be performed with portable instruments."

Declaration

In the sections that precede the "Critical review" the phrasings and wordings of stakeholders' explanations and arguments have been adopted from the documents provided by the stakeholders as far as required and reasonable in the context of the evaluation at hand. Formulations were only altered 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
Pb	Lead
PPE	Platinized platinum electrodes

6.1. Background

Platinized platinum electrodes (PPE) are used in measurement instruments and said to be necessary for the measurement of "*wide range, high accuracy, high reliability for high concentration of acid and alkali*". It is explained that PPE are a platinum electrode coated with a very thin layer of platinum black that can increase the effective electrode surface area by a factor of 1,000. In order to achieve the above performance, lead is used in the electro deposition process of platinum black. The elimination of lead in the plating solution has been studied by many electrochemists for several decades, however there are no research papers regarding the elimination or substitution of the substance. (JBCE 2017a)

Against this background the Japan Business Council in Europe (JBCE 2017a) applies for the renewal of Ex. 37 of Annex IV of the RoHS Directive and proposes to maintain the current exemption formulation:

> *"37. Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies:*
> *(a) wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0,1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations;*
> *(b) measurements of solutions where an accuracy of +/– 1 % of the sample range and where high corrosion resistance of the electrode are required for any of the following:*
> *(i) solutions with an acidity < pH 1;*
> *(ii) solutions with an alkalinity > pH 13;*
> *(iii) corrosive solutions containing halogen gas;*
> *(c) measurements of conductivities above 100 mS/m that must be performed with portable instruments.*
> *Expires on 31 December 2018."*

The renewal is requested for a duration of seven years for monitoring and control instruments (category 9 of Annex I of the directive) - the maximum duration that can be granted for exemptions available to equipment in the scope of this category.

6.1.1. The history of the exemption

JBCE originally requested the exemption in 2012. The request was evaluated in the course of 2012-2013 (Gensch et al.) and it was concluded that "*The use of lead cannot currently be fully eliminated in PPE applications, neither through possible substance substitutes, nor through the use of alternative methods for measuring conductivity. The scope of applications for which it is not possible to currently replace PPEs has been clearly established and therefore there is sufficient clarity to recommend an exemption in line with the criteria stipulated in article 5(1)(a) of the RoHS Directive*". The consultants recommended granting the exemption for an initial period of 5 years, which was deemed sufficient to accommodate the required research into the existing substitute candidates, identified through the evaluation process, and for the respective development of possible alternatives. The European Commission granted the exemption with the wording detailed in section 6.1, for a five year period.

6.1.2. Amount of lead used under the exemption

JBCE (2017a) states that based on the composition of the plating solution a small amount of lead remains in the platinum black, which is on the electrode. The amount of lead, related to platinized platinum electrodes used in measurement instruments and placed on the EU market, is estimated to be less than 1 gram per year. In a later communication, JBCE (2018) explains this estimation to be based on an assumption that 1,000 electrodes are sold in the EU per annum.

6.2. Description of requested exemption

In electrochemistry, the standard potential of a chemical species is measured as the voltage difference between the oxidation-reduction potential of hydrogen and the species using the standard hydrogen electrode because the oxidation-reduction potential of hydrogen is zero volts. The standard hydrogen electrode is a thin platinum plate with platinum black electrodeposition on its surface (i.e. a PPE). The platinum functions as a catalyst to efficiently stimulate the oxidation-reduction reaction of hydrogen and platinized electrode is used to create lager surface area of the electrode so as to generate a stable oxidation-reduction potential.

The PPE is applied as an electrode among others in electrical conductivity meters used for inspecting and testing various kinds of water, such as water in rivers, seawater, distilled water, drinking water, industrial water, and industrial effluents. (JBCE 2017a)

Platinized platinum electrode comprises of a platinum electrode covered with a thin layer of platinum black. A small portion of lead is concentrated in the layer of platinum black during the electrodeposition process used to produce these electrodes. (JBCE 2017a)

JBCE (2017a) states that "*Platinization is conducted using the plating solution prepared from a water solution of 30g/L of hydrogen hexachloroplatinate(IV) hexahydrate (CAS#:18497-13-7) and 0.25g/L of lead(II) acetate trihydrate (CAS#:6080-56-4). A suitable plating apparatus consists of a 6 V DC supply, a variable resistor, a milliammeter, and two electrodes. Good platinized coatings are obtained using from 1.5 to 3 C/cm^2 of electrode area. For example for an electrode having a total area (both sides) of 10 cm^2, the plating time at a current of 20 mA would be from 12.5 to 25 min. The current density may be from 1 to 4 mA/cm^2 of electrode area*." The platinization method is described in EN27888:1993 (ISO 7888:1985), "Water quality - Determination of electrical conductivity" and is explained to provide good adherence of the platinum black to the substrate.

Additional details as to the production and principle function of electrical conductivity meters can be found in the application document (JBCE 2017a) as well as in the report of the first evaluation of this request (Gensch et al.).

Since lead remains present in the PPE at a concentration above 0.1 %, an exemption is needed to allow its further placing on the market.

6.3. Applicant's justification for exemption

JBCE (2017a) justifies the exemption on the lack of available substitutes both on the technological and the substance level. Despite various technologies, it is not possible to eliminate the presence of lead beyond a 0.1% concentration:

- Platinum is used because it prevents chemical reactions in the solution. Since the performance of the electrode as catalyst and its electric capacitance is proportional to its surface area, platinum black electrodeposition is done to enlarge the surface

area of the metal electrode to about 1,000 times the surface area of the flat electrodes without platinum black electrodeposition. (JBCE 2017a)

- Lead is used in the platinization solution to generate the platinum black, enlarging the surface area of the electrode. Electrodeposition using lead acetate is superb in relation to the resulting surface area and adherence of platinum black to the substrate platinum as shown in Feltham and Spiro in a 1970 publication[11]. (JBCE 2017a)
- JBCE (2017a) explains that other measurement methods are not suitable for the application areas specified in the exemption formulation: "If the measurement requires wide range, high accuracy, high reliability for high concentration of acid and alkali, small size etc., the PPE is necessary". The PPE is required, for example, in order to measure, electrical conductivity under such conditions.

6.3.1. The availability of alternatives for lead in the platinization process

JBCE (2017a) states that the elimination of lead in the plating solution has been studied by many electrochemists for several decades, and some reviews have been issued (e.g. Feltham and Spiro , 1070). But the platinized platinum electrode, in which lead(II) acetate is used as the component of the plating solution, is still required to measure the solutions with low electrical conductivity accurately. As of 30th June 2017, there is no research paper on alternative substances. Therefore, there are no alternative substances.

Feltham and Spiro (1970) detail a number of further substances that could be considered as alternatives for lead in the platinizing process, including copper sulphate, gold and thallium. JBCE was asked as to research of manufacturers regarding these candidates that were already identified in the 2013 evaluation report. JBCE (2018) responded that from the viewpoint of chemical resistance and corrosivity, that materials such as copper sulphate and gold are inferior to platinum. Therefore, lead in platinized platinum is explained to be the only substance to satisfy the applications for which the exemption is needed.

6.3.2. Environmental arguments

JBCE (2017a) does not provide information as to possible environmental arguments.

6.3.3. Road map to substitution

JBCE (2017b) states that the elimination of lead in the PPE plating solution has been studied by many electrochemists for several decades, however research papers referring to alternatives that could eliminate or substitute lead in this application are not available. It is further explained that it is difficult for PPE manufacturers to research and develop the technology. "*However, we should continue to investigate whether there is any progress on the technology. If the substitution technology is*

[11] JBCE (2017a) provides the following reference in this regard: PLATINIZED PLATINUM ELECTRODES, A. M. FELTHAM AND M. SPIRO, Department of Chemistry, Imperial College of Science and Technology, London S. W. 7, England Received July 29, 1970 (Revised Manuscript Received October 23, 1970). It is noted that this reference was also provided in the course of the initial evaluation in 2012-2013.

established, then so PPE manufactures move on to the phase to development the application." In a later communication, JBCE (2018) estimate that 5-10 years shall be needed to allow the implementation of a possible future candidate as a substitute in new equipment models.

JBCE (2018) elaborates that manufacturers of measuring instruments are not material specialists or research institutions and cannot research and develop substitute materials themselves as it is very specialized and is not a simple matter.

6.3.4. Socio-economic aspects

JBCE were asked to provide information as to various possible socio-economic impacts of relevance to the exemption and its possible revoke. JBCE (2017b) provided the following input:

- There is no information on the volume of EEE that would be affected by a revoke of the exemption, nor as to the total amount of Pb to be avoided on the market under such a scenario. Also, from the view point of competition law, it is difficult to find it out by companies or organizations.
- There is no information on the amounts of waste to be generated should the exemption not be granted (i.e. should replacement parts not be available for use).
- There is no information on possible impacts on employment should the exemption not be granted.
- There is no information on the additional cost associated with a forced substitution should the exemption not be granted, and how this is divided between various sectors. However, it is understood that depending on the user, the kind of samples to be measured with the PPE and what is to be measured is different and this is understood to affect the range of possible impacts.

JBCE (2018) later stated that if the electrode would no longer be available, the measuring instrument itself would also need to be discarded. JBCE does not know exactly how many measuring instruments are currently used in the EU, but anticipate that over tens of thousands of measuring instruments could be discarded. JBCE also notes that there is no other way to measure without this electrode, so there should be research facilities and production facilities that must be discarded because data they rely on for their activity would not be measureable. This would lead to immeasurable losses in related EU research.

6.4. Stakeholder contributions

Contributions were not submitted regarding this exemption in the course of the stakeholder consultation.

6.5. Critical review

6.5.1. REACH compliance – Relation to the REACH Regulation

If granted, the exemption would allow the use of lead in PPE to be used in measurement equipment.

Annex XIV of the REACH Regulation lists various substances that require an authorisation for use in the EU. The following lead compounds are listed n Annex IV:

- Lead chromate – identified uses in the REACH Annex XV dossier prepared by France include as a pigment in paints and varnishes, in the formulation of detergents and bleaches, in the manufacture of pyrotechnic powder (in retardants detonators), use in embalming/restorative art products and in photosensitive materials (State of France 2009a);
- Lead sulfochromate yellow - (C.I. Pigment Yellow 34) – identified uses in the REACH Annex XV dossier prepared by France include paints, printing inks, vinyl and cellulose acetate plastics, textile printing, leather finishing, linoleum, paper, artist's paints, varnishes and mastics. (State of France 2009c);
- Lead chromate molybdate sulphate red - (C.I. Pigment Red 104) – identified uses in the REACH Annex XV dossier prepared by France include paints, printing inks, vinyl and cellulose acetate plastics, alkyl resin enamels, textile printing, leather finishing, linoleum, paper, artist's paints, varnishes and similar coatings and mastics. (State of France 2009b);

Based on the known uses of these compounds, none of them is of relevance to the PPE and as such an exemption would not weaken the protection afforded by REACH in this respect.

Annex XVII of the REACH Regulation contains several entries restricting the use of lead compounds:

- Entry 16 restricts the use of lead carbonates in paints;
- Entry 17 restricts the use of lead sulphates in paints;

Neither of these entries are relevant for the use of lead in PPE and thus an exemption would not weaken the protection afforded by REACH in this respect.

Appendix 1 of this report lists entry 28 and entry 30 in Annex XVII of the REACH Regulation, stipulating that specified lead compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public. A prerequisite to granting the requested exemption would therefore be to establish whether the intended use of lead in this exemption request might weaken the environmental and health protection afforded by the REACH regulation. In the consultants' opinion, the use of lead in the PPE 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, entry 28 and entry 30 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 May 2018). 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.

6.5.2. Scientific and technical practicability of substitution

Alternative measurement methods exist and were reviewed in detail in the original evaluation of the exemption in 2013 (see Gensch et al. for details). At the time, measurement areas were identified in which such methods did not provide performance comparable to that of the PPE and on this basis the exemption formulation was specified so as to limit the exemption to applications for which alternatives to the PPE were not available. From the information provided by JBCE, the PPE is still needed in these application areas as new technologies have not become available that could replace the PPE and respectively the equipment in which it is used.

As for possible alternatives for the use of platinum as the hydrogen electrode, JBCE explains that platinum functions as a catalyst to efficiently stimulate the oxidation-reduction reaction of hydrogen. For the applications in which the PPE is used, it is understood that alternatives do not provide comparable performance to that of the hydrogen electrode.

On the substance level, JBCE explains that the platinization process is based on the use of lead acetate, which provides good adherence of the platinum black to the substrate. Substitutes for lead in the platinization of the PPE are explained not to have become available since the exemption was originally granted in 2013. This is understood to be based on JBCE's search over the last years for publications on research into possible alternatives.

Though substances were identified in the past evaluation that could be considered as candidates for possible substitution (including copper sulphate, gold and thallium), JBCE states that from the viewpoint of chemical resistance and corrosivity, that such materials are inferior to platinum. However, the consultants understand this statement to be based on general knowledge and not on new research into these candidates as potential substitutes. The Feltham and Spiro (1970) study also states that lead acetate is understood to provide the best results, however the level of inferiority was not specified by JBCE in the past or in the current evaluation and data as to this aspect has not been found by the consultants in the public domain. It remains to be clarified whether the difference in performance would be acceptable as a compromise for allowing the elimination of lead in this application or if these compounds would not provide a viable substitute.

6.5.3. Environmental arguments

JBCE (2017a) do not provide information as to possible environmental arguments.

6.5.4. Socio-economic aspects

JBCE provide only general statements as to possible impacts associated with a revoke of the exemption. In general such impacts may differ between users, where the PPE is the only viable measurement method, depending on the values to be measured and how measurement data is further used, i.e. what further activities depend on the ability to measure respective values. For example, as the PPE is used in research facilities, should it no longer be available on the market, the equipment in which it is used would have to be discarded and research depending on such results could not be completed. JBCE do not have exact data, but anticipate that over tens of thousands of measuring instruments could be discarded.

Though these statements can be followed based on the known uses of the PPE, on the basis of available information it is not possible to estimate the range of impacts that could be linked to a revoke of the exemption. JBCE estimate that the exemption revoke could affect tens of thousands of measuring instruments, however in parallel they estimate the amount of lead coming on the market through this exemption (1 gram) on the basis of 1,000 PPE sold on the EU market per annum. Based on this data, were lead based PPE no longer available, at least 10 years would need to go by before all existing equipment would be in lack of a replacement electrode. In this sense, though there may be tens of thousands of instruments using the PPE, it needs to be concluded that the service life of a single electrode is relatively long, and that impacts related to a revoke of the exemption shall incur gradually over a long period of time.

6.6. Scope of the exemption

Based on the questioning of JBCE, it is understood that the exemption is still needed for all application areas for which it was initially granted.

6.6.1. Conclusions

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

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

From the information provided by JBCE, it can be followed that there are currently no substitutes for lead in the PPE nor for the PPE itself. In relation to the candidate substitutes specified in the Feltham and Spiro (1970) publication, there remains no data to allow clarifying whether the performance that could be provided by these substances would be in an acceptable tolerance for substitutes. Though candidates

exist, their applicability or inapplicability still needs to be shown on the basis of research data. As for alternative measurement methods that could provide comparable results in the relevant PPE applications, new methods that could replace the PPE have not been identified. Existing methods were investigated in detail in the past evaluation and served to limit the exemption formulation to application areas where they do not provide comparable performance (reliable and accurate measurements) or cannot be used at all. In this sense substitution and elimination are still understood to be scientifically and technically impracticable.

Though some of the alternative measurement methods available may be used in the monitoring of parameters currently measured with the PPE (see details in Gensch et al.), they are understood to be less accurate and in this sense not to provide comparable reliability.

Environmental aspects were not raised by JBCE and the consultants thus assume that the third criteria of Article 5(1)(a) is not relevant for the justification of the exemption.

The consultants view the exemption as justified on the basis of the Article 5(1)(a) criteria, in light of the lack of substance substitutes and the non-compatibility and non-reliability of existing alternative measurement methods – i.e. the two first criteria are fulfilled. Nonetheless it is noted that the members of JBCE are not pursuing research into substitutes. In relation to the candidate substitutes specified in the Feltham and Spiro (1970) publication, JBCE (2018) states that from the viewpoint of chemical resistance and corrosivity, that materials such as copper sulphate and gold are inferior to platinum. JBCE does not support this statement with information or data from research into the candidate substances and the consultants understand that JBCE and its members are not aware of such research being performed in the past nor at present.

It is plausible that the development of substitutes for lead in this application would require material specialists, understood not to be at the disposal of manufacturers. However, the consultants would expect manufacturers to pursue the development of substitutes: As a minimum, this could be done through communication with suppliers or with research facilities investigating electrodes and/or measurement methods, so as to motivate possible research in this direction.

6.7. Recommendation

The consultants conclude that the exemption can be justified on the basis of the Article 5(1)(a) criteria as on the substance level new substitutes have not become available and on the technological level the existing alternative measurement methods are either not reliable enough for the measurement of relevant parameters or could not be used for such applications to begin with (i.e. here too there has not been further progress in replacement PPE applications).

The consultants thus recommend granting a renewal of the exemption with the same wording currently appearing in Annex IV of the Directive:

"37. Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies:

(a) wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0,1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations;

(b) measurements of solutions where an accuracy of +/– 1 % of the sample range and where high corrosion resistance of the electrode are required for any of the following:

(i) solutions with an acidity < pH 1;

(ii) solutions with an alkalinity > pH 13;

(iii) corrosive solutions containing halogen gas;

(c) measurements of conductivities above 100 mS/m that must be performed with portable instruments.

JBCE state that once an alternative is found (research) that it shall take between 5 to 10 years to allow the implementation in new equipment models. And thus the exemption could be granted for the maximum allowed duration of 7 years. However, if the Commission also views the lack of involvement of relevant manufacturers in the research of alternatives as a point of concern, a shorter period could be granted, such as three or five years. This could be accompanied with a communication that failure to provide evidence of a strategy for the research and development of alternatives in future applications of the exemption renewal shall result in the revoke of the exemption.

7. Annex IV, Ex. 41

"Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases."

Declaration

In the sections that precede the "Critical review" the phrasings and wordings of stakeholders' explanations and arguments have been adopted from the documents provided by the stakeholders as far as required and reasonable in the context of the evaluation at hand. Formulations were only altered 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

IL	Instrumentation Laboratory
Pb	Lead
PPE	Platinized platinum electrodes
PVC	Polyvinyl chloride

7.1. Background

Instrumentation Laboratory (IL 2017a) (2017a; IL) manufactures the GEM Premier diagnostic medical analyser. This instrument is used to analyse the blood of patients and provide clinicians with accurate measurements of specific analytes vital to medical diagnostics and patient treatment. The heart of the GEM Premier family is explained to be the sensor card where the electrochemical measurements of the above analytes take place. According to IL, due to the complex electrochemical processes in the sensor card, it has not been possible yet, to find a stabilizer other than lead that works without affecting analytical performance of analyte measurements of the various GEM models.

Continued use of lead in the sensor card of the GEM Premier analysers is required while the search continues for an alternative stabilizer. Against this background, IL (2017a) has applied for a renewal of Ex. 41 of Annex IV of the RoHS Directive. They request the renewal of the exemption, maintaining the existing wording:

> "*Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases. Expires on 31 December 2018*"

The IL equipment explained to be covered by this exemption is specified to fall under the RoHS Annex II category 8 sub-group: in-vitro diagnostic medical devices. (IL 2017a)

IL (2017b) states that the exemption is needed until 31st December 2025.

7.1.1. Amount of lead used under the exemption

In equipment falling under the scope of Ex. 41, lead is explained to be used as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors. The concentration of Pb used in the sensor cards varies between the GEM models. IL specifies that a concentration of 2.7% is applied in the GEM Premier 4000 model cartridges and a concentration of 6.6% is applied in the GEM Premier 3000, 3500 and 5000 model cartridges. IL estimates the amount of substance entering the EU market annually through applications for which the exemption is requested at 48.14 kg. This amount is explained to be based on the 2017 forecast for GEM Premier cartridge shipments to the EU, i.e. to represent only IL equipment benefiting from the exemption. This amount is stated to be sent to energy return at end-of-life, as it is comprises medical waste and thus cannot be recycled. (IL 2017a)

In a later communication, IL (2017b) explains the specific formulations of the PVC and sensor designs used by each manufacturer are generally proprietary information and for that reason it is not feasible for IL to provide the actual amount of lead placed on the EU market through blood analysers of all manufacturers. Nonetheless based on a rough estimation of IL it is assumed that 144.43 kg of lead are placed on the EU market annually through blood analysers.

7.2. Description of requested exemption

IL (2017a) requests the exemption to allow the continued use of lead in the sensor card of the GEM Premier analysers (GEM Premier 3000/3500/4000/5000 instruments) until an alternative stabilizer is found and applied. The alternative stabilizer must not interfere with measurements of any analyte on the system over the claimed product shelf life (up to 9 months at room temperature) and use life (up to 4 weeks in the analyser). To support the request, IL also provides results of an LCA to show that the current GEM Sensor Card performs better in environmental terms in comparison to the currently researched potential alternatives.

7.2.1. Applicant's justification for exemption

The sensor card in the disposable cartridge is made of polyvinyl chloride (PVC). Use of PVC as the sensor card material dates back to the 1980s when the GEM- Stat and GEM 6 analysers were first launched, and the same moulded card has been carried forward to the currently manufactured analysers (GEM Premier 3000, GEM Premier 3500, GEM Premier 4000 and GEM Premier 5000). The sensor card is located in the disposable cartridge which is used in these instruments. Electrochemical sensors for the following critical care analytes are located on the sensor card: partial pressure of oxygen and

carbon dioxide (pO2 and pCO2), pH, Na+, K+, Ca++, Cl-, glucose, lactate and haematocrit. (IL 2017a)

PVC has specific advantages as a sensor card material for the electrochemical sensors used in the GEM Premier products. Sensing membranes used for certain sensors (pH, Na+, K+, Ca++, pCO2) are based on PVC membranes and are solvent cast directly on the sensor card from a solution of tetrahydrofuran (THF). Because THF is a strong solvent for PVC, there is strong adhesion between the cast membranes and the PVC card, which is a critical requirement for sensors to have long use life and shelf life. The PVC sensor card is produced by injection moulding. Lead compounds have been traditionally used as a thermal stabilizer to prevent breakdown of the polymer at the high temperatures required for the injection moulding process. IL has determined that the presence of lead in the PVC sensor card does not interfere with measurement of any analytes on the GEM Premier family of analysers. In fact, recent testing has shown that presence of lead in the plastic sensor card appears to enhance performance and is required for proper functioning of certain sensors deposited on the PVC sensor card; specifically, pO2, glucose, lactate and haematocrit. (IL 2017a)

IL (2017a) states that data from the GEM Premier family of critical care analysers are used daily in hospitals around the world to make life-saving decisions regarding patient health. It is imperative that these data have the highest possible reliability and accuracy. At present IL claims that the reliability of the substances investigated as possible candidates for substitution is not ensured.

IL (2017a) admits that additional blood analysers exist on the market, such as the Siemens RapidPoint 500 and Roche Cobas 123), however claims that the GEM Premier analysers offer several advantages:

- According to IL the GEM analyzers utilize the Intelligent Quality Management (iQM™) system which automatically detects, corrects, and documents all errors, and confirms resolution ensuring patient safety and the highest quality of test results:
  - iQM™ reduces the time to error detection to minutes instead of the hours required by traditional manual or Automated Quality Control (AQC) that normally are run every 8 hours.
  - iQM™ also eliminates manual intervention to correct sensor errors, such as removal of blood clots from the system, thereby significantly reducing time needed for the testing process and enhancing ease of use. According to IL, the reduced testing time will, in critical situations, improve patient safety significantly by producing rapid and correct results and reducing the need for repeat testing.
  - IL explains that iQM results in a longer usable lifetime of the disposable cartridge, compared to other analyzers based on AQC technology. The iQM system conducts quality control as an integrated part of the testing process whereas AQC counts quality control samples as separate tests thus reducing available number of patient blood samples during cartridge life.
- The GEM Premier analyzers are said to be the only systems of their kind to offer a single, disposable measurement cartridge which can be stored up to 9 months at

room temperature. Other competing technologies utilize multiple cartridges to perform the same functions, some of which require refrigerated storage.

- It is further explained that every sensor card produced for the GEM Premier family of analysers is 100% tested at the factory to assure highest levels of quality to the customer, whereas other competing technologies use the concept of Acceptable Quality Limit (AQL) testing, where a sample of manufactured parts are tested to find whether the entire production lot meets the product specifications.

7.2.2. The availability of alternatives for lead in the platinization process

During the existing exemption period, IL has been working to replace lead as a thermal stabilizer in the PVC sensor card. IL explains that several initial candidates, considered as thermal stabilizers to replace lead in the sensor card, have been investigated and shown to produce: deterioration in accuracy of the sodium sensor, decreased sensitivity of the oxygen sensor, and increased imprecision for measurement of glucose, lactate and hematocrit in blood on the GEM Premier family of instruments. (IL 2017a)

IL (2017a) summarise the following findings from testing they have performed of PVC resins containing alternative thermal stabilizers, since 2012:

- All RoHS compliant resins had decreased sensitivity (slope) of the pO2 sensor.
- All resins containing organo-tin compounds resulted in deterioration in accuracy of the GEM Premier sodium sensor outside of product specifications. In addition, thioorgano-tin compounds resulted in increased glucose and lactate sensor imprecision outside of GEM Premier product specifications.
- CaZn stearate and Zn stearate stabilizers resulted in increased glucose and lactate sensor imprecision outside of product claims. These stabilizers also resulted in decreased pCO2 sensor slope (sensitivity).
- The majority of PVC resins containing organic based stabilizers (OBS) resulted in increased glucose and lactate sensor imprecision outside of product claims. However, two resins containing OBS stabilizers (Teknor Apex 8009B-1 and 8009B-2), considered proprietary formulations by the Teknor Apex Corp., passed specifications for glucose and lactate imprecision, but were significantly worse than that of production resin containing lead thermal stabilizer. Results were close to the limit and are considered at risk for not meeting product specifications with normal variation in product performance.
- Color Master 1304 resin, containing various thermal stabilizers plus 0.098% lead (in the form of tribasic lead sulfate, TBLS) met product specifications, however even these formulations were significantly worse than that of production resin containing lead thermal stabilizer. Results were close to the limit and are considered at risk for not meeting product specifications with normal variation in product performance.

IL (2017a) thus conclude that no RoHS-compliant resin has yet demonstrated acceptable performance for all sensors, although resins containing 0.098% lead have shown improved performance. The consistency of negative impact on glucose and

lactate precision and loss of pO2 sensor slope (sensitivity) across tests of different RoHS compliant resins containing various thermal stabilizers, leads IL to conclude that the problem is likely from the reduction of lead rather than from addition of some unknown interfering substance. Some of the alternative PVC thermal stabilizers initially researched, when used in addition to minimal quantities of lead in concentrations below 0.1% in the sensor card (i.e. lead in a concentration below the limit specified by the EU RoHS directive), have shown results moving in a positive direction to address the performance problems seen with the alternative thermal stabilizers alone. The focus of continued investigations thus includes optimizing the selection of an alternative thermal stabilizer in addition to presence of 0.098% lead in the PVC resin of the GEM Premier sensor card. Further details are given in the exemption application.

The EU Directive 98/79/EC on in-vitro diagnostic medical devices specifically mandates that a manufacturer must meet its product claims for analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection. Therefore the investigated alternative stabilizers are not technically practical or viable alternatives at this time as they impede the reliability of test results carried out with the sensor card, thereby preventing the analyser from performing its intended function within established product claims. (IL 2017a)

IL (2017a) concludes that presence of lead in the PVC sensor card is enhancing sensor performance, which is important to provide the optimum performance claimed in product publications. At present, the search continues for an alternative, RoHS compliant thermal stabilizer which will restore sensor functions to their original level of performance, consistent with product claims.

7.2.3. Environmental arguments

IL (2017a) has submitted a life-cycle analysis report as annex to its application. The LCA results are summarised in IL's application, from which the following has been reproduced (IL 2017a):

> "*The LCA analysed the current card, compared with two potential alternative cards. The results are shown for 1 GEM Premier 3000/3500 Sensor Card (the product). The whole life cycle of the product was analysed.*
>
> *[...] The LCA made the following assumptions:*

- *The card is manufactured in the US, and used in Europe*
- *The current card and the two alternatives are all assumed to provide the same functionality and lifespan*
- *Both potential alternative cards contain an Organic Based Stabilizer (OBS) to replace the lead in the current card*

> *The results of the LCA are as follows:*
>
> *[...]The carbon footprint results show that the current card has a carbon footprint of 10.5 gCO2eq, compared with 13.9 and 13.5 for the two alternatives*

(lower carbon footprint is better). The carbon footprint of the current card is 22% lower than the next lowest card.

The LCA also analysed other environmental measures [...] Considering 23 environmental impact measures, the current card was found to have the lowest environmental impacts in 20 categories, and the highest in the remaining 3 categories. The current card was found to consume less energy in its production, distribution, use and disposal than both alternative cards.

[...] the European LCA methodology used in this LCA [...] provide one approximate general human health parameter termed Human Toxicity. All three card configurations showed Human Toxicity results within the same order of magnitude. To further investigate human health issues, another LCA methodology was also applied, the US Environmental Protection Agency (EPA) methodology. This showed that the combined Human Toxicity values were not significantly different for the three cards, supporting the European methodology results."

Based on the results of the LCA, IL concludes that the current GEM Premier Sensor Card performs better in environmental terms than the potential alternatives.

7.2.4. Road map to substitution

IL (2017a) states that upon identification of the RoHS compliant resin, additional time will be needed for development and update of the EU compliance documentation required for medical devices for a new sensor card according to applicable EU legislation and other applicable worldwide regulatory requirements for medical devices. IL is confident that the successful replacement of lead as a stabilizer in the PVC material of the sensor card across the entire GEM Premier product line will be concluded within the coming 7 years. The exemption application includes details on the substitution project plan (see Table 7-1) and estimates RoHS Compliance of GEM Sensor Card Resin to be accomplished by April 1, 2022.

Table 7-1: Revised Project Plan: Duration column represents number of working days for each activity and start/finish dates columns include non-working days except Shelf Life testing.

Task Name	Duration (number of working days)	Start	Finish	% Complete
RoHS Compliance of GEM Sensor Card Resin	**1975 days**	**September 8, 2014**	**April 1, 2022**	**21%**
Procure vendors and resin materials	**180 days**	**September 8, 2014**	**May 15, 2015**	**100%**
Procure vendors and raw materials	90 days	September 8, 2014	January 9, 2015	100%
Mold and prepare sensor cards	90 days	January 12, 2015	May 15, 2015	100%
Screen new resin candidates	**330 days**	**May 18, 2015**	**August 19, 2016**	**100%**
Evaluate new resin candidates	180 days	May 18, 2015	January 22, 2016	100%
Optimize internal processes	90 days	January 25, 2016	May 27, 2016	100%
Data analysis and review	60 days	May 30, 2016	August 19, 2016	100%
Feasibility	**220 days**	**August 22, 2016**	**July 07, 2017**	**90%**
Select Top 2 resin candidates using GEM 3000	90 days	August 22, 2016	December 23, 2016	100%
Cartridge use life study GEM 3000	30 days	December 26, 2016	February 3, 2017	100%
Cartridge use life study GEM 4000	30 days	March 20, 2017	April 28, 2017	100%
Cartridge use life study GEM 5000	30 days	May 23, 2017	June 23, 2017	50%
Select top resin candidate (Data analysis and review)	10 days	June 26, 2017	July 07, 2017	0%
Design and Process Optimization	**270 days**	**June 26, 2017**	**July 6, 2018**	**0%**
Compounding and evaluation of new co-stabilizers with top resin using GEM 3000 candidate	90 days	June 26, 2017	October 27, 2017	0%
Cartridge use life study GEM 4000 - Optimized resins	30 days	October 30, 2017	December 8, 2017	0%
Cartridge use life study GEM 5000 - Optimized resins	30 days	December 11, 2017	January 19, 2018	0%
Data analysis and review to select top candidate	30 days	January 22, 2018	March 2, 2018	0%
Improve internal processes to get optimal performance of top resin candidate	90 days	March 5, 2018	July 6, 2018	0%
Pre-POP GEM 3000 and 4000	30 days	March 5, 2018	April 13, 2018	0%
Pre-POP GEM 5000 and ChemSTAT	30 days	April 16, 2018	May 25, 2018	0%
Data analysis	10 days	May 28, 2018	June 8, 2018	0%
Formal Design Review	5 days	June 25, 2018	June 29, 2018	0%
Process Validation - Resin Compounding	90 days	March 5, 2018	July 6, 2018	0%

Process Validation - Sensor Card Molding	**240 days**	**April 16, 2018**	**March 15, 2019**	**0%**
Mold Validation GEM 3000 sensor card	60 days	April 16, 2018	July 6, 2018	0%
Mold Validation GEM 4000 sensor card	60 days	July 9, 2018	September 28, 2018	0%
Mold Validation GEM 5000 sensor card	60 days	October 1, 2018	December 21, 2018	0%
Mold Validation GEM ChemSTAT sensor card	60 days	December 24, 2018	March 15, 2019	0%
Shelf Life	**240 days**	**June 30, 2018**	**February 24, 2019**	**0%**
Shelf life GEM 3000 sensor card	8 mons	June 30, 2018	February 24, 2019	0%
RoHS Compliance of GEM Sensor Card Resin	**1975 days**	**September 8, 2014**	**April 1, 2022**	**21%**
Procure vendors and resin materials	**180 days**	**September 8, 2014**	**May 15, 2015**	**100%**
Procure vendors and raw materials	90 days	September 8, 2014	January 9, 2015	100%
Mold and prepare sensor cards	90 days	January 12, 2015	May 15, 2015	100%
Screen new resin candidates	**330 days**	**May 18, 2015**	**August 19, 2016**	**100%**
Evaluate new resin candidates	180 days	May 18, 2015	January 22, 2016	100%
Optimize internal processes	90 days	January 25, 2016	May 27, 2016	100%
Data analysis and review	60 days	May 30, 2016	August 19, 2016	100%
Feasibility	**220 days**	**August 22, 2016**	**June 23, 2017**	**75%**
Select Top 2 resin candidates using GEM 3000	90 days	August 22, 2016	December 23, 2016	100%
Cartridge use life study GEM 3000	30 days	December 26, 2016	February 3, 2017	100%
Cartridge use life study GEM 4000	30 days	March 20, 2017	April 28, 2017	75%
Cartridge use life study GEM 5000	30 days	May 1, 2017	June 9, 2017	0%
Select top resin candidate (Data analysis and review)	10 days	June 12, 2017	June 23, 2017	0%
Design and Process Optimization	**270 days**	**June 26, 2017**	**July 6, 2018**	**0%**
Compounding and evaluation of new co-stabilizers with top resin using GEM 3000 candidate	90 days	June 26, 2017	October 27, 2017	0%
Cartridge use life study GEM 4000 - Optimized resins	30 days	October 30, 2017	December 8, 2017	0%
Cartridge use life study GEM 5000 - Optimized resins	30 days	December 11, 2017	January 19, 2018	0%
Data analysis and review to select top candidate	30 days	January 22, 2018	March 2, 2018	0%
Improve internal processes to get optimal performance of top resin candidate	90 days	March 5, 2018	July 6, 2018	0%

7.2.5. Socio-economic aspects

In relation to the impact on employment, IL estimates (2017b) that 90% of the blood gas analyser offerings would no longer be acceptable for use due to the exemption not being granted and would jeopardize the capabilities of European medical educational facilities, hospitals, and clinics. This would have a significant impact on healthcare quality and treatment outcomes, especially in critical care and point-of-care departments. In addition, employment and operations would be impacted due to direct effect and business-to-business dependencies in areas such as those listed here:

- *"Werfen Affiliates in EU*
- *Other medical device manufacturers with headquarters and offices located in the EU and throughout the world (e.g. Radiometer HQ based in Denmark, etc.)*
- *Roncello, Italy IL facility, where the GEM products and ancillary devices are shipped to/from and stored*
- *EU local distributors/distribution centers for GEM analyzers*

- *Logistics and processing of Refurbished units (e.g. replace/rebuild/QC/parts management, etc.)*
- *Worldwide raw material, and sub-assembly manufacturers*
- *Worldwide processing service suppliers*
- *Sales force and Marketing for customers based in Europe*
- *Technical Support e.g. call center(s) and on-site Service would be impacted*
- *Hospitals and medical clinics would be adversely impacted due to limitations in analytical capabilities to enable physicians to diagnose and treat ailments.*
- *Hospital financial budgets would be adversely impacted due to a limited if any selection of currently RoHS compliant options and the changes that could be required in infrastructure which would impact time to make such a transition (e.g. LIS, LIM, revalidations, etc.).”*

IL (2017a) also details that for executing the substitution project plan it has allocated 2 full time employees and committed in excess of $2.5mm (USD) from 2017 until the end of 2021 and they are committed to provide more resources as and when needed for the success of this project in timely fashion.

In relation to the amount of EEE placed on the market through the application under the scope of Ex. 41 of RoHS annex III, IL (2017b) estimates that approximately 963 kg (or 0.74 m^3) is to be placed on the EU market per annum through sensor cards of the GEM blood analysers. As a rough estimation for EEE to be placed on the EU market annually through sensor cards of all blood analysers using PVC resin sensor cards, IL specify 2,889 kg (or 2.22 m^3). As blood analysers cannot operate without the sensor card, IL further provides estimations of the amount of EEE that would need to be scrapped were RoHS compliant sensor cards no longer available on the EU market. In relation to the IL GEM models, this is estimated to amount to 111,640 kg (or 316.84 m^3) and for all blood analysers using PVC sensor cards 334,921 kg (950 m^3). The EEE volume provided here is calculated from the dimensions of the GEM analysers and it is assumed that other manufacturers’ systems have similar dimensions as the GEM analysers.

IL (2017b) specifies that if the exemption is not granted, then it will become challenging for hospitals and other medical care facilities to have these critical care analysers to diagnose and treat patients that assure exceptional outcomes from well-equipped healthcare institutions. This scenario is guaranteed to impose great liabilities on medical practitioners limited in analytical measurement systems and consequently data to interpret for an accurate diagnosis and treatment plan. For the patient, this means a substantially higher margin for error by physicians to make good medical decisions to provide the proper care and sustain life. Consequently, patients with diminished health may not be able to aptly perform their job functions or care for themselves and family members due to the compromised quality of healthcare that would be possible without these medical equipment providing critical information. Based on an estimated total of greater than 19,000 analysers by all manufacturers placed in the EU, this accounts for approximately 282,159,600 tests (in the EU-28, the

population total was 508,401,000[12]). In conclusion, an exemption not being granted will assuredly impact health and safety. Therefore, the societal and economic magnitude is much larger for not permitting these medical devices than permitting their use while manufactures continue to explore and pursue RoHS compliant solutions.

7.3. Stakeholder contributions

During the stakeholder consultation, a contribution was received from a healthcare facility in Germany (dated 3.12.2017), stating that the facility (hospital and laboratory) vitally depends on results from blood gas analysers such as the Instrumentation Laboratory GEM Premier products. "*Currently we have 16 GEM 4000 and GEM 5000 analysers in use at our hospital. Per year we report over 175.000 patient results. Our patient population would be seriously and adversely impacted if these manufacturers were blocked from supplying these instruments. The current product technology is well known proven and has the necessary level of reliability. Reliability in performance of these analysers is vital and absolutely non-negotiable.*"

Two further healthcare providers submitted similar contributions in support of the request, however, these were submitted after the consultation had closed. As the contributions do not provide additional information, they are not further reproduced here.

7.4. Critical review

7.4.1. REACH compliance – Relation to the REACH Regulation

According to Article 5(1)(a) an exemption may "*not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006*". If granted, the exemption would allow the use of lead in the PVC sensor cards of blood analyser devices. The REACH Regulation has thus been consulted in this respect.

Annex XIV of the REACH Regulation lists a few substances, the use of which would require an authorisation in the EU:

- Lead chromate – used in printing inks, paints and to colour vinyl, rubber and paper[13];
- Lead sulfochromate yellow –used as a pigment, a dye and as a paint and coating additive[14];

[12] IL states that this figure is based on information sourced from "Population on 1st January by age and sex", Eurostat. Retrieved 14 June, 2017. http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=proj_15npms&lang=en

[13] Data on uses from Pubchem: https://pubchem.ncbi.nlm.nih.gov/compound/lead_chromate#section=Top

[14] Data on uses from Pubchem: https://pubchem.ncbi.nlm.nih.gov/compound/53488191#section=Use-and-Manufacturing

- Lead chromate molybdate sulphate red –understood to be used as a pigment;

Seeing as the exemption for lead as a stabilizer in sensor cards of blood analysers 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 contains several entries restricting the use of lead compounds:

- Entry 16 restricts the use of lead carbonates in paints;
- Entry 17 restricts the use of lead sulphates in paints;
- Entry 63 restrict the use of lead and its compounds in jewellery and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children.
- Entry 28 and entry 30 stipulate that various lead compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public.

In the consultants view, the exemption for lead as a stabilizer in sensor cards of blood analysers 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 as a stabilizer of PVC sensor cards used in blood analysers 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, entry 28 and entry 30 of Annex XVII of the REACH Regulation would not apply. It is concluded that a renewal of the exemption would not weaken the protection afforded by REACH through entries 16, 17, 28, 29 and 63.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status April 2018). 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.

7.4.2. Scientific and technical practicability of substitution

IL argues the justification of the exemption first and foremost on the basis of the lacking reliability of the substitutes it has tested in its effort to comply with the substance restrictions:

- Though candidates have been identified that could be used to substitute lead as a stabilizer in IL's PVC sensor cards, their testing reveals that they do not provide the same reliability over time as the current stabilizer. IL (2017a) summarises some of the findings, for example specifying that all tested RoHS compliant resins resulted in decreased sensitivity (slope) of the pO2 sensor, that resins containing organo-tin compounds resulted in deterioration in accuracy of the sodium sensor, etc. (see Section 7.2.2 for further findings).

- The consistency of negative impact on glucose and lactate precision and loss of pO2 sensor slope (sensitivity) across tests of different RoHS compliant resins containing various thermal stabilizers, leads IL (2017a) to conclude that the problem is likely linked to the reduction of lead rather than to the addition of some unknown interfering substance. IL intends to focus further research on optimizing the selection of an alternative thermal stabilizer in addition to the presence of 0.098% lead in the PVC resin of the GEM Premier sensor card.

It can be understood that a wide range of substitutes exist, however their successful implementation as substitutes depends on finding the correct resin in terms of it providing comparable performance to that of the original resin. The consultants understand this compatibility to be affected from various factors, i.e the choice of resin can result in non-reliability of the sensor cards on various levels. The substitute is required not to affect the use life (once inserted in the device) and shelf life of the sensor card itself (comprised of a PVC resin). It may also not affect neither the use life nor the shelf life of the sensors for each of the measured parameters - these sensors are required to provide reliable measurements throughout their expected lifetime (1 month of use, 9 months shelf-life). In other words, both a general decreased sensitivity as well as deterioration in the reliability of results in relation to all or to one specific sensor throughout the use of a card would render a substitute not acceptable.

Investigation of the status of substitution of other producers of blood analysers suggests that research into the proper substitute is a result of tedious trial and error testing, however it is also observed that for a few manufacturers the exemption renewal is not needed.

- **Radiometer** contributed to the stakeholder consultation of the former evaluation process in 2013 through support of the request. Radiometer was contacted in February 2018 to clarify if its equipment would also require the renewal of the exemption. It responded that Radiometer will substitute the PVC with lead before the exemption expiration deadline. "*After several attempts we have found a solution that works for our specific use of the PVC. We are not sure how other manufacturers use the PVC with lead, but the substitution might be difficult and in any case the approval process is long for materials used in IVD*." (Radiometer 2018)
- **Siemens Healthineers** has also confirmed that its devices that made use of RoHS Annex IV, Ex. 41 in the past shall no longer need this exemption once it expires on 31 December 2018. Here too, the search for the suitable substitute is understood to have been a tedious process.
- As for **Abbott's I-STAT**, it is understood from IL's answers to clarification questions that it uses a silicon cartridge, eliminating the need for the lead stabilizer. Nonetheless, the I-STAT is a smaller device (handheld) that provides the service of single used tests, where silicon has traditionally been used (IL 2017b) and is not understood to be comparable. Though it is possible that materials used for single use test sensor cards would not provide the necessary reliability for multi-use test sensor cards, data is not available to allow a conclusion on this aspect, i.e. as to the feasibility of silicon as a suitable alternative material for

producing the sensor cards used for multi-use testing in equipment such as that of IL or as to the opposite.

As for substitutes for lead in the PVC cards, it is understood that some manufacturers have found suitable alternatives and shall complete the substitution before the current expiration date of the exemption, i.e. 31.12.2018. This raises a question as to whether the GEM blood analysers can be seen as comparable to equipment of other producers or whether they offer certain advantages that may justify the continued use of lead in this case. In terms of comparability of devices, various factors need to be considered.

A first aspect of importance regards the variety of analytes that can be tested by different equipment. Sensors for such analytes are located on the PVC sensor card and in the consultants view it is plausible that the precision of their measurement can be affected by its composition. In relation to the GEM blood analysis devices, IL (2017a) has detailed the following parameters: partial pressure of oxygen and carbon dioxide (pO2 and pCO2), pH, Na+, K+, Ca++, Cl-, glucose, lactate and haematocrit. To check comparability, a few devices were compared in terms of the measureable analytes - see Table 7-2. This comparison is not comprehensive but is assumed to provide a first basis to draw conclusions as to comparability of this aspect.

Table 7-2: Comparison of measurable analytes of various blood and blood gas analyses devices, compiled on basis of available specifications

	Manufacturer	Radiometer	IL	Siemens Healthineers	
	Model	**ABL90 FLEX**	**GEM Premier 5000**	**Rapid Point 500**	**RAPIDLab 348EX Blood Gas System**
Measured analytes:		**Given as specified or not in available specifications**			
Sub-groups	**Analyte**				
pH/ blood gas:	pH (acidity)	Specified	Specified	Specified	Specified
	pCO2 (carbon dioxide tension)	Specified	Specified	Specified	Specified
	pO2 (oxygen tension)	Specified	Specified	Specified	Specified
Oximetry:	ctHb (total hemoglobin concentration)	Specified	Specified	Specified	Specified
	sO2 (oxygen saturation)	Specified	Specified	Specified	Not specified
	FO2Hb (fraction of oxyhemoglobin in total hemoglobin	Specified	Specified	Specified	Not specified
	FCOHb (fraction of carboxyhemoglobin in total hemoglobin)	Specified	Specified	Specified	Not specified
	FHHb (fraction of deoxyhemoglobin in total hemoglobi	Specified	Specified	Specified	Not specified
	FMetHb (fraction of methemoglobin in total haemoglobin	Specified	Specified	Specified	Not specified
	FHbF (fraction of fetal hemoglobin)	Specified	Not specified	Not specified	Not specified
	ctBil (concentration of total bilirubin in plasma)	Specified	Specified	Specified	Not specified
Electrolytes:	cK+ (potassium ion concentration)	Specified	Specified	Specified	Specified
	cNa+ (sodium ion concentration)	Specified	Specified	Specified	Specified

	Manufacturer	Radiometer	IL	Siemens Healthineers	
	cCa2+ (calcium ion concentration)	Specified	Specified	Specified	Specified
	cCl– (chloride ion concentration)	Specified	Specified	Specified	Specified
Metabolites:	cGlu (D-glucose concentration)	Specified	Specified	Specified	Not specified
	cLac (L(+)-lactate concentration)	Specified	Specified	Specified	Not specified
Haematocrit:	Hct	Not specified	Specified	Not specified	Specified
	HCO3-	Not specified	Not specified	Not specified	Specified
	ctCO2	Not specified	Not specified	Not specified	Specified
	Calculated analytes - analytes marked in green text when they correspond to those not directly measurable.	Not specified	BE(B), BE(ecf), tHb(c), Ca^{++} (7.4), Anion gap (AG), P/F ratio, pAO_2, CaO_2, CvO_2, p_{50}, O_2cap, $sO_2(c)$, O_2ct, HCO_3 – std, TCO_2, HCO_3 – (c), A-aDO_2, paO_2/pAO_2, RI, CcO_2, a-vDO_2, Q_{sp}/Q_t (est), Q_{sp}/Q_t, Hct(c)	Not specified	ctHb, O2SAT, O2CT, HCO3-act, HCO3-std, ctCO2, Beb, BEecf, pO2(A-a), pO2 (a/A), pO2/FiO2, Ca++(7.4), Anion Gap,

Sources:
Radiometer: http://www3.hscni.net/stlabs/webhb/poct/documents/poctabl90man.pdf
Instrumentation Laboratory: http://www.instrumentationlaboratory.com/en/gem-premier-5000
Siemens Healthinieers: https://static.healthcare.siemens.com/siemens_hwem-hwem_ssxa_websites-context-root/wcm/idc/groups/public/@de/@lab/documents/download/mdax/odmw/~edisp/dx-de-rapidpoint500-technspezifikation-00882771.pdf; and https://static.healthcare.siemens.com/siemens_hwem-hwem_ssxa_websites-context-root/wcm/idc/groups/public/@global/@lab/documents/download/mdaw/mtg5/~edisp/rapidlab_348ex_brochure_final_2_web-00173655.pdf

From the comparison specified in Table 7-2, it is apparent that different devices have slight differences in terms of the analytes measured. In each case, many of the analytes compared can be measured, whereas a few are measurable only by some equipment (for example FHbF and haematocrit are not directly measurable in most devices), though they may be calculated on the basis of measured parameters in some cases. Though this comparison shows that each device has a different range of parameters that can be measured (or derived based on other measurements) it does not allow concluding whether devices of a specific manufacturer have a preference over those of others.

To confirm this assumption, the German Healthcare facility that submitted the stakeholder contribution was contacted and provided additional information (M.D. 2018b). The representative, which provided feedback is a M.D. which has specialised in laboratory medicine and which has over 17 years of experience in this area, including being responsible for the analytical activities of a few medical facilities over the last decade. To begin with, it was emphasized that blood analysis equipment in the focus of this exemption request is considered "point-of-care" equipment. This means that such equipment is used by medical practitioners to measure various blood parameters in proximity to where the patient is being taken care of (emergency rooms, intensive care units, operation rooms). Such devices provide results within relatively short periods (e.g., between 30-95 seconds from blood sample introduction) and are of importance to allow rapid diagnosis and decisions as to further care. The alternative of sending blood samples to the central laboratory requires more time and

also does not provide results for parameters unique to blood gas analysis devices (pH, pO2, pCO2, HCO3-see below).

"Blood gas analyzers require a fast turnaround-time, small amounts of blood and need to measure fast and accurate. Also they need to be as simple as possible since most staff that uses these kinds of instruments are not medical technicians but nurses or doctors. Nevertheless most modern blood gas analyzers measure not only typical blood gas analytes (i.e. pH, pO2, pCO2, HCO3-) but also other critical analytes that are mandatory in an acute care setting (i.e. glucose, hemoglobin, potassium)". (M.D. 2018a)

As for the preferences of medical facilities towards specific equipment, it was explained that these differ from blood analysis devices used in central laboratories, where it is quite common to use devices of multiple manufacturers and types. In contrast, in blood gas analysis at point-of-care, though some facilities use equipment of a few manufacturers, there is a growing tendency to use equipment of a single manufacturer and at that, to prefer the use of a single device or a small number of devices. (M.D. 2018b).

It was further elaborated (M.D. 2018a) that *"in a typical German hospital setting, the blood gas analyzers are usually from one vendor and preferably only one model is used. Reasons for this are standardization and harmonization as well as a general contract or a winning bid after a tender. Multiple instruments mean higher cost and require intensive training of staff. Also different instruments produce different values since measurement of certain analytes are not standardized. If you have only one type of blood gas analysers you get same results on every instrument in the hospital. Also standardization is advantageous in case of a system failure. The staff can quickly change to a similar instrument in a different ward"*.

To support this point, two examples were given of different German health facilities, one using 16 GEM devices manufactured by IL and the other using a similar number of blood gas analysis devices of Radiometer (M.D. 2018b).

To summarize, it can be understood that facilities may have a tendency towards using equipment of a single vendor. In contrast, as there are a number of manufacturers providing facilities with such equipment (different facilities shall have different preferences) it can be concluded that in general the relevant analyte measurements can be provided with equipment of different manufacturers and are not unique to the IL devices. As explained in Section 7.4.5, there are different considerations for deciding as to the provider of blood gas analysis devices, many of which are not related to the technical specifications of a single device but rather to aspects of its operation within the facility and the costs thereof.

In this sense, other devices could be used to substitute the GEM devices, however it is noted that in practice this would result in various impacts as detailed in Section 7.4.3 and Section 7.4.5 (waste management aspects, risk of emissions as well as costs for health care facilities, additional waste from scrapped devices prior to end-of-life, use of resources for manufacturing new devices, etc.).

A few other aspects were mentioned by IL that could be considered as possible benefits of its equipment.

- IL (2017a) stated that other competing technologies utilize multiple cartridges to perform the same functions, some of which require refrigerated storage. Refrigerated storage could mean that some equipment may have additional energy consumption relating to this requirement. Nonetheless, from the review of publicly available information on devices of other manufacturers, it can be understood that IL is not the only manufacturer of devices that do not require refrigerated storage. It is understood that the Siemens Rapidpoint 500[15] also uses a single cartridge which contains "*all components required to measure the critical analytes in a single cartridge - without gas tanks and reagent bottles*". Nonetheless, quality control (QC) is understood to take place in a separate component, whereas in the GEM devices these two functions are combined into a single unit. The Radiometer ABL90 FLEX blood gas analyser[16] is also understood to have separate locations for the sensor card and for the solution pack which is relevant for QC, though reagents are not stored separately.
- From the comparison of the time to results of various equipment it is observable that the GEM requires between 45 to 90 seconds for results from sample introduction (IL 2018), in comparison to for example the Siemens Rapidpoint 500 (60 seconds). However, the GEM results are continuously monitored for error detection and correction through the iQM system. Specifications of Siemens and Radiometer devices reviewed were not completely clear on this point; quality control was specified to be automatic and intervals for calibration were specified between 30 minutes to 8 hours, depending on the calibration type. However quality control and calibration are understood not to be the same and thus it is difficult to conclude from one as to the other. Furthermore, this aspect does not seem to be related to the use of lead in the PVC sensor cards and would not justify an exemption. The use of lead or of a substitute resin is understood to affect the reliability of measurements performed within the sensor card, i.e. the various sensors are not as reliable over time when alternative resins are used. Though the sensor card and the process control components are assembled in a single unit in GEM devices, they are considered by the consultants as separate components[17]. In other words it can be concluded that the use of lead is not necessary to ensure the continuous quality control.

7.4.3. Environmental arguments

IL provides a detailed life cycle analysis comparing the lead based resin to possible alternatives that they have been testing. Though the analysis suggests that the lead based resin has environmental advantages over other resins tested, the comparison is on the basis of the GEM equipment and the resins tested by IL. It does not allow concluding as to the comparability of substitutes applied by other producers and the

[15] See information on Siemens Rapidpoint 500 under: https://www.healthcare.siemens.co.uk/blood-gas/blood-gas-systems/rapidpoint-500-systems

[16] See page 32 in user's manual: http://www3.hscni.net/stlabs/webhb/poct/documents/poctabl90man.pdf, last accessed 13.06.2018

[17] See illustration provided under: http://www.instrumentationlaboratory.com/en/gem-premier-3000

lead based resin used by IL in the GEM devices. In this sense, on the basis of available data, it is not possible to conclude whether the GEM lead based resin has a total lower environmental impact than substitute resins applied in PVC sensor cards used in equipment of other producers or not.

Another two aspects are of importance for the evaluation of this request regarding waste management and the risks for emissions of lead at this stage.

Blood gas devices are professional medical devices, constructed as complex electronic devices for performing tasks related to blood gas analysis. Both purchase and disposal of these devices are understood to be performed on a business to business level (disposal sometimes leading to a refurbishment of the device rather than its management as waste). In this sense, it can be understood that the devices, including their complex electronics are expected to be disposed of properly. Scrapping of the devices prior to end-of-life results in the premature end-of-life of complex electronics, e.g. printed circuit boards, etc. Furthermore, the sensor card, which analyses bodily fluids (e.g., blood) needs to be retrieved and disposed of as medical waste. Sensor cards are collected by health facilities and sent for respective treatment (incineration) in the EU where it is expected that emissions are controlled as required by relevant legislation.

Though a revoke of the exemption would prevent lead from being placed on the market through the sensor cards, it seems that this would not achieve any direct benefits in terms of emission prevention or improved waste management:

- Lead emissions through its use in the sensor card are not expected - lead does not emit during use; nor are uncontrolled emissions expected in light of cards not being sent to proper waste treatment; whereas the treatment of the cards as medical waste is expected to be performed according to EU standards and to avoid emissions.
- The waste management of blood-gas analysis equipment is not understood to be affected by the compliance of the sensor cards with the substance restrictions, i.e. equipment is to undergo the same waste management regardless of whether sensor cards contain lead (IL equipment) or not (compliant competitors).
- In contrast, the fact that IL equipment shall not be operable once the sensor cards are denied market access would mean that relevant devices, expected to contain a significant amount of electronics and respective resources, would be scrapped early. Though this negative impact on the environment could be justified should positive environmental and/or health impacts be expected, the fact that actual emissions of lead can be expected to remain unchanged suggests that this is not the case.

7.4.4. Roadmap to substitution

IL requests the exemption for an additional 7 years, i.e. until 31 December 2025. The information that IL provides see Table 7-1) as to their revised project plan begins with a total estimation of the time necessary to achieve compliance and specifies 1 April 2022 as the final date for this process. It is also specified in their application that they

expect to complete updating the CE technical file of their devices by January 2022 (IL 2017a).

Aside from this data specified for the total process, the stages specified with the latest dates are (IL 2017a):

- Shelf life GEM 3000 sensor card specified to end on 24 February, 2019.
- Process Validation - Sensor Card Moulding specified to end on 15 March 2019 - this stage covers mould validation of sensor cards of GEM 3000, GEM 4000, GEM 5000 and GEM CHEMSTAT, only the last of which is expected to end at this date.

IL were asked about the time needed to complete compliance and responded in October 2017 that "*the selection of a resin candidate was planned to occur by 23rd June 2017 according to the Revised Project Plan provided in Table 3 of the application received on 16th June. We've tested substantial resin candidates that have demonstrated limitations in performance for our GEM products; therefore, none have been suitable to replace the existing resin formulation*" (IL 2017b). In this sense the consultants understand that the revised project plan provides insight as to the time needed to achieve compliance, but is not updated in relation to the actual time needed to achieve compliance. From this plan, it can be understood that were a suitable resin candidate identified by 23 June 2017, compliance could be achieved by April 2022, i.e. within ca. four years and nine months. Assuming a candidate were to be selected by now (September 2018), it would be plausible that compliance could be achieved by 1 April 2023.

7.4.5. Socio-economic aspects

IL provides some information as to the various socio-economic impacts that could result should the exemption no longer be available. Information is summarised in the table below.

Table 7-3: Possible impacts related to a scenario in which the exemption is no longer available

Impact area	General	Impact related to IL equipment	Impact related to all equipment benefiting from the exemption in the past
Lead avoided on the market and in the waste stream	Lead not to be placed on the market through PVC sensor cards using lead based stabilizers.	48.14 kg of lead to be avoided on the market	144.43 kg of lead to be avoided on the market – assumed an overestimation as some devices have achieved compliance without the exemption.
Generation of additional waste EEE	Possible equipment to be scrapped should PVC sensor cards no longer be available	111,640 kg (or 316.84 m^3) of waste could be generated if sensor cards are not available.	334,921 kg (or 950 m^3) of waste could be generated if sensor cards are not available. This is assumed to be an overestimation as some devices have achieved compliance without the exemption.
Employment	Impacts on producers of blood analysers	Employment in offices and facilities related to the manufacture and distribution of equipment in the EU would be affected (manufacture facilities,	Employment in facilities related to the manufacture of non-compliant devices would be affected (see detail in relation to IL equipment). As for producers of compliant equipment such as for example Radiometer and Siemens, these are not expected to

Impact area	General	Impact related to IL equipment	Impact related to all equipment benefiting from the exemption in the past
		suppliers, Werfen affiliates in the EU, Roncello Italy facility, EU distributors, marketing and servicing of the GEM analysers, logistics and processing of refurbished units).	have negative impacts and could also experience an increase in business should sales increase where other devices are not yet compliant. It is assumed that such impacts could be temporary or limited in range, depending on how fast compliance of the GEM devices and possibly of other non-compliant equipment is achieved.
Other impacts	▪ Impacts on European medical educational facilities, hospitals, and clinics. This would impact healthcare quality and treatment outcomes, especially in critical care and point-of-care departments. Hospitals and medical clinics would be adversely impacted due to limitations in analytical capabilities to enable physicians to diagnose and treat ailments.	▪ Based on information provided by IL (2018) equipment is understood to account for around 30% of the EU market share (and up to 40-50 % in some member States). Impacts were not further quantified.	▪ Based on information provided by IL (see section 7.2.5), equipment of other producers is understood to account for around 67% of the market share (slightly below 12,700 devices). Nonetheless, it can be understood that a share of this equipment is compliant (e.g., Radiometer, Siemens). Facilities using such equipment would not be affected (or would be affected less, depending on their blood analysis "portfolio").
	▪ Impacts on patients (health) for which the same level of medical care cannot be guaranteed. This may subsequently affect businesses should the rate of illness of the EU population rise.	▪ Impacts are in relation to an approximate total of 94,078 thousand tests performed with the GEM devices.	▪ Impacts are in relation to an approximate total of 282,160 thousand tests, though as some producers have reached RoHS compliance without the exemption, this is understood to be an overestimation.

Though a rough estimation is provided in relation to all relevant blood analysis equipment placed on the EU market, it seems that at least some of the producers of alternative equipment have substituted lead and would thus not be negatively affected from a scenario in which the exemption were no longer available. In this sense, though it cannot be excluded that additional producers may place equipment on the market for which the exemption is needed, it is concluded that the estimation IL provides in relation to its own equipment is probably closer to the impacts actually expected than the figures provided for the complete market.

There is concern in relation to blood analysis devices placed on the market before the exemption is to expire (31.12.2018). Without the PVC sensor cards, equipment legally placed on the market before this data would effectively no longer be operable once the stock of sensor cards of a specific facility is exhausted. Though it can be understood that research is being undertaken to develop substitutes that can be applied in the sensor cards used in models already on the market, a lack of supplies at present would result in idle equipment in the short term and could result in equipment being

scrapped before its end-of-life, should a longer period be needed to find and apply substitutes. To reduce the negative impact of a non-exemption scenario on health facilities already working with the GEM equipment (or with other non-compliant equipment), it would be important to ensure further supply of PVC sensor cards for existing equipment.

In this respect, Recital 20 of the Directive states that "*As product reuse, refurbishment and extension of lifetime are beneficial, spare parts need to be available*". Article 4(f) of the Directive further stipulates that the RoHS substance restrictions shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of "*EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned*". In relation to this recital and article, the consultants understand the intention of the legislator to have been to ensure that equipment placed on the market in the past could still be repairable, even in cases of a malfunction requiring the supply of a part no longer compliant with the Directive.

In the case of Ex. 41, however, it is not clear whether the PVC sensor card can be seen as a spare part. Replacement of the card is part of standard operation and not understood to be a malfunction requiring repair. Replacement is also not understood to support reuse, updating of functionalities or upgrading of capacities as once the card is replaced functionalities and capacities would be restored to their previous level. And yet without replacements for the sensor card the equipment would become non-functional.

Thus, in relation to impacts on end-users, where the PVC sensor card is not yet RoHS compliant, it is assumed that a revoke scenario of the exemption will result in non-operability of the devices already on the market once the stock of sensor cards is exhausted (shelf life of the IL sensor cards is up to 9 months). This would require replacing all relevant devices. For estimating impacts on end-users, it needs to be considered to what degree health facilities may be dependent on devices expected not to be compliant such as the IL Devices. As explained above, health facilities are likely to have preferences in relation to the devices they purchase:

> "*The decision process towards new blood gas systems is highly sophisticated, time and money consuming. You have to evaluate the pros and cons of the different manufactures and instruments on the market. Than you have to look closely at the analytical and technical performance of the instruments. For example you will have to evaluate how long it takes until the measurement is performed (so called turn-around-time), how much blood is needed for the measurement, how often the instrument needs service or maintenance and a lot of other issues".* (M.D. 2018a)

Given the expected costs of a single device, the German Healthcare facility estimates costs of such a scenario:

On investment costs: "In regards to our hospital, this equals investment costs of over 300.000 € [...] If you identified all the crucial points you will most certainly need a Europe-wide tender, since the instruments and reagents are not cheap. After

the bidding you will need to revaluate everything. Often the winner of the tender is required to demonstrate the instrument under real life conditions at the hospital. This whole process can take up to one year.

Afterwards you will also need to connect the new instruments to your hospital information system, most often by middleware. The connection requires further expenses [...] I estimate these costs at 20.000 €.

After that all staff that uses the instruments (nurses, doctors) need training. The training and its proper documentation is required by law. In our hospital around 1.200 employees were trained after we implemented the IL Werfen blood gas systems in 2007. If you train every employee at our hospital for only 1 hour this equals 1.200 hours of unproductive work time." (M.D. 2018a)

In the case of a request for exemption renewal which is denied, the exemption expires and the EU COM is required by the Directive to grant a transition period of between 12-18 months. It is noted that should the exemption expire (end of 2018), health facilities using IL equipment that would purchase new equipment would only have a short period to implement the shift from IL equipment to other suppliers. It is not clear how much time would be needed for the health sector to become aware of the need to replace existing equipment. The German Health facility estimated around a year to complete respective tendering processes, acquisition and installation of equipment and training of staff for its facility specified to have a moderate size and to operate 16 devices.

To give context to the depreciation of these investments it is noted that the average service life of blood gas analysers was estimated to be between *"5 to 7 years, depending on several facts like service and maintenance. In a heavily used environment and not properly taken care this is sometimes shorter, but I have also seen instruments running more than 8 years without any problem.* (M.D. 2018a). This also gives an idea of the relevant stock that would need to be replaced - non-compliant devices purchased over the last 5 to 7 years. Devices could also be refurbished, allowing an extension of the service life, thus it is assumed that replacement would apply to older devices as well.

Furthermore, from the available data it is apparent that IL has a significant market share and it is not clear how fast competitors could fulfil a possible supply gap. IL was thus asked to provide information as to their market share to allow understanding the amount of devices that could be affected. IL (2018) specifies their market share in the EU to be in the order of 30 % of devices, accounting for 40-50 % of the national market share in some EU countries. IL further estimate the total blood gas device stock in the EU to be in the order of 30,000 devices, with annual sales of between 3,000 to 5,000 devices per year.

The estimated IL market share of 30 % would mean that the stock of IL devices in operation in the EU accounts for around 9,000 devices and that IL annual sales would account for around 1,200 devices (based on a total of 4,000 devices sold per year).Based on the cost estimations of the German health care facility and assuming that all facilities using IL equipment are medium sized hospitals, operating around

15 devices, would suggest that 500 facilities would need to spend a total of 228 million € to replace all IL devices currently in use. These costs need to be seen in perspective of the prevention of an annual amount of ~48 kg of lead being placed on the market through the sensor cards needed to operate these devices. To give further context, assuming 9,000 IL Devices are affected, would mean that the phase-out would cost an average of 25,333 € per device to be replaced, including updating of middleware and training of staff. Assuming IL would require until April 2023 to achieve compliance, 156.6 kg of lead related to the sales of three years and three months (the time between the current expiration date and expected compliance) would be prevented. Additional costs and benefit factors may apply as detailed below, however these have not been quantified and are thus not addressed in this estimation.

Additional costs of relevance to such a scenario include:

- The cost to the environment of devices that would need to be scrapped before end-of-life as they could no longer be used without the PVC sensor card. It is possible that some devices could be sold for refurbishment, reducing the number of devices to be scrapped. It is however understood that such devices could no longer be placed on the EU market as refurbished devices and it is thus not clear if the total IL EU market share (stock of ~9,000 devices) could benefit from this practice. As a further option, should consumers decide to retain devices until the substitution is achieved, this would require additional space for storing equipment in facilities at a certain cost, though reducing the environmental costs of additional scrap;
- From the perspective of environmental costs, additional resources would also be needed to produce the replacement devices for the scrapped ones (i.e. before the end-of-life of devices are to be replaced).

It is concluded that the socio-economic costs of an exemption revoke scenario would particularly be considerable for health care facilities, in light of the understanding that this would require replacing all non-compliant devices still in use within a relatively short period, i.e., at minimum all 9,000 IL devices currently in operation in the EU. In this respect it should also be noted that this investment is for the most part to be perceived as an unexpected one, meaning that it is not planned for in health budgets and shall require a reallocation of resources from other health investments to allow realisation. Thus, despite the understanding that replacement is possible, a phase-out would not just create financial costs for health facilities but also have an impact on the investment in other services at the time of replacement and in this sense subsequently on the services (their range and/or quality) provided to patients.

It is obvious that an exemption revoke shall result in a loss of business for IL, affecting its general market share in the EU at least temporarily. Though it is possible that some facilities would revert back to IL equipment with time, once substitution is achieved, it is assumed that this may not be the case in all facilities and in any case would be expected to be a gradual process. In contrast, competitors which have achieved RoHS compliance would benefit from the phase-out of blood-gas devices, expanding their market share to replace IL devices. As for impacts related to other health services, some of these may be device related, also affecting manufacturers (though not necessarily the same ones).

In terms of use of resources, a phase-out is also expected to result in costs related to the early scrapping of replaced devices and related to the manufacture of new replacement devices. Devices at end-of-life are generally replaced with new ones; also resulting in the scrapping or use of new resources (i.e. impacts are not additive). However, the difference to an exemption renewal scenario in which these impacts incur gradually, as devices reach end-of-life, is that in case of revoke the impacts are expected to incur within a short period (at latest 9 months after sensor card stocks are exhausted). In contrast, where the exemption is renewed, sensor cards are being developed to be compatible with older equipment, meaning that a natural phase-out is not underway.

As for the placing of Pb on the market through the sales of sensor cards needed for operation of devices, here the benefit is not just related to new blood gas devices placed on the market but also to devices already in operation. The quantities of lead estimated by IL to be placed on the EU market are related to all sensor cards placed on the market, i.e. those to be used in new equipment as well as those to be used in already operative equipment. This quantity shall be avoided completely should the exemption be revoked, and vice versa. Nonetheless, the avoidance of this amount of lead understood not to affect the potential for lead emissions, which are not expected regardless of the use of lead (see Section 7.4.3).

7.4.6. Conclusions

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

I. 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**;
II. the **reliability** of substitutes is not ensured;
III. 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 review of Ex. 41 of Annex IV of the Directive, in relation to scientific and technical progress, it can be understood that alternative resins are available on the market. Some producers (e.g. Radiometer, Siemens Healthineers), have finalized testing of such resins and can already implement them as substitutes in equipment, whereas others, such as IL are still in the process of testing and certifying an alternative for use in their equipment.

IL has provided sufficient information to show their efforts into the search after a substitute. Though in their case, available resins which have been tested have not been found to be sufficiently reliable, at least for some producers reliability has been established and alternatives are to be applied to allow compliance of sensor cards of blood analysers of respective equipment, so that the exemption shall no longer be needed after 31.12.2018 for such equipment. Though the IL equipment may have an advantage over other equipment in terms of the continuous quality control that it provides, this function is not understood to be affected by the use of lead and thus an

exemption is not considered justifiable on this basis. It could also not be concluded that the devices have a wider range of technical capabilities in relation to the parameters that can be measured. Though the replacement of existing devices is considered to have high costs, in theory it is understood to be possible for users to replace existing non-compliant devices of one manufacturer with those of others.

As for information related to environmental impacts, a comparison of the resins used by manufacturers who have established compliance and between the resins used in the GEM PVC sensor cards is not possible on the basis of available information. Nonetheless, as sensor cards are in contact with bodily fluids, it can be understood that they are to be treated at end-of-life as medical waste. In this sense, all cards can be expected to be collected and sent to proper waste treatment, preventing possible emissions related to improper treatment. Though the revoke of the exemption shall remove lead from the market (positive impact) this is not expected to affect the potential for lead emissions during the sensor card lifecycle phases. In parallel, the revoke shall result in a premature scrapping of equipment which would otherwise be operable with the sensor card once it achieves compliance. **The prevention of lead** (ca. 48 kg per annum or **157 kg** assumed IL shall achieve compliance by April 2023) **thus needs to be weighed against the negative impact related to premature end-of-life of blood-gas equipment (111,640 kg** or 316.84 m^3 of WEEE). The composition of this WEEE is not clear. It can be assumed to contain various heavy metals (for example in printed circuit boards) and is thus not to be perceived as completely harmless. Though it is clear that a substitution shall result in both positive and negative impacts on the environment and possibly on health, it cannot be concluded whether the total negative impacts caused by substitution are likely to outweigh the benefits thereof.

As the PVC sensor is understood to be inherent to the function of GEM blood analysers (and possibly also to the function of non-compliant equipment of other manufacturers), it can furthermore be concluded that the discontinuation of the exemption can be expected to have a considerable impact on health service providers using equipment already on the market, as such devices shall become non-functional once PVC sensor cards cannot be replaced. Such equipment has been stated to account for a large share of the market (GEM devices are understood to have a ~30 % market share of blood analysers in the EU (IL 2018)). The renewal of the exemption would prevent the expected impacts on health facilities as devices already on the market (and understood to comprise a significant part of the EU stock) could continue to be used. An exemption revoke would further avoid costs related to resources through premature scrapping of existing devices and premature production of new devices - in both cases the volume is estimated at ~112 tonnes or 317 m^3 of equipment. It would also however prevent the placing of Pb on the EU market, estimated to relate to 48 kg Pb per year or ~157 kg assuming IL achieve compliance by April 2023, though this is not understood to result in actual benefits in the form of decreased Pb emissions.

In the consultants' opinion, possible costs related to a scenario of exemption revoke would be significant, particularly for health facilities, as the PVC card is not expected to benefit from the Article 4(f) spare part exclusion and all relevant blood gas

equipment would thus become non-operable once the stock of PVC sensor cards is exhausted (assumed at latest 9 months after the end of a transition period).

If in the European Commission's view, the removal of ca. 157 kg of lead from the market (not expected to affect Pb emissions) does not justify the negative impact of scrapping devices (ca. 112 thousand kg), for which compliant sensor cards are still in development, the exemption should be renewed on the basis of fulfilment of the third Article 5(1)(a) main criteria.

Should a renewal be considered, it would be recommended to provide it for the period assumed to be needed by IL to achieve compliance. As specified in Section 7.2.4, this is assumed to require four years and nine months, once a substitute is selected. It is assumed that time has gone by since the last communication with IL and research into further candidates (i.e., resins that include less than 0.1 % Pb) may have progressed. Though testing of candidates until suitability is concluded requires some time, it is assumed to be a stage that could be reached in the short future, or that may have already been achieved in the last months. Under the assumption that a suitable candidate has been identified by the time of writing of this report, September 2018, an exemption valid until the April 2023 should provide sufficient time for achieving compliance, while also allowing application for renewal should this process prove more challenging.

7.5. Recommendation

Substitutes have become available and are understood to be applied reliably by other blood gas manufacturers. Nonetheless, it is not clear whether the negative impacts of substitution would outweigh the benefits thereof or not. If the European Commission does not regard the premature generation of ca. 112 thousand kg of WEEE to be justified by the prevention of ca. 157 kg of lead coming on the market (no change to emissions), an exemption on the basis of the Article 5(1)(a) main criteria (III) could be granted. Socio-economic impacts, particularly for health care facilities faced with the need to phase-out all relevant blood-gas devices in operation ca. 9 months following a transition period are also in support of an exemption renewal, though not sufficient to justify an exemption on their own. Should the exemption be granted, the current formulation of Ex. 41 of Annex IV should be retained, providing a validity until April 2023.

Exemption	Duration
Annex IV, Ex. 41: Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.	31.03.2023

Otherwise, the exemption is recommended for revoke, providing a transition period of 18 months to ease the transition.

Exemption	Duration
Annex IV, Ex. 41: Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.	A transition period is recommended for 18 months.

8. Request 2017-3

"Lead in solders of alpha spectrometers, pulse-processing electronics, scintillation detectors and spectroscopy systems used in equipment to identify radiation, expiring on 23 July 2024"

Declaration

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

Acronyms and definitions

AMETEK	AMETEK–Advanced Measurement Technology
EoL	End of life
Pb	Lead
Sn	Tin
RoHS, RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment

8.1. Background

AMETEK requests an exemption for:

> "*Lead in solders of alpha spectrometers, pulse-processing electronics, scintillation detectors and spectroscopy systems used in equipment to identify radiation*".

The exemption is requested to be added to RoHS Annex IV and to be valid for the maximum seven years until 23 July 2024. (AMETEK 2017b)

AMETEK (2017b) explains that alpha spectrometers, pulse-processing electronics, scintillation detectors and spectroscopy systems are designed and used in the nuclear and laboratory environments. The life cycle of these products are considered long term, reaching seven or more years of continuous sustained service and they are manufactured under IPC class II electronics assembly standards. Where possible, the electronic components have been replaced with lead-free substitutes. The use of a tin/lead solder is required due to the potential effects of tin whisker growth from utilizing a solder mixture of less than 3 % Pb. These instruments primarily operate in environments where the risk for tin whiskers could cause a failure in identifying or

classifying radioactive materials, which would be more harmful to the environment than allowing these instruments to utilize tin/lead solder. Since these instruments are designed for long term use in nuclear environments where replacement is not fiscally reasonable, an exemption is requested for these product lines.

8.2. Technical description of the requested exemption

8.2.1. Scientific and technical background

According to AMETEK (2017a) scintillation detectors (NaI), pulse-processing electronics, alpha spectrometers are instruments specifically designed to be used in nuclear research and measurement. Typically, these devices are integrated into systems specifically configured for the end user's application. The application may be in nuclear power plants, in research departments of nuclear science and in the monitoring of quantities and location of nuclear materials around the world.

AMETEK (2017b) uses solders with 37 % of lead, the rest being tin, to connect electronic components and electrical wirings to printed wiring boards. Lead solders are known to prevent crystalline whisker growth over the long lifetimes of the products in the scope of the requested exemption. Signals are susceptible to interference/shorting caused by tin whiskers, which would reduce the expected performance and life of the product.

8.2.2. Amount of lead used under the exemption

AMETEK (2017a) expects approximately 4.5 kg of lead per annum to be used worldwide under the requested exemption based on the estimated quantity of lead used per solder connection multiplied by the average number of solder connections per unit sold worldwide of the instruments within this exemption request. The share of lead in the EU is calculated to be around 0.7 kg per year:

M= ρ x V or Weight = density x volume
M = 11.342 mg/mm³ x 170,000 mm³
M = 1.928 kg of lead solder with 37 % of Pb
M = 1.928 x 37 %
M = 0.7134 kg

8.3. Applicant's justification for the requested exemption

8.3.1. Substitution of lead

AMETEK (2017b) states that there are no alternatives to the use of lead in solders to reliably prevent whiskers, and that at the time being, there are no substitutes available in the market for the current products. As the life cycles of these products are ending, the replacements are being designed to meet the requirements of the RoHS Directive, where design requirements and customer approval will allow.

AMETEK (2018b) declares that they will achieve RoHS compliance for approximately 61 of the 123 initially requested products by the Category 11 expiration[18] date in 2019. The remainder of products primarily consists of the NIM product family which AMETEK will continue to strive to reduce environmental impact of, when it is feasible to do so. AMETEK claims that the team has made significant progress on many of the products already. Some of the originally 419 products can probably not be made compliant for purely economic reasons, which represents a loss of these products to EU customers. Others will naturally be removed from AMETEK's price list because of obsolescence of key components and depletion of lifetime-buy components. Ultimately, AMETEK (2018b) says, if their request for exemption is granted, before the end of the requested exemption period 2024 they will either have made the products compliant or removed them from their price list.

8.3.2. Environmental arguments

AMETEK (2017b) claims that the total negative environmental, health and consumer safety impacts caused by the substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof. AMETEK (2017a) underpins this statement putting forward that tin whiskers could lead to inaccurate measurements or failures to identify nuclear material in power plants or nuclear research facilities could be detrimental to the welfare of public health and safety.

AMETEK (2018b) adds that these products are low volume and the entities that utilize these products follow strict regulations in the disposition of equipment used in nuclear science applications eliminating the risk of any hazardous materials making its way into the environment in an uncontrolled manner.

8.3.3. Socioeconomic impacts

AMETEK (2017a) states that annually, AMETEK and other manufacturers place around 300 to 500 units of devices in the scope of the requested exemption on the EU market. The electronic assemblies sold in the EU are integrated into AMETEK's support systems that make up 25 % of AMETEK's annual sales. The implications of not having the exemption granted would be detrimental to the U.S. based manufacturing facility and EU based sales and customer service locations. It would force layoffs in both the U.S. and in the European overseas sales forces and service centres currently housed in the United Kingdom, Germany, Spain, Italy and France. AMETEK (2018e) estimates their total number of employees with 220 in the USA and 40 in the EU. AMETEK (2018e) would have to lay off 13 of these 260 employees in the US and the EU in total.

AMETEK (2018b) finds it worth noting that they were the first commercial entity to develop high purity germanium radiation detection systems. Therefore, AMETEK's products are generally much older than the competitor's products. Most of the products in AMETEK's list were developed 20 to 40 years ago and have been relatively

[18] The applicant considers its devices not to fall under cat. 9 (industrial monitoring and control instruments), but under cat. 11 (other EEE not covered by cat. 1 to 10), which has to be RoHS-compliant from July 2019 on. Cat. 9 industrial monitoring and control instruments have to comply since July 2017 already.

unchanged since then, except for minor component replacements due to obsolescence. (AMETEK 2018b) states that the cost of redesigning these products is significantly greater than the value of the revenue that AMETEK obtains from them. The estimated cost of redesigning these instruments with RoHS-compliant versions is upward of eleven million dollars. This includes the research and development cost for the redesign of the electronic assemblies plus the extensive industry acceptance testing for nuclear instrumentation that is required before a product can be introduced into the market. The AMETEK Product Management Team will have to meet customers to determine if there is a market to invest the resources to re-engineer RoHS-compliant versions of these instruments. If there is a market projected past the seven-year exemption request, AMETEK will strive to replace these instruments with new versions that meet the RoHS directive.

If the exemption request is rejected AMETEK (2017a) says that there are no substitutions or replacements on the market for the instruments covered by the exemption request. AMETEK instrumentation are nuclear science and nuclear monitoring instruments specifically designed for use with integrated systems to meet AMETEK's customers' requirements. AMETEK (2018a) states that nuclear research is built upon years of study and experimentation. To complete years of study in a reliable and repeatable method the instruments being used must be highly reliable but also perform the exact same way each time they are used. Nuclear research laboratories design and build the experiments based on the function and characteristics of the instruments available on the market. A laboratory will take years to design their facility for their specific purpose and, in most cases, make design decisions based on the performance of the equipment. When a group of instruments are removed from the market the laboratory or research facility must replace the equipment when the existing instruments service life is expired, or the instrument is damaged beyond repair. When this occurs, and a new piece of equipment is required the experiment must be revalidated. Each piece of equipment is designed to perform a specific function whether it is counting, timing, amplifying, discriminating or detecting. If equipment cannot be procured that performs in the same manner or is not compatible with the existing array of instruments they are coupled with, the facility is forced to replace the entire array in which the same method of monitoring may not be available. Once a method is approved for facilities they are propagated throughout the installations that are maintained by the controlling entity. Since facilities can take decades to come online, it is critical that the customer has the equipment that has been approved to be available yet the order for the equipment cannot be made until the implementation date is within the correct timeline for the installation. If the products requested within this exemption are removed from the market prematurely there is the issue of the facility having to request the approval of an alternate method of monitoring.

8.4. Critical review

8.4.1. REACH compliance – Relation to the REACH Regulation

If granted, the exemption would allow the use of lead in solders of certain EEE. Annex XIV of the REACH Regulation contains several entries for lead compounds, use of which requires authorization:

- 10. Lead chromate
- 11. Lead sulfochromate
- 12. Lead chromate molybdate sulphate red

In the applications in the scope of the reviewed exemption, lead is used in solders that become parts of articles. None of the above listed substances is relevant for this case, neither as directly added substance nor as substance that can reasonably be assumed to be generated in the course of the manufacturing process.

Annex XVII of the REACH Regulation bans the use of the following lead compounds:

- 16. Lead carbonates in paints
- 17. Lead sulphate in paints

Neither the above substances nor their applications are, however, relevant for the exemption request in the scope of this review.

Appendix 1 of this report lists entry 28 and entry 30 in Annex XVII of the REACH Regulation, stipulating that lead and its compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public. A prerequisite to granting the requested exemption would therefore be to establish whether the intended use of lead in this exemption request might weaken the environmental and health protection afforded by the REACH regulation.

In the consultants' understanding, the restrictions for substances under entry 28 and entry 30 of Annex XVII do not apply. The use of lead in EEE in the scope of the exemption in the consultants' point of view is not a supply of lead and its compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, entry 30 of Annex XVII of the REACH Regulation does not apply.

Entry 63 of Annex XVII stipulates that lead and its compounds:

- "shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0.05 % by weight."
- "shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0.05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children."
  This restriction does, however, not apply to articles within the scope of Directive

2011/65/EU (RoHS 2). Neither are EEE in the scope of the reviewed exemption expected to be accessible to children under normal or reasonably foreseeable conditions of use, nor can they be foreseeably and reasonably be expected to be placed in the mouth by children.

The restrictions of lead and its compounds listed under entry 63 thus do not apply to the applications in the scope of this requested exemption.

No other entries of relevance for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status April 2018). 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.

8.4.2. Scientific and technical practicability and reliability of substitution and elimination

Whisker risk and mitigation in other EEE and in the automotive sector

Tin whiskers are a risk that can at least be mitigated if not completely avoided. Lead-free solders are standard meanwhile in other EEE and in vehicles which have long life cycles, which are operated in harsh environments, and/or which are safety relevant. The applicant was therefore asked why the risk of whiskers for his devices is different to a degree that would justify an exemption.

AMETEK (2017a) explained that the level of reliability required for nuclear systems is inherently higher than that of consumer electronics and even higher than the automotive industry. Long life cycles stretch far greater than that of consumer or automotive. The applicant routinely services instruments built in the past thirty years. The continued use of a 37 % lead solder has mitigated tin whiskers growth so that routinely serviced instruments built in the past thirty years have not displayed any evidence of tin whisker growth. The consumer market and automotive industry can also easily replace a failed component. Annealing, conformal coatings and other methods utilized to reduce tin-whisker growth are not viable in these applications. Annealing impacts heat sensitive components and conformal coatings reduce the serviceability. Items other than the equipment in the scope of this exemption request which operate in harsh environments and/or are of safety relevance are replaceable instead of requiring serviceability. This enables mitigating methods that force replacement rather than service at a component level.

Over the past ten years AMETEK-AMT has replaced non-RoHS components with RoHS versions where the impact did not affect form, fit or function or had zero impact on the functionality of the instruments (AMETEK 2017a). The assemblies within this exemption request still utilize through-hole technology (THT) when most of the industry has moved over to surface mount technology (SMT). This has forced AMETEK (2017a) to procure life time buys and secure contracts from inventory management companies to ensure the procurement of materials necessary to manufacture their electronic assemblies and supply the instrumentation that meet their customers'

specifications and demands. The solder used to secure these components, however, has not been replaced due to the impact of heat sensitive components and the high-reliability required for the application.

AMETEK (2017a) further on states that "*the impact of modifying the instruments past their initial designs to meet RoHS requirements will change the form fit and function from their originally designed purpose and will have a negative impact on the applications our customers use them in. Most of these instruments have been on the market for twenty years, some as long as forty-five years*". The applicant's customers have been using these same instruments in their application for just as long. To have a major modification to the electrical characteristics of the circuitry by replacing leaded assemblies with new lead-free designs would be detrimental to the function of the instruments and force customers to rebuild entire laboratories and research facilities along with impacting the standardized nuclear material monitoring methods. AMETEK (2017a) intends supplying its customers these instruments until all available stock is used up which forces the obsolescence of the products. The plan for the obsolescence of these assemblies is going to be determined by the availability of the components.

8.4.3. Competitors' arguments as to the practicability of lead substitution

The consultants contacted AMETEK's competitors to clarify whether they have found lead-free alternatives. Berthold (2018), Canberra/Mirion (2018a), FAST ComTec (2018) and CAEN S.p.A. (2018) thereupon confirmed the RoHS-compliance of their equipment in the scope of the requested exemption. Canberra/Mirion (2018a) even claims a 95 % overlap with AMETEK's product portfolio, either on a one-to-one basis or on instrumentation that can fulfil the same functions and supported this claim with a list of these products. Berthold (2018), Canberra/Mirion (2018a), FAST ComTec (2018) and CAEN S.p.A. (2018) therefore stated that

- they produce products comparable to the AMETEK products in the scope of AMETEK's exemption request;
- these products do not require the use of lead in the applications which are in the scope of the exemption request

AMETEK (2018b) pointed out that the competitors' products do not conform to the same product types and therefore the competitor's statement that these types of devices can be produced lead-free does not hold true for most of the products AMETEK is requesting the exemption for.

Furthermore, AMETEK (2018b) say that the competitors' products are not a NIM-based (Nuclear Instrumentation Modules) product line which represents over 70 % of the exemption request. NIM are designed for a specific purpose and to the requirements of DOE NIM standards DOE/ER-0457T for the common footprint for electronic modules used in particle and nuclear physics. The removal of this product line from the market will force customers in the EU to replace existing system designs with more expensive alternatives if there are any available. In addition, AMETEK (2018b) claim that their products are not just for commercial use in research laboratories or universities. They

are built to meet the NQA-1 QL-3 requirements for use in important-to-safety or mission areas or to a higher quality requirement when required by contract. Canberra/Mirion (2018b) gives an overview on the standards mentioned above and in the discussion that follows.

Table 8-1: Overview of standards relevant for the exemption request

Standard	Scope
NQA-1 QL-3	More recent US higher level (more abstract) standard very general for construction of Nuclear Power Plants. It is sort the highest level not particularly associated with electronics or instrumentation. It also describes choice of land, building materials, procurement and QA testing requirements etc. Here is the notion of QL or Quality level introduced. QL-3 is a Low Risk level.
DOE/ER-0457T (NIM)	NIM standard: Technical standard prescribing exact physical dimensions, connector layout, required power, interconnections, impedance of inputs, signal parameters (max voltage, speed, …) and allowed connector types. If the instruments do not fulfil this standard they cannot be called "NIM" and they will essentially not be able to be used in a NIM instrumentation chain.
IEC 61226 and IAEA SSG-30	More abstract standards describing in general terms what different safety instruments and monitoring is required when operating a Nuclear Power plant and/or nuclear reactor. It describes the different categories or classes of instruments that are needed to safely operate a reactor. It then lists per categories, and again in general terms, what level of integrity, example seismic resistance, is needed and what level of robustness and redundancy is required.

Source: Canberra/Mirion (2018b)

The question arising from the technical point of view is thus whether the AMETEK equipment in the scope of the exemption request has to comply with stricter quality and reliability requirements than their competitors' equipment so that the use of lead is scientifically and technically impracticable in AMETEK's devices, while the competitors' products are RoHS-compliant. Upon request, Canberra/Mirion (2018b) and FAST ComTec (2018) both confirmed that they have RoHS-compliant NIM equipment in their portfolio as well, and Canberra/Mirion (2018b) additionally confirmed that some of their products also comply with NQA-1 QL3 or even up to QL-1 (High Risk) depending from product to product and the intended use in nuclear power plants. None of the competitors supported AMETEK's exemption request. Adding to this, AMETEK (2018b) themselves say that they have achieved RoHS compliance already for 61 out of the 123 products originally in the scope of their exemption request, and that, if their request for exemption is granted, before the end of the requested exemption period 2024 they will either have made the products compliant or removed them from their price list.

Based on the above information, the consultants conclude that that scientifically and technically, the substitution of lead is practicable in the applications in the scope of this exemption request. Even though tin whiskers are a potential threat to reliability of lead-free electronics, AMETEK's competitors prove that these risks can be managed and mitigated to a degree that enables the production of at least sufficiently reliable lead-free soldered products. Adding to this, if the use of lead was, as AMETEK declare,

technically impracticable, AMETEK could not have achieved RoHS compliance for any of these products. Granting an exemption would thus not be in line with Art. 5(1)(a)(i) in the consultant's point of view.

8.4.4. Environmental arguments

Art. 5(1)(a)(III) would allow granting an exemption if 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. AMETEK (2017a) believe that this applies for the continued use of the lead in their devices putting forward that tin whiskers could lead to inaccurate measurements or failures to identify nuclear material in power plants or nuclear research facilities, which could be detrimental to the welfare of public health and safety. Since the substitution of lead is, however, scientifically and technically practicable as detailed above, the consultants do not see that this risk would actually occur to a degree that would exceed the current risk level with lead-containing devices.

AMETEK (2017a) also argue that their products are low volume, and the entities that utilize these products follow strict regulations in the disposition of equipment used in nuclear science applications eliminating the risk of any hazardous materials making its way into the environment in an uncontrolled manner.

Sound treatment of waste EEE certainly avoids or at least reduces adverse environmental and health impacts and thus may result in a situation that the continued use of a restricted substance may actually be likely to outweigh negative environmental, health and safety aspects of its substitution. The consultants do not see, however, that the environmental and health risks of substitution put forward by AMETEK actually apply. AMETEK's argument would therefore not justify granting an exemption based on Art. 5(1)(a)(III). Beyond this, Art. 5(1)(a) does not foresee granting exemptions purely on the base that devices containing restricted substances are properly taken care of at their end-of-life stage.

8.4.5. Socioeconomic Impacts

AMETEK puts forward the following economic aspects that would occur in case the requested exemption is not granted[19]:

- The cost of redesigning some of the equipment in relation to the sales potential is too high to enable an economically viable shift towards RoHS compliance;
- AMETEK would have to lay off 13 of their staff in the EU (40 total) and in the USA (220);
- Around 1,000 laboratories in the EU could be affected in their work, would have to scrap old equipment and have to invest in new equipment;

Even though FAST ComTec (2018) offers RoHS compliant NIM and other equipment in the scope of the requested exemption, they confirmed that from an economical point of view, the limited number of customers and shrinking market for such devices may not offer the potential to provide an adequate financial compensation for the required

[19] For details see section 7.2.5 on page 52

efforts. It can therefore not be completely excluded that AMETEK produces some type of equipment that would no longer be available should the exemption not be granted.

According to Berthold (2018) and AMETEK (2018e), timing and cost for changing from NIM to a newer standard equipment varies by user and is dependent on the scope of their system design and measurement processes. Arguably, a transition away from NIMs to alternative technologies could take anywhere from six months to three or more years driven by customers' financial budgetary process and system/experiment test and requalification. Total costs could easily exceed hundreds of thousands of dollars for the system itself, and possibly millions depending on the extent of system redesign and process requalification.

Canberra/Mirion (2018a) stated that although the original installed base of NIM based units was indeed in the order of 1000 installed devices and that only a fraction of these installations really needs qualification and validation testing. The vast majority (~90%) are in Universities and Research Institutes used in different experiments. The individual units are re-assembled per each experiment and generally don't need extensive validation by the nature of the users.

According to Canberra/Mirion (2018a), from this initial installed base, customers whose application requires validation by regulatory authorities, have moved to more compact digital electronics in the last 10 years. Such replacements have been done with digital electronics hardware from Mirion/Canberra, Ortec, and other suppliers such as e.g. CAEN, TIK. Canberra/Mirion (2018a) cannot exclude that there are still a few users that run on very old electronics but these would typically not be in the industrial area where validation is required.

Most of the devices in the scope of AMETEK's exemption request is NIM standard equipment. Canberra/Mirion (2018a) explicates that the big advantage of the NIM standard is that the individual electronic modules are fully interchangeable between the different manufacturers. There is no problem to exchange Ametec/Ortec units with for example CAEN NIM modules. Furthermore, this interchangeability is valid also at the interface to other hardware such as radiation detection devices and/or other data processing technology/IT. By no means are users of NIM standard bound to AMETEK equipment.

AMETEK (2018c) admits that Canberra/Mirion's statements are not false, but rather cannot be used as the sole determination of industries need or usage for nuclear instrumentation. Input from actual end-users of the equipment must be included and cannot be made solely from one or two select entities. AMETEK (2018c) end-user customers have purchased and are using AMETEK's equipment in their labs, universities, and businesses throughout Europe. Difficulties imposed by a forced transition of technology must be fully understood and calculated into the equation. It is not simply about the cost and availability of any one device, but the need of end-users to redesign entire measurement systems, and then to conduct detailed testing, analysis, and qualification to ensure any "new" system provides reproducible results with the same level of performance as previously achieved. According to AMETEK (2018c), this can consume time and cost far beyond the cost of specific devices and create financial challenges that are not sustainable by customers in various industries.

AMETEK (2018d) was asked whether some of their customers could confirm that now and in the foreseeable future they can only use AMETEKs equipment in their laboratories and businesses, and what would be the consequence for them if the exemption is not granted. AMETEK, however, did not provide such information.

The core socioeconomic question is whether and how far laboratories in the EU or the European Economic Area would be affected should the exemption not be granted. Overall, the available information does not provide a clearer picture as to whether and to which degree and in which numbers laboratories might be affected. Statements from laboratories, even though requested from AMETEK, are not available. The consultants cannot completely rule out that some laboratories might be affected, but assume that the impact would be limited given the shrinking market and the possibility that other manufacturers offer RoHS-compliant NIM and other equipment in the scope of this exemption request. Further on, Art. 4(4)(e) would still allow "repair and upgrade" of those devices placed on the market prior to 22 July 2017 or 22 July 2019 respectively[20] so that these products remain operational.

Should AMETEK's customers nevertheless be seriously affected and see no possibilities to continue their work adequately without certain AMETEK equipment, they could still request this exemption again for those specific AMETEK devices that remain indispensable to avoid that EU nuclear research and safety would be seriously affected. Since AMETEK's markets outside the EU would remain available for their equipment as long as there are no regulations similar to the EU RoHS, it can be assumed that the devices will be continued to be produced and will still be available for the EU market should the exemption be granted after a successful exemption request.

Concerning the employment, the consults assume that the job losses (13 at AMETEK) are not severe enough as a socioeconomic impact to justify granting an exemption, the more as some of the 13 jobs lost at AMETEK might be replaced by additional employment at competitors whose market share might increase if the exemption is not granted.

8.4.6. Conclusions

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

(I) the 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;
(II) the reliability of substitutes is not ensured;

[20] The 2019 deadline applies for AMETEK's categorization of the equipment in the scope of this exemption request as category 11. Since the categorization of equipment is the producers' responsibility and because the consultants recommend not to grant the exemption, the consultants did not go into deliberations as to whether AMETEK's equipment in the scope of this exemption request should be considered as cat. 9 or 11.

(III) 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.

Further on, decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account the availability of substitutes and the socioeconomic impact of substitution. Decisions on the duration of any exemptions shall take into account any potential adverse impacts on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant.

The substitution of lead is scientifically and technically practicable in the equipment in the scope of AMETEK's exemption request. The risk of tin whiskers, the applicant's main scientific/technical justification for the use of lead, can be mitigated and managed to avoid failures. Other manufacturers of equipment in the scope of this exemption request successfully substituted lead in their devices. Art. 5(1)(a)(I) and (II) therefore do not give ground for recommending the exemption to be granted.

The applicant argues that the exemption should also be granted because tin whiskers might cause fatal failures in nuclear measurements resulting in serious health, environmental and safety problems to a degree that is likely to outweigh the benefits of lead substitution. Since the risk of tin whiskers can, however, be mitigated and managed, the applicant's arguments do not hold true for justifying an exemption based on Art. 5(1)(a)(III).

Finally, AMETEK argues with adverse socioeconomic impacts to justify the requested exemption, i.e. loss of jobs, the disproportionate cost of RoHS compliance for some equipment and serious problems for nuclear research and other laboratories in case the exemption is not granted. The information available for the consultants actually suggests that the cost for redesigning some specific types of equipment may actually be economically prohibitive so that certain devices might no longer be available should the exemption not be granted. The consultants understand that substitution of the equipment in the scope of this exemption request is, however, in principle possible with other manufacturers' RoHS-compliant devices, the more as AMETEK did not provide supporting evidence from their customers of the opposite, despite the consultants having requested such evidence. Overall, the consultants can nevertheless not fully exclude that some laboratories and other AMETEK customers may experience serious adverse effects.

In the consultant's appraisal of the situation, based on the accessible information and the criteria stipulated in Art. 5(1)(a), an exemption would not be justified . Should this actually result in crucial and indispensable equipment no longer being available and seriously affect laboratories or other AMETEK customers, the exemption could still be requested for such equipment specifically, provided it can be proven that RoHS-compliant devices are either not available or the use of such alternatives is cost-prohibitive.

8.5. Recommendation

Based on the accessible information, the consultants recommend not to grant the requested exemption. Substitution of lead is scientifically and technically practicable and at least sufficiently reliable; the environmental, health and safety impacts of substitution are not likely to outweigh the benefits thereof; and potential socioeconomic impacts (c.f. section 8.4.5 on page 81) on laboratories and the applicant's other customers seem to be limited. Art. 5 (1) (a) in the consultants' understanding does not justify granting an exemption.

9. Request 2017-6

"Bis (2-ethylhexyl) phthalate in rubber parts such as O-rings, seals, vibration dampers, gaskets, hoses, grommets and cap-plugs that are used in engine systems including exhausts and turbochargers that are designed for use in equipment that is not designed solely for consumer use."

Declaration

In the sections that precede the "Critical review" the phrasings and wordings of stakeholders' explanations and arguments have been adopted from the documents provided by the stakeholders as far as required and reasonable in the context of the evaluation at hand. Formulations were only altered 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

DEHP	Bis(2-ethylhexyl)phthalate
EEE	Electrical and electronic equipment
EUROMOT	The European Association of Internal Combustion Engine Manufacturers
ETRMA	European Tyre & Rubber Manufacturers Association
NRMM	Non-road mobile machinery
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment
SVHC	Substance of Very High Concern

9.1. Background

The European Association of Internal Combustion Engine Manufacturers (EUROMOT) has submitted a request for exemption for:

> "*Bis (2-ethylhexyl) phthalate in rubber parts such as O-rings, seals, vibration dampers, gaskets, hoses, grommets and cap-plugs that are used in engine systems including exhausts and turbochargers that are designed for use in equipment that is not designed solely for consumer use*."

EUROMOT (2017a) explains that the engine systems are used in a variety of types of professional and industrial equipment that are in the scope of the RoHS recast Directive (2011/65/EU, referred to as RoHS 2).

DEHP has been listed in Annex II of RoHS 2 and shall be restricted in electrical and electronic equipment (EEE) as of July 2019. In consequence, rubber components used in engine systems relevant to this exemption request may no longer contain DEHP as of this date. Such rubber parts are thus now being proved for compliance and need to

undergo long-term testing on different levels to establish reliability that includes testing on the component level, on the level of the engine system and on the equipment-level.

EUROMOT (2017a) agrees that alternative plasticisers to DEHP are readily available. However, EUROMOT (2018d) further explains that though industry testing is underway, the manufacturers have encountered supply chain limitations as for the availability of DEHP-free rubber components. Therefore, reliability testing of engines has not been completed. As a result, the availability of reliable engines with DEHP-free rubber components cannot be assured by July 2019. Thus an exemption is requested.

EUROMOT (2017a) requests the maximum validity period for the exemption. According to Article 5 (2) of the RoHS 2 Directive, the maximum validity period is 5 years for EEE falling under category 11 (EEE not covered by categories 1-10).

9.1.1. Amount of DEHP used under the exemption

EUROMOT estimates the amount of DEHP entering the EU market annually through the application for which the exemption is requested to amount to ~1 tonne DEHP per year.

EUROMOT (2017a) calculated an amount of DEHP per engine of 15 grams based on the following assumptions:

- average weight of components of 10 grams,
- estimated average DEHP concentration in components 5%,
- average number of parts per engine 30.

EUROMOT estimates a quantity of 68,000 engines to be sold on the EU market per year, which accounts for a share of 8,1% of the global engines sales. Thus, EUROMOT (2017a) assumes the quantity of DEHP on the global market to be 12.5 tonnes per year.

Please note that the average number of parts per engine is an estimate. There are more complex engines with a higher number of rubber parts (see examples of engines in section 9.3.1) and vice versa.

9.2. Description of requested exemption

EUROMOT (2017a) explains that this exemption is requested for different rubber components plasticised with DEHP and used in engines that fall under category 11.

According to the applicant (EUROMOT 2017a), DEHP is added to rubber material as plasticiser in order to provide flexibility. The rubber components are used as flexible connections between parts of engine systems and assure prevention of leakage, sealing of engine parts and protection from vibration or dirt and fluids over the long lifetime of the engines for which the exemption is requested. In its application,

EUROMOT (2017a) lists the following rubber components in relation to the exemption request, detailing the relevant essential properties for each component sub-group:

- Flexible hoses: resistance to any contact material (e.g. fuel, lubricant oil, coolants, gases) possibly under pressure and in combination with severe surrounding conditions (e.g. dirty building sites, chemical plant or oil refineries), resistance to vibration and heat;
- Gaskets: resistance to chemicals, temperature and vibration;
- Seals, O-rings: resistance to oil, engine fluid, exhaust gases, reliability throughout maintenance of the seal under conditions such as vibration or compression;
- Grommets and cap plugs: resistance to dirt, engine fluids, protection of electrical connections;
- Vibration isolators or dampers: resistance to vibration.

EUROMOT (2017a) argues that there no alternative plasticizers available that provide reliable rubber material with the specific requirements.

Each type of engine can be used in a variety of end products, so that most engine components have to be tested to a variety of performance and test standards to ensure reliability for all end-use applications EUROMOT (2018a) under a wide a range of conditions e.g. as EUROMOT (2018d) explains in "*a genset in the Arctic, a compressor in the Sahara Desert, a pump on an oil drilling platform*". As one type of engine, EUROMOT (2017a) mentions a diesel engine.

According to EUROMOT (2017a), the engines are used in types of equipment "*which includes stationary equipment and those types of machinery that can be moved from location to location, so are not permanently fixed at one location, but are stationary when in use, which can be for long periods*". The following examples are given by EUROMOT (2017a):

- *"Fixed and mobile generators*
- *Fixed and mobile compressors*
- *Agricultural irrigation pumps. These are standalone equipment which may be moved from one field to another, but are stationary when in use*
- *Drilling machines*
- *Rock crushers*
- *Welding sets that are mounted onto trailers.*
- *Commercial types of equipment that may be sold to leasing companies and that could be used by both professionals and consumers. These would include chain saws, leaf blowers, some types of mowers, small-size diggers, etc."*

Article 3(28) of the RoHS 2 Directive[21] refers to non-road mobile machinery (NRMM), excluding equipment with a traction drive powered by an external power source from the scope of the directive. An amendment of this article published in 2017, does not significantly affect the scope of equipment that requires this exemption according to

[21] Published in the Official Journal on 21.11.2017, available under http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017L2102&from=EN

EUROMOT (2018a). Thus, the exemption request and its scope is not affected by this RoHS2 amendment that came into force during the evaluation process.

9.3. Applicant's justification for exemption

9.3.1. Possible alternatives for substituting RoHS substances

In the original application, EUROMOT (2017a) discusses alternative plasticisers and alternative polymers based on literature data. EUROMOT (2017a) initially claimed that "*manufacturers of the types of rubber components that are used in engines have carried out little research and none appears to be published*". According to the application, the essential chemical and physical properties of DEHP that provide the combination of hardness / stiffness and flexibility of the rubber material that remains stable over the lifetime of the engines are a low volatility, low migration rates, low solubility of the plasticiser in the contact fluids, high viscosity. EUROMOT (2017a) initially states that no alternative plasticizer is available that provides these properties in the rubber polymers that are usually used in engines (chloroprene rubber, nitrile rubber (NBR), ethylene propylene polymers (EPM and EPDM rubbers) and epichlorohydrin (ECO) rubber). EUROMOT (2017a) also discusses alternative polymers but states that they act differently / provide a lower performance in relation to essential requirements. However, in later communication, EUROMOT (2017d) explains that engine manufacturers have been facing ongoing challenges in obtaining clear information about the RoHS compliance of their suppliers. The information obtained indicates that DEHP is a commonly used plasticizer in rubber engine components. EUROMOT (2018d) further explains that the information requirements under REACH on SVHC according to Article 33 of the REACH Regulation No. 1907/2006 did not assist manufacturers to obtain information on SVHC in articles from suppliers *"as the full engine had been regarded as the "article""* before European Court of Justice ruling on the definition of articles according to EUROMOT (2018d). From the whole engine, DEHP in rubber components is only a small percentage of the overall article, given that most of an engine is steel.

As for the complexity of the supply chain, one member of EUROMOT (EUROMOT 2018d) explains that they have 30 to 50 suppliers for a specific rubber component eventually supplying their rubber material from additional tier suppliers; despite possible rubber formulation differences, the specific rubber components have the identical part number for the engine manufacturer. EUROMOT (2018d) further illustrates the complexity of the supply chain for a vibration damper used in engines of the requested scope:

- *„Vibration dampers are bought by engine manufacturers from a vibration damper manufacturer who produce these components from rubber sheet, steel and other materials.*
- *The vibration damper manufacturer buys rubber from their suppliers. Usually they will have several suppliers, as reliance on a sole supplier is risky if that supplier shuts down. Thus, even though an engine manufacturer does not have contact*

with these rubber suppliers, they must try to ensure that all sources of rubber a) are RoHS-compliant, b) meet their technical specification, and c) do not change rubber supplier or composition without prior notice. As several sources of rubber may be used, the engine manufacturer will need to validate all of these, first at the component level and then in engine testing.

- *Rubber suppliers themselves often do not manufacture the rubber, but are traders, importers, etc. and these can involve several additional supply chain steps. They thus may purchase rubber from direct rubber manufacturers.*"

EUROMOT (2018d) summarizes that "*manufacturers thus find that their suppliers source sub-components (including rubber parts) from various sources, and rubber components can be added at multiple stages of the assembly process. Engine manufacturers often have no contact with the rubber manufacturers; in many cases, they do not even know who these manufacturers are, given that their suppliers handle supplier lists and assembly methods as proprietary company information. Though manufacturers request data from their suppliers in order to comply, they have no way to verify or demonstrate that this data is reliable, short of dismantling the components themselves and re-testing each individual component – and little protection if suppliers change sub-suppliers without notification*."

EUROMOT (2018d) notes that "*supply chains are even more complex when engine manufacturers buy complex subassemblies that contain rubber components such as alternators, starters, turbochargers, fuel injection systems, pumps, compressors or controllers. In these circumstances, it is the sub-assembly manufacturer who obtains either the rubber components or simpler subassemblies that contain rubber components. This complexity adds 2–4 additional stages in the supply chain which lengthens the time taken to determine RoHS status and to obtain samples for testing.*

Moreover, if an engine manufacturer's original supplier is not willing to change the materials they use (a common challenge given that many of these sub-assembly suppliers are primarily focused on their largest customers, heavy-goods road vehicles), the manufacturer must change suppliers, triggering a long round of testing and approval of complex parts from another supplier. These realities mean that it takes much longer to identify and test DEHP-free sub-assemblies than to test, verify, and substitute simple components."

As for the availability of DEHP-free rubber components, EUROMOT (2018d) states that the number of components known to contain DEHP has been significantly reduced since the RoHS DEHP restriction was published.

EUROMOT (2018d) further states that the inventory of the rubber components on RoHS compliance has so far revealed that there are at least for specific components some suppliers that use DEHP-free formulations. Manufacturers have been testing DEHP-free components and have identified the easiest potential substitute components.

Regarding the extent at which DEHP-free rubber components have been identified in the inventory at least by single manufacturers, EUROMOT (2018d) states that this "*varies considerably between engine types*", giving the following examples:

- *"One manufacturer has estimated that at present, 72% of rubber components have been identified as DEHP-free versions.*
- *Another confirms that only 11% of gaskets are not known to be RoHS-compliant (although many gaskets do not contain rubber so this figure may not be representative).*
- *Another manufacturer found in 2016 that the DEHP content of 88.7% of their rubber parts were still unidentified, but by early 2018, this had been reduced to only about 2%. This is a similar value to other manufacturers […]."*

To illustrate the current situation, EUROMOT (2018d) provides examples of engines with a list of the rubber parts and their distribution pattern that are shown in the table below. Furthermore, the table shows the proportion of rubber parts that needs a validation or re-engineering, which is due to the substitution with DEHP-free rubber material.

Table 9-1: Examples of different engines listing the components that comprise of or contain rubber

Engine A		
Total number of Unique Components	2,843	
Total number of Components at Risk for Containing DEHP	417	Components Pending Validation or Re-Engineering
Hose	63	47
Connector	15	13
Coupling	23	17
Isolator	4	3
Seal	103	70
Gasket	91	56
Tube	68	52
Belt	1	0
O-ring	49	32

Engine B		
Total number of Unique Components	1002	
Total number of Components at Risk for Containing DEHP	189	Components Pending Validation or Re-Engineering
Hose	9	5
Connector	12	8
Coupling	3	2
Isolator	7	6
Seal	84	51
Gasket	17	14
Tube	13	13
Belt	1	0
O-ring	43	23

Engine C		
Total number of Unique Components	893	
Total number of Components at Risk for Containing DEHP	178	Components Pending Validation or Re-Engineering
Hose	19	15
Connector	4	3
Coupling	2	1
Isolator	3	1
Seal	68	39
Gasket	17	9
Tube	19	17
Belt	1	0
O-ring	45	24

Note: Connectors are electrical connectors which contain rubber seals that make them waterproof; isolators are vibration dampers; hoses are more flexible than tubes; belts include drive belts and fan belts.

For the examples of engines, EUROMOT (2018d) provides information on the status of the search for substitutes in relation to the total number of parts in more detail, as shown in the following table.

Table 9-2: Status of the search for substitutes in relation to the total number of parts

Question	Engine A	Engine B	Engine C
Total number rubber parts (from table above)	417	189	178
1. Components that are confirmed available as DEHP-free	147 = 35%	67 = 35%	68 = 38%
2. Proportion of identified parts that have been tested at component level	117 = 28%	44 = 23%	46 = 26%
3. Proportion of parts undergoing testing at component level	93 = 22%	24 = 12.7%	21 = 11.8%
4. Proportion of parts not yet tested at component level due to ongoing investigation of the potential DEHP-alternative	240 = 58%	93 = 49%	82 = 46%
5. Components for which potential DEHP-free versions not yet identified	7 = 1.7%	5 = 2.6%	0 = 0%

Notes: The total number of parts associated with questions 1-5 will not equal the total number of parts for a given engine, as some parts have multiple suppliers and/or may also be shared amongst more than one engine.
Set #4 includes parts in which the plasticizer used in the application is still under investigation.
Set #5 includes parts for which a reliable substitute to DEHP has not yet been identified.

To conclude on Table 9-2, the situation according to the information provided by EUROMOT is the following:

- There are DEHP-free components that are identified as being available;
- DEHP-free components have so far partly been tested and are partly still in testing at the component level;
- There is a substantial proportion of parts where the availability of DEHP-free components are still under investigation and thus has so far not been tested at the component level;
- For a minor proportion of components, DEHP-free alternatives have not been identified yet.

EUROMOT (2018d) explains that only after all components have been tested on the components level, can full engine testing followed by reliability testing in finished equipment be performed (see also section on road map to substitution 9.3.4).

9.3.2. Environmental arguments

EUROMOT (2017a) states that environmental assessment is *"considered as not applicable to this exemption request"* and *"not needed as exemption required due to reliability being not assured"*.

9.3.3. Socio-economic impacts

Similarly, EUROMOT (2017a) considers socio-economic impact as being *"not applicable to this exemption request"* in the original application. On more detailed questions regarding possible socio-economic aspects, EUROMOT (2017d) answers the following:

- On possible **amounts of waste generated through a forced substitution** should the exemption not be granted, EUROMOT (2017d) states that *"this is difficult to calculate because, engine manufacturers may not be permitted to supply less reliable engines in the EU. This would be applicable to engines that are also in scope of the NRMM Emissions Regulation as explained in the exemption request."*
- On possible **impacts on employment**, EUROMOT (2017a) estimates that *"failing to grant this request would likely have a negative impact on EU jobs and competitiveness if many engine types and associated equipment cannot be sold in the EU, and a broader negative impact if equipment sold in the market is less reliable, as this would negatively impact productivity."*
- As for **additional costs**, EUROMOT (2017d) iterates that *"there is unlikely to be an additional cost because engine manufacturers will have to conduct the research and testing of engines with substitute components when these become available if they want to supply to the EU market (as they are already working to do). This process could not easily be accelerated (e.g. by higher expenditure) because the availability of suitable engineers is limited and this cannot be changed in the short to medium term. The biggest negative impact would be to EU users who would not be able to buy new equipment and so would either be forced to use old increasingly unreliable equipment (if this is available) or not be able to operate in the EU."*
- EUROMOT is not able to provide estimations on the size of the EU market for all equipment expected to benefit from an exemption should one be granted. *("Not known at present.")*

9.3.4. Road map to substitution

EUROMOT (2017a) schedules the following stages and timeframes, once possible substitutes are identified:

- **Component testing** comprising a component specific range of tests: 1 year
- **Engine testing** for reliability in laboratory conditions: 2 years;
- **Reliability testing in finished equipment**: 2 years.

According to EUROMOT (2017a), the total elapsed time per engine type once suitable RoHS compliant rubber parts are available will be about 5 years.

It is understood from the information provided by EUROMOT (2018d) that the **component testing** can be done for single components. EUROMOT (2017a) explains that the rubber components such as e.g. O-rings, seals, gaskets, etc. "*have to be able to maintain their essential physical properties for at least 10 years in use and so these are tested to determine whether the components' properties remain within acceptable values when exposed to the conditions that they will experience in an engine.*"

As for the **engine testing** for reliability, EUROMOT (2017a) stated that "*when all of the DEHP-free rubber parts have been tested and confirmed to meet the required specifications, these will be tested in engines. This will be possible only when all rubber parts are available as RoHS-compliant versions as there is no point in starting these tests until all parts comply. Engine testing is likely to use up to 50 engines which will run for long periods to assess the reliability of rubber components. These engine tests are carried out in controlled laboratory conditions and so may not be as severe as conditions experienced in the field. This work typically takes 2 years.*"

As for the third and final stage, **reliability testing in finished equipment**, EUROMOT (2017a) explains that this is done in field trials: "*The reliability of rubber parts will be assessed in engines in a variety of types of equipment that are used in a variety of conditions and environments. These tests are intended to be severe and assess reliability under the extreme conditions that the equipment will be exposed. Engines in finished equipment may be exposed to a variety of chemicals that could affect rubber components, be exposed to extremes of temperature, be exposed to dirt that could be abrasive and corrosive and experience non-ideal maintenance conditions that may influence reliability. These tests typically take two years to complete including dismantling engines at the end of tests to assess the condition of the rubber parts in order to estimate if they will be reliable over at least a 10 year lifetime.*"

9.4. Stakeholder contributions

During the public consultation, one contribution was submitted related to the exemption request by the Swedish Chemicals Agency KEMI (KEMI 2017). Against the understanding that exemptions from the RoHS directive should be for specific applications, KEMI states that the proposed scope of the exemption is too broad and not specific enough. KEMI further states that "*it is difficult to ascertain exactly which products that will be covered with the proposed wording in enforcement activities.*"

After the consultation, European rubber manufacturers associations were contacted to find out if they support the exemption request or alternatively do not need the requested exemption.

The European Tyre & Rubber Manufacturers Association (ETRMA 2018) stated that among their products, its members produce rubber parts that are used in engine systems such as O-rings, seals, vibration dampers, gaskets, hoses, grommets and cap-plugs where prevention of leakage, sealing of engine parts and resistance to vibration / heat / dirt and fluids over a long lifetime of the engines are needed.

As for the use of DEHP in rubber parts, ETRMA (2018) stated that, in light of the listing of this substance in Annex XIV of the REACH Regulation, they performed an internal survey back in 2014 and concluded at that time that:

- The use of DEHP had already decreased in many applications;
- and for those applications in which DEHP was still in use, companies had already found a way to replace it (i.e. candidate substitutes).

ERTMA thus assumes that DEHP is no longer present in rubber parts manufactured in the EU by its members. As for the alternative plasticizers used as substitutes, ETRMA (2018) explained that *"in some cases this is the know-how of the company"*, and cannot be revealed for confidentiality reasons.

9.5. Critical review

9.5.1. REACH compliance – Relation to the REACH Regulation

If granted, the exemption would allow the use of DEHP in rubber components in engine systems of certain equipment. A prerequisite to granting the requested exemption would therefore be to establish whether the intended use of DEHP in this exemption request might weaken the environmental and health protection afforded by the REACH regulation.

Annex XIV of the REACH Regulation contains DEHP, use of which requires authorization: DEHP has been included in the SVHC REACH candidate list for the reason of being toxic for reproduction in 2008 and has been added to Annex XIV in 2012. In July 2017, DEHP has been additionally recognized for endocrine disrupting properties.

Thus, DEHP cannot be placed on the market or used after the 21 February 2015 (Sunset date), unless an authorisation is granted.[22]

There were 15 applications for authorizations for the manufacturing or use of DEHP in the EU according to the ECHA webpage on adopted opinions and previous consultations on applications for authorisation.[23] None of these applications covered rubber material.[24] Therefore it can be understood that European rubber manufacturers

[22] Uses generally exempted from the authorization process are uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC. However these applications are not relevant for the exemption request in the scope of this review.

[23] https://echa.europa.eu/applications-for-authorisation-previous-consultations

[24] The applications for authorisation cover the following uses:

- 6 applications on the use of recycled soft PVC
- 6 applications on the use in PVC production
- 1 application one the use in ceramic /metallic printing paste
- 1 application in the military/defence sector (DEHP as a minor constituent in Cast Double Base (CDB) propellant mixtures which are used in rockets and tactical missiles)
- 1 application on the use in production of aero engine fan blades (DEHP onto titanium sheets) Two applications have been withdrawn.

producing rubber parts for engine systems use alternative plasticizers. In line with this, EUROMOT (2017d) explains that *"all of the rubber components for which this exemption is requested are sourced from manufacturers located outside of the EU where REACH authorization of the use of chemicals is not applicable. […] Our understanding of the current situation is that EU rubber manufacturers are not able to make rubber containing DEHP in the EU, but EU component manufacturers are able to import rubber sheet, block and other forms which contain DEHP from rubber manufacturers located outside of the EU as these forms are defined as articles."*

Additionally, DEHP is referred to in **REACH Annex XVII**:

- Appendix 1 of this report lists **entry 51** in Annex XVII of the REACH Regulation, stipulating that DEHP shall not be used in concentrations greater than 0.1 % by weight of the plasticised material, in toys and childcare articles. Toys and childcare articles containing DEHP in a concentration greater than 0.1 % by weight of the plasticized material shall not be placed on the market.

  Whereas basically, this restriction could apply to certain articles within the scope of Directive 2011/65/EU (RoHS 2), it is not in the scope of this requested exemption. The rubber components to be used in engine systems' articles are not expected to be accessible to children under normal or reasonably foreseeable conditions of use.
- **Entry 30** of Annex XVII is also relevant; DEHP is listed in Appendix 6 of the Annex, which is a list of substances to which entry 30 applies, which have been found to be "Toxic to reproduction: category 1B (Table 3.1)/category 2 (Table 3.2)". Entry 30 in Annex XVII of the REACH Regulation, stipulating that DEHP shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public.

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

Furthermore, there is a restriction proposal for DEHP (together with the other phthalates DBP, BBP and DiBP) in articles for: i) indoor use and ii) outdoor use, if in contact with human skin or mucous membranes.[25] "*Prolonged contact with human skin*" is to be understood as covering a daily overall contact with skin of more than 10 minutes continuously or 30 minutes discontinuously. EUROMOT (2018b) states that they estimate that handling time required to insert, replace or remove a rubber part would be expected to be less than about two minutes, far less than the length of minimum contact time laid out in the draft restriction proposal. Furthermore EUROMOT expects national worker safety legislation to require the use of suitable personal protective equipment, such as gloves. These requirements were originally designed to avoid skin contact with other substances, such as lubricants and dirt, but would also protect workers against contact with DEHP-inclusive rubber parts.

[25] https://echa.europa.eu/de/previous-consultations-on-restriction-proposals/-/substance-rev/1904/term

No other entries, relevant for the use of DEHP in the requested exemption could be identified in Annex XIV and Annex XVII (with the status of April 2018). 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.

9.5.2. Scientific and technical practicability of substitution

Whereas in the original application, the categorical availability of substitutes was paramount, in the following exchange with the applicant it became apparent that rather supply chain limitations hinder substitution.

As for the technical requirements of the rubber components, it has to be noted that they experience severe conditions of e.g. temperature, vibration and abrasion and have to work reliably in the engine systems that are designed for use in finished equipment that have a normal lifetime of at least 10 years. However it can be concluded that basically substitutes are available as:

- Österreichisches Umweltbundesamt – The Environment Agency Austria (EAA 2014) concluded in the RoHS Annex II Dossier DEHP that the use and technical feasibility of possible substitutes were determined: "*The use of DEHP in EEE is not deemed essential, however, some niche application cannot be ruled out.*"
- The European Tyre & Rubber Manufacturers Association (ETRMA 2018) assumes that DEHP is no longer present in rubber parts manufactured in the EU by its members producing rubber parts that are used in engine systems such as O-rings, seals, vibration dampers, gaskets, hoses, grommets and cap-plugs where prevention of leakage, sealing of engine parts and resistance to vibration / heat / dirt and fluids over a long lifetime of the engines are needed. (The full ETRMA statement is detailed in section 9.4).
- As for the specific alternatives used, ETRMA (2018) as well as EUROMOT (2018d) concordantly explained that *"in some cases this is the know-how of the company"*, and cannot be revealed for confidentiality reasons (ETRMA 2018) respectively that *"suppliers handle supplier lists and assembly methods as proprietary company information"*, which also applies for the rubber component composition.

From the information provided by EUROMOT (2018d) it can be summarized that its members are still underway to reveal availability of DEHP-free rubber components EUROMOT (2018d). Thus, it is understood, that EUROMOT was not able to complete component testing because there is a substantial proportion of parts where the availability of DEHP-free components are still under investigation and thus has so far not been tested at the component level and because for a minor proportion of components, DEHP-free alternatives have not been identified yet. To conclude on the status of the supply chain survey EUROMOT (2018d), it becomes apparent that engine testing and reliability testing in finished equipment could not have started yet. EUROMOT (2017a) estimates a duration of one year to complete the testing on the component level. Completed with the information on the supply chain survey EUROMOT (2018d), this timescale can be followed.

It is understood, that a high reliability level is required as the engines have to work for a long lifetime (at least 10 years) under varied environmental conditions. Therefore it can be followed that the timescale for validation of engines and the subsequent reliability testing in finished equipment is a major undertaking which can easily require about 4 years duration (2 years for engine testing and 2 years for reliability testing in finished equipment).

The information discussed above suggests that a time frame of 5 years for the exemption request is plausible.

To summarize the status of substitutes, it is understood that DEHP can basically be replaced as plasticizer in rubber components designed for the use in engine systems. However substitutes are not readily available for all of the numerous different rubber components needed in one engine system, which is also due to the complexity of the supply chain. Therefore, the rubber components that are manufactured with alternative plasticizers have not completed the reliability testing on the engine level and on the equipment level. It cannot finally be concluded on the technical practicability of these alternative rubber components in the engine systems for the equipment in scope of this request.

9.5.3. Environmental arguments

EUROMOT did not provide any information regarding environmental arguments.

9.5.4. Socio-economic impacts

From the information provided by the applicant (EUROMOT 2017d) it can be understood that socio-economic arguments are not taken into consideration.

The consultant understands that the applicant might not be able to consider a business as usual scenario because additional regulation constantly demand material and engine validation: Under the NRMM Emissions Regulation 2016/1628 different emission values will apply from 2019 – 2021, depending on the type and power rating of the engine. This leads to the situation that a minor proportion of the engine systems fall under the RoHS Directive due to the fact that the final professional and industrial equipment are in scope of RoHS 2. The substitution to DEHP-free components such as any changes to materials used in the engines will require that they are revalidated for compliance with the NRMM Emissions Regulation EUROMOT (2017a).

EUROMOT (2018a) argues for examples that *"the use of less durable components [because DEHP-free and not tested at all levels yet] would be impractical and would create additional waste. Regardless of this hypothetical situation, we cannot demonstrate that any DEHP substitutes – even those that may be less durable – are reliable, as durability requires extensive and time-consuming testing, not only of the components, but also of engines built using substitute components and field trials of equipment with these engines. It is only after completion of all of these trials that durability and reliability of substitutes can be ascertained. Therefore, at present, the durability of substitute materials in finished equipment is unknown."*

Against this background, and reminding the low volume of engines requiring the exemption request per year (68,000 placed on the EU market annually according to EUROMOT (2017a)), it can be followed that EUROMOT is not able to further specify impacts on employment and additional costs further than the very general statement on the expected "*negative impact on EU jobs and competitiveness if many engine types and associated equipment cannot be sold in the EU, and a broader negative impact if equipment sold in the market is less reliable, as this would negatively impact productivity"* or the statement that there is *"unlikely to be an additional cost because engine manufacturers will have to conduct the research and testing of engines with substitute components when these become available if they want to supply to the EU market (as they are already working to do)."*

9.5.5. Scope of the exemption

Following the initial review of the exemption request application, efforts were made to specify the formulation of the exemption request that was estimated as being general and very wide in terms of scope. This estimation was also confirmed by the contribution of the Swedish Chemicals Agency KEMI (see section 9.4).

Specifications for different aspects have been discussed with EUROMOT but the following have not been found to be constructive:

- According to types of rubber engine components for which substitution is possible at an earlier stage than for others: EUROMOT argued that the timeline for substitution and verification has to be completed for all components to ensure that any revisions to the material formulation still meet the technical specifications as set forth by the equipment manufacturer. EUROMOT expects to start engine testing when DEHP-free substitutes have been identified for all components and have undergone components testing.
- Easier replaceability: EUROMOT (2017d) argued that this would not be feasible, *"as most rubber parts can be replaced only by dismantling the entire engine, which means that the equipment cannot be used for several days at least. […] Another issue is when engines are maintained in the field, there is a risk of dirt ingress every time this is carried out and dirt can shorten engine life-time because of increased abrasion and wear."*

Specific rubber engine components with different ranges of DEHP was agreed to be the most promising possibility as already in the original application it was stated by EUROMOT that "typically there are two main ranges, about 2 – 10% DEHP in rubber parts such as hoses, O-rings and seals and about 10 – 30% DEHP in rubber coatings on gaskets". In the further discussions on this possibility, EUROMOT (2018d) added that in this case complex-sub assemblies have to be mentioned in the item specifying a higher threshold.

Examples of these sub-assemblies include starter motors, alternators, compressors, emissions pumps and dosers, exhaust after treatment systems and hydraulic pumps. EUROMOT (2018e) summarized that that the environmental conditions experienced in some of the complex sub-assemblies may be more severe than in other parts of the engine, e.g. due to contact with a wide variety of fuels over the lifetime of the engine.

This could be followed as well as the argument that for complex sub-assemblies, the supply chain becomes more complex, adding 2 to 4 tiers in the supply chain. EUROMOT (2018e) further argued that the supply chain is somehow reluctant to react on RoHS compliance: *"Complex sub-assemblies are generally often designed by suppliers to fit a variety of applications, most of which are not in scope of the RoHS directive. Therefore, it is unlikely that the manufacturer of a given complex sub-assembly will specifically design a product to be RoHS compliant when the vast majority of their market does not require it."*

The threshold for DEHP in complex-subassemblies was verified by EUROMOT stating in a personal communication that "*based on additional supplier surveys that EUROMOT members were in the process of conducting earlier in the process, and additional supplier data received only over the past few weeks, we are now comfortable confirming that a 30% maximum threshold for DEHP would be sufficient*" for rubber components in complex sub-assemblies.

It was agreed with EUROMOT (2018e) on a definition for complex sub-assemblies instead of an exhaustive list because the terms might not be unambiguous or the list might not give room for innovations. The definition was agreed as follows: "*A complex sub-assembly can be defined as an assembly of at least three components using electrical, mechanical or hydraulic energy to do work, and is attached to the engine.*"

With the aim of specifying the formulation, EUROMOT agreed to the following formulation:

"Bis (2-ethylhexyl) phthalate in rubber components in engine systems, designed for use in equipment that is not intended solely for consumer use

i. Not exceeding 30% by weight for
   - gasket coatings;
   - solid-rubber gaskets; or
   - rubber components included in complex sub-assemblies.

   A complex sub-assembly is defined as an assembly of at least three components using electrical, mechanical or hydraulic energy to do work, and is attached to the engine.

ii. Not exceeding 10% by weight of rubber for rubber-containing components not in the scope of item i."

9.5.6. Conclusions

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

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II **is scientifically or technically impracticable**;
- the **reliability** of substitutes is not ensured;

- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

From the available information it is observed that substitutes have been developed and are placed on the market. However, the above described supply chain limitations lead to an insufficient availability of rubber components with alternative plasticisers for the engine systems in scope of this request. Thus, in the consultants' view, the provided results and information sufficiently show that for such alternatives it has not been possible to perform the testing for reliability on the level of the engine systems and on the level of the finished professional and industrial equipment, where long life and special requirements such as resistance to any contact material (e.g. fuel, lubricant oil, coolants, gases, dirt), temperature and vibration play an important role in the operation of equipment.

This finished equipment sold in low volumes works under varied environmental conditions. The special requirements for rubber components require a long time to verify reliability on the level of engine systems and finished equipment. The consultants understand this to mean that the reliability of substitutes may not be ensured at present, meaning that, on the basis of fulfilling the second criterion, an exemption could be justified.

In this sense, the consultants conclude that even though substitution of DEHP is in principle scientifically and technically viable in rubber components, the reliability of these substitutes still needs to be ensured for the specific uses in the engine systems designed for use in professional and industrial equipment in the scope of this requested exemption. An exemption can therefore be justified based on the Article 5(1)(a) criteria.

9.6. Recommendation

EUROMOT has confirmed that DEHP-free rubber components for engine systems have been developed and are placed on the market for some components. However, supply chain limitations have not allowed establishing substitute availability for all applications. The consultants can follow that an exemption would be justified as one of the article 5(1)(a) criteria are fulfilled. Therefore the consultants recommend granting the exemption request with the following wording:

"Bis (2-ethylhexyl) phthalate in rubber components in engine systems, designed for use in equipment that is not intended solely for consumer use

i. Not exceeding 30% by weight for
   - gasket coatings;
   - solid-rubber gaskets; or
   - rubber components included in complex sub-assemblies.

A complex sub-assembly is defined as an assembly of at least three components using electrical, mechanical or hydraulic energy to do work, and is attached to the engine.

ii. Not exceeding 10% by weight of rubber, for rubber-containing components not in the scope of item i"

EUROMOT have requested an exemption for the maximum validity period of five years. The various stages of substitute testing are detailed, clarifying that 5 years may be needed once substitute candidates are found for all components and it is thus recommended to provide a five year duration for the exemption should it be granted.

DEHP has been added to REACH Annex XIV and cannot be placed on the market or used since 21 February 2015 (Sunset date), unless an authorisation is granted. The consultants conclude that EU rubber manufacturers have completed substitution of DEHP in rubber components as authorisations for this use have not been granted. Since the REACH authorisation requirement is not applicable outside the EU, it is possible that manufacture of rubber for relevant components is currently only performed in non-EU countries. Should a RoHS exemption be granted, the consultants understand it to only benefit non-EU manufacturers. Though this cannot be considered to be incoherent with the REACH Regulation, the fact that the substance is prohibited for use in the EEE should be kept in mind in the final decision of the EU, whether to grant the exemption or not. In general, a prohibition of a new substance can be expected to need a certain transition period for implementation. For non-EU manufacture this period began when it was decided to add DEHP to Annex II of RoHS. Though the RoHS restriction was granted with a transition period between June 2015[26] and July 2019, it is possible that for some applications additional time is needed.

[26] In June 2015, the Commission published Delegated Directive (EU) 2015/863 of 31 March 2015, amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the listing of DEHP in the list of restricted substances.

10. Request 2017-7

"Lead in solders of sensors, actuators and engine control units (ECUs) that are used to monitor and control engine systems including turbochargers and exhaust emission controls of internal combustion engines used in equipment that are not intended to be used solely by consumers."

Declaration

In the sections that precede the "Critical review", the phrasings and wordings of stakeholders' explanations and arguments have been adopted from the documents provided by the stakeholders as far as required and reasonable in the context of the evaluation at hand. Formulations were only altered or completed in cases where it was necessary in order 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

ECU	Engine control unit
EEE	Electrical and electronic equipment
ELV	End of Life Vehicles
EUROMOT	The European Association of Internal Combustion Engine Manufacturers
NRMM	Non-Road Mobile Machinery
Pb	Lead
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment

10.1. Background

The European Association of Internal Combustion Engine Manufacturers (EUROMOT 2017b) requests an exemption for

> "*Lead in solders of sensors, actuators and engine control units (ECUs) that are used to monitor and control engine systems including turbochargers and exhaust emission controls of internal combustion engines used in equipment that are not intended to be used solely by consumers*"

The exemption is requested for five years and for equipment stated to be under RoHS category 11 (EUROMOT 2017b).

The conditions experienced in and close to an engine and exhaust can be very severe with elevated temperatures and vibration levels that may cause early failure of solder bonds (EUROMOT 2017b). Each engine is designed with specific types of sensors (as

well as actuators and ECUs) that have been thoroughly tested to ensure that they will be reliable, and the engines will meet the emissions limits. If sensors have to be replaced by different sensors from different suppliers or by sensor types of different designs, reliability cannot be assured, and engines may not meet emissions limits. Like-for-like exact equivalents, where the only difference is that tin/lead solder is replaced by lead-free solders, very often do not exist. RoHS-compliant sensors that are made with lead-free solders are increasingly available for passenger cars to comply with the restriction of lead in passenger vehicles of the EU ELV Directive. However, where a sensor is available and appears to be useable, its reliability in engine applications cannot be assured without extensive testing, as the use conditions are different to passenger cars (EUROMOT 2017b).

EUROMOT (2017b) states that as a result, the reliability of engines made with lead-free solders cannot be assured and extensive research needs to be carried out. If an engine is redesigned so that lead-free soldered components can be used, re-validation under the Non-Road Mobile Machinery (NRMM) Emissions Regulation[27] will be required, as this has mandatory emissions and durability requirements and also involves extensive engine testing. According to EUROMOT (2017b), the exemption is needed at this time as any changes to engines that could affect safety, reliability or emissions of substances regulated by the NRMM Emissions Regulation result in a very long development and reliability validation cycle.

EUROMOT (2017b) has requested the exemption for the maximum validity period, which is 5 years under category 11.

10.1.1. Amount of lead used under the exemption

Lead is a constituent of solder alloy used to make electrical connections to components. The applicant states that 35 – 40 % lead is used in solder (EUROMOT 2017b).

The applicant (EUROMOT 2017b) provides data on representative sensors, actuators and ECUs, for which the amount of lead used in solders for an average engine has been quantified:

- 5 g lead in solder in sensors per engine;
- 6 g lead in solder in actuators per engine (1g per actuator);
- 35 g lead in solder in the ECU;
- Total amount per engine is therefore: 46 g.

The number of engines that are placed on the EU market annually and that are in scope of RoHS was estimated by EUROMOT as about 68,000 units. This is estimated to be about 12% of the global total of 570,000 units.

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

On this basis, the applicant estimates that about 3 tonnes of lead enter the EU market per annum through the application for which the exemption is requested. About 25 tonnes lead are estimated for the global market per annum (EUROMOT 2017b).

10.2. Description of the requested exemption

10.2.1. Legislation addressing equipment for which the exemption has been requested

EUROMOT (2017b) bases much of the argumentation regarding the necessity of the requested exemption on the fact that the equipment in scope of this exemption request is also in scope of the NRMM Emissions Directive.

The NRMM Emissions regulation requires combustion engines in its scope to be type-approved, whereby a Member State competent authority certifies that it meets the essential technical requirements of the legislation. Any change in design or supplier of engine components such as sensors, actuators, and ECUs may impact the engines emissions, which in turn, requires lengthy emissions testing and recertification (EUROMOT 2017b).

RoHS Article 2(4)(g) excludes "*Non-road mobile machinery made available exclusively for professional use*" from its scope. In Article 3(28) such equipment is defined as: "'*machinery, with an on-board power source or with a traction drive powered by an external power source, the operation of which requires either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working, and which is made available exclusively for professional use*."

However, consequence to the definition, some types of NRMM are understood to be in the scope of RoHS, including:

- NRMM fulfilling the Article 3(28) definition, however made available to both professionals and consumers, for example via their point of sale or for example professional NRMM that are leased among others also to non-professional users; and
- NRMM that do not meet the RoHS definition of "Non-road mobile machinery made available exclusively for professional use" because they are used at fixed working locations for extended periods of time and thus do not fulfil the above cited definition ("…the operation of which requires either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working…").

These types of equipment are stated not to meet the RoHS definition of NRMM and thus are not excluded from the scope of RoHS. Nonetheless, they are explained to be in scope of the NRMM Emissions regulation and thus changes necessary for achieving RoHS compliance are explained to require lengthy emissions testing and recertification.

10.2.2. Technical description of the requested exemption

Solders are used in most types of sensors, actuators and in electrical circuitry of engine control units (EUROMOT 2017b). The solder is usually an alloy of tin and lead (SnPb), or an alloy of tin, lead and silver (SnPbAg).

Sensors

Lead is used in solders to make electrical connections internally within the sensor components. Many of the sensors are built into modules with control electronics (e.g. a small PCB) that generates a stable output that is sent to the engine control unit (EUROMOT 2017b). All engine sensors convert a parameter into an electrical signal which is used to control the running of the engine. Each design and model of engine uses a specific range of sensors that are selected to ensure the correct performance, fuel efficiency and emissions. Some engines have many more sensors than others (EUROMOT 2017b).

The examples of sensors used in EEE in scope of this exemption request provided by EUROMOT (2017b) include, but are not limited to:

- Air pressure sensors;
- Air temperature sensors;
- Ammonia sensors;
- Engine exhaust temperature sensor;
- Fluid level sensors; and
- Particulate sensors.

The sensors measure a characteristic of the engine / exhaust system and transmit the information to the engine's control unit. The signals from sensors control the engine to ensure maximum fuel efficiency and control the composition of exhaust gas emissions. Because of their function, most of the sensors have to be located next to or even within an engine, attached to the exhaust system or to a turbocharger. Most of these locations will be at high temperature and subject to vibration, large temperature cycles and be subjected to sudden high g-force shocks (EUROMOT 2017b).

According to the applicant, RoHS-compliant sensors that are made with lead-free solders are increasingly available for passenger cars to comply with the EU ELV Directive restriction of lead. However, where a sensor is available and appears to be useable, its reliability in engine applications needs to be assured through testing as the use conditions are different to passenger cars (EUROMOT 2017b).

Actuators

Actuators are electromechanical devices that control the operation of engines, such as by regulating the opening of valves that control air flow rate, pumps for fuel and other devices that are parts of engines. Illustrative examples of the types of actuators that might be used in engine systems in scope of RoHS are listed as follows (EUROMOT 2017b):

- Solenoid;
- Exhaust throttle;
- Fuel transfer pump;
- Diesel exhaust fluid (DEF) pump; and
- Fuel injectors.

Most actuators contain electrical devices that move when a voltage is applied. Many types use electric motors which require motor control circuits to ensure that the movement distance is correct. Electrical connections, using solder bonds will always be required in these electromechanical devices that convert an applied voltage into a precise movement (EUROMOT 2017b).

Engine control units

All sensors and actuators are connected to engine control units (ECU) that monitor and control the operation of the engine. These are essential to ensure that emissions are limited to acceptable levels and that fuel efficiency is maximized. ECUs are fairly complex electronic assemblies that contain one or more printed circuit boards. Some are made by engine manufacturers and others are designed and produced by third parties. Some are manufactured using lead-free solders, but their long-term reliability in most types of equipment that are in scope of RoHS is not yet assured (EUROMOT 2017b).

Manufacturers of equipment that contains engines determine where ECUs are located, but frequently the most appropriate location is attached to the engine and so the solder bonds of these units are exposed to the same temperatures, vibration and shock as the sensors that are installed in engines (EUROMOT 2017b).

Types of equipment with engines that require sensors, actuators and ECUs

The following list includes illustrative examples of types of equipment that are in scope of the RoHS Directive and for which, according to EUROMOT (2017b), the exemption has been requested*:

- Generator sets[28];
- Diesel engine powered compressors;
- Pumps, such as irrigation pumps, water and sewage pumps, etc.;
- Drilling machines;
- Rock crushers;
- Welding sets that are mounted onto trailers;
- Products that are typically leased to both professionals and consumers and so are not excluded by the RoHS definition of professional NRMM, for example, some types of chain saws, leaf blowers, some types of mowers, small-size diggers, etc.; and

[28] The consultants understand some generators sets to be excluded from the scope of RoHS through the exclusions of large-scale stationary industrial tools (LSIT) and large-scale fixed installations (LSFI) (Art. 2(4)(d) and Art. 2(4)(e), respectively), but others to need to comply with the substance restrictions, such as generator sets mounted to trailers and not fixed to a specific location.

- Stationary equipment that is too small to be excluded from RoHS as a part of a large-scale fixed installation or as a large-scale stationary industrial tool that will thus be in scope and so may need this exemption.

** The consultants understand only such equipment with a combustion engine to be relevant to the request and not for example cable or battery-operated drilling machines.*

Further examples have been provided in the applicant's response to the first clarification questionnaire (EUROMOT 2017c)*:

- Rotavators;
- Vibrating plate for compacting hardcore, sand or gravel;
- Shredders (of branches, logs, etc.);
- Brush cutters; and
- Cement mixers.

** The consultants understand only such equipment with a combustion engine to be relevant to the request and not for example cable or battery-operated shredders and brush cutters.*

10.3. Applicant's justification for the requested exemption

In the consultants' view, the applicant's justification for the requested exemption can be summarized as follows (see further elaboration below):

- The equipment for which the exemption is requested is of a limited group, due to the exclusion of NRMM for professional use from the scope of RoHS (see section 10.2.1) and the exclusion of LSIT and LSFI[28]. Consequently, the supply chain of this industry has little incentive to manufacture RoHS-compliant versions of components for this sub-group of equipment, complicating the transition. This limits the availability of lead-free components for engines in the scope of the exemption request.
- The reliability of available lead-free components does not always appear to be sufficient for the equipment in scope of the exemption request and must be tested before substitutes can be applied in machinery to be placed on the market.
- All equipment for which the exemption is requested is understood to be in scope of the NRMM Emissions regulation. The NRMM Emissions Regulation has mandatory emissions and durability requirements and requires extensive engine testing before equipment is allowed on the market. Subsequently, switching to RoHS-compliant components requires long testing and verification periods.

As described in section 10.2.1 of this report, only a small subgroup of NRMM are both in the scope of the NRMM Directive and the RoHS Directive. (EUROMOT 2017b) estimates the number of engines placed on the EU market annually that are in the scope of RoHS to be about 68,000 units. Consequently, according to EUROMOT (2017b), the suppliers of components such as sensors, actuators and ECUs, have little economic incentive to design and certify specific lead-free components for a relatively limited market.

EUROMOT (2017b) describes that the reliability of lead-free solders is inferior to lead-based solders under various environmental loads (temperature, vibration, drop shock, etc.). It is argued that even when lead-free components are available, extensive testing needs to be carried out to ensure reliability. In-engine testing is only viable once all components are available as lead-free versions, to ensure an engine functions reliably with all lead-free components. EUROMOT (2017b) could not provide an estimate regarding when this may be the case, as it depends on specific actors in the supply chain.

EUROMOT (2017b) elaborates that the total elapsed timescale for design, testing, approval and manufacture of a new design of engine that complies with both the RoHS Directive and other applicable legislation such as the NRMM emissions Regulation is estimated to be about eight years in elapsed time. Out of those eight years, three are said to be spent on accelerated stress testing on component-level (sensors, actuators, ECUs). Upon completion, two years are spent on system-level testing (in-engine testing) and an additional timespan of two years on field-testing of the engines. Finally, upon approval from an EU Notified Body for compliance with the NRMM Emissions Regulation, preparing manufacturing capacities (incl. staff and factories) for production of the new engine takes one additional year (EUROMOT 2017b). This information is summarised in Table 10-1 below for convenience.

Table 10-1: Summary of estimated timeframe of achieving RoHS compliance

Phase	Required time
Accelerated stress testing on component-level (sensors, actuators, ECUs)	3 years
System-level testing (in-engine testing)	2 years
Field-testing of the engines	2 years
Approval of equipment by an EU Notified Body for compliance with the NRMM Emissions Regulation	Not specified, but a pre-condition for next stage
Preparing manufacturing capacities (incl. staff and factories) for production of the new engine	1 year
Total	8 years

Compiled based on EUROMOT (2017b)

According to EUROMOT (2017b), lead-free solder alloys are the most promising substitute material for lead-based solders. Sensors, actuators and ECUs would not have to be redesigned if lead-free components were available. Lead-free solder alloys are widely used by the electronics industry and have recently also been used in passenger cars and small vans in scope of the EU ELV directive. However, lead-free solders are not required by legislation in large commercial road vehicles or in types of NRMM, such as excavators and bulldozers, which are outside of scope of the RoHS Directive. Due to this circumstance, RoHS-compliant components are often not available for those NRMM that are in the scope of RoHS.

EUROMOT (2018f) argues that the industry sector is on the path towards full RoHS-compliance, but that the above issues with availability and reliability of electronic

components (i.e. sensors, actuators, ECUs) mean that the process will take many more years.

10.3.1. Environmental arguments

No environmental arguments have been brought forward by the applicant.

10.3.2. Socio-economic impacts

In the original application, EUROMOT (2017a) considered socio-economic impacts as being *"not applicable to this exemption request"*.

10.4. Stakeholder contributions

During the public consultation, one contribution was submitted related to the exemption request by the Swedish Chemicals Agency KEMI (KEMI 2017). Against the understanding that exemptions from the RoHS Directive should be for specific applications, KEMI states that the proposed scope of the exemption is too broad and not specific enough: *"No. Article 5 in the RoHS directive (2011/65/EC) stipulates that exemptions can be included in Annexes III and IV for materials and components of EEE for specific applications. The proposed scope of the exemption is too broad. Additionally, the applicant gives examples of types of equipment that are in scope of RoHS that require this exemption. Furthermore, it is difficult to ascertain exactly which products that will be covered with the proposed wording in enforcement activities."* (KEMI 2017)

10.5. Critical review

10.5.1. REACH compliance – Relation to the REACH Regulation

If granted, the exemption would allow the use of lead in solders of sensors, actuators and ECUs of internal combustion engine in NRMM in scope of RoHS, except for equipment solely indented to be used by non-professional consumers.

Annex XIV of the REACH Regulation contains several entries for lead compounds, use of which requires authorization:

- 10. Lead chromate
- 11. Lead sulfochromate
- 12. Lead chromate molybdate sulphate red

In the applications in the scope of the reviewed exemption, lead is used in solder that becomes part of articles. None of the above listed substances is relevant for this case, neither as directly added substance nor as substance that can reasonably be assumed to be generated in the course of the manufacturing process.

Annex XVII of the REACH Regulation bans the use of the following lead compounds:

- 16. Lead carbonates in paints
- 17. Lead sulphate in paints

Neither the above substances nor their applications are, however, relevant for the exemption request in the scope of this review.

Appendix 1 of this report lists entry 28 and entry 30 in Annex XVII of the REACH Regulation, stipulating that lead and its compounds shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public. A prerequisite to granting the requested exemption would therefore be to establish whether the intended use of lead in this exemption request might weaken the environmental and health protection afforded by the REACH regulation.

In the consultants' understanding, the restrictions for substances under entry 28 and entry 30 of Annex XVII do not apply. The use of lead in solder in sensors, actuators and ECUs within engines is, in the consultants' point of view, not a supply of lead and its compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, entry 30 of Annex XVII of the REACH Regulation would not apply.

Entry 63 of Annex XVII stipulates that lead and its compounds…

- "*shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0.05 % by weight.*"
- "*shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0.05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children.*"
  This restriction does, however, not apply to articles within the scope of Directive 2011/65/EU (RoHS 2). Nor are the sensors, actuators and ECUs to be used in professional use non-road equipment engines articles expected to be accessible to children under normal or reasonably foreseeable conditions of use.

The restrictions of lead and its compounds listed under entry 63 thus do not apply to the applications in the scope of this requested exemption.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status April 2018). 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.

10.5.2. Scientific and technical practicability of substitution

Most engines produced by the affected industry sector do not need to be compliant with RoHS, as a large share of the equipment they manufacture is excluded from scope, e.g. as a form of transport or as NRMM for professional-use. The remainder,

which is in scope of RoHS, consists of a large variety of different machines, which are often placed on the market in small annual volumes. Consequently, the market power of engine producers to incentivise the supply chain to develop RoHS-compliant parts is relatively small and the process may be lengthier than for equipment produced n high volumes.

Alternatives in the form of lead-free solders are available, however it can be understood that these have been developed for other applications, such as passenger vehicles or other EEE applications. Thus, the reliability of such solders in sensors, actuators and ECUs installed in equipment of relevance to this request still needs to be ensured.

It is understood that a high reliability level is required as the engines have to work over a long lifetime under varied environmental conditions. Additionally, the NRMM Directive sets emission limits and requires type-approval of new engine designs.

EUROMOT (2017b) elaborates that the total elapsed timescale for design, testing, approval and manufacture of a new design of engine that complies with both the RoHS Directive and the NRMM emissions Regulation is estimated to be about eight years. EUROMOT further puts forward information as to where its members currently stand within this process towards achieving compliance:

The first effort by the industry sector has been to screen for potential substitute components. Where these could be identified, they were tested on the component level and will be tested on equipment (engine) level, once alternatives are found for all other components. EUROMOT (2018f) illustrates an example of a typical engine to demonstrate the complexity of this screening process. In the example, 77 % (or 923 parts) of all electronic components (incl. sensors) used in one manufacturers' engines are available as RoHS-compliant versions, while the remaining 23 % (or 276 parts) are currently non-compliant or require additional testing and development time to ensure reliability (EUROMOT 2018f). Engine testing is stated not to be feasible until all components have been sourced as RoHS-compliant versions (EUROMOT 2017b). For some components, the process may be lengthier where an alternative needs to be developed, but the manufacturers have described their work towards achieving compliance.

To evaluate the current state of progress of engine manufacturers, it is important to understand the context of this equipment group in the scope of the RoHS Directive. Such equipment has been described by EUROMOT to have first been added to the scope of the Directive through the 2011 recast and is explained to be covered by Annex I category 11 "*Other EEE not covered by any of the categories above*". In the 2011 recast, a date was not specified as to when this category comes into scope and there were uncertainties as to the equipment newly in scope among stakeholders and the date of application. In a consultation performed as part of a 2014 Oeko-Institut study of the scope of the Directive (EEE newly in scope), EUROMOT[29] and other

[29] See contribution to stakeholder consultation from 7.3.2014 under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IA_2_2/Products_newly_in_scope/20140307_EUROMOT_RoHS_2_Oeko-Institut_Review_EEE_newly_in_Scope-Questionnaire_Final_Response_2014-03-07.pdf

stakeholders raised these uncertainties. It was argued that equipment with an internal combustion engine was mostly excluded and that those equipment newly in scope should also be excluded[30]. Following this review, the Directive was amended on 15.11.2017, specifying among others in Article 4(3) that "*Paragraph 1 shall apply [...] to all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market from 22 July 2019*". Though the consultants are aware that many stakeholders of Cat. 11 products started their efforts towards compliance following the approval of the recast in 2011, it can be followed that EUROMOT members delayed these efforts until certainty was obtained through the 2017 amendment. In this sense, though it is clear from earlier communications that some efforts towards compliance started at an earlier date, it can also be followed the efforts were increased following the 2017 amendment and are still to be completed.

EUROMOT have estimated that the timescale for validation of engines and the subsequent reliability testing in finished equipment is a major undertaking which can take up to 8 years elapsed time. Against the understanding that some of the efforts towards compliance have first been addressed intensively in the last few years a time frame of 5 years for the exemption request is plausible.

10.5.3. Environmental arguments and socioeconomic impacts

The applicant has not put forward environmental arguments.

10.5.4. Socio-economic impacts

Regarding possible socio-economic aspects, (EUROMOT 2017b) only stated that engines as well as equipment made with such engines would not be available in the EU without the exemption being granted.

The equipment in scope of the exemption request is used in a broad range of applications (c.f. section 10.2.2 on page 106). The non-availability of equipment may thus have impacts in many fields of the EU economy, however the consultants can follow that the applicant may not be able to estimate the consequences of such a scenario in terms of their financial impacts and effect on unemployment.

Without further information being available, it is not possible to conclude as to the range and severity of possible impacts.

10.5.5. Scope of the exemption

Following the initial review of the exemption request, efforts were made to specify the phrasing, as the scope was assessed as being too wide. This assessment was also confirmed by the contribution of the Swedish Chemicals Agency KEMI (see section 10.4).

In further discussions with the applicant, EUROMOT (2018f) suggested the following wording to narrow the scope:

[30] This argumentation was raised by EUROMOT for "otherwise Large Scale products that are not permanently installed".

- "*Lead in sensors, actuators and ECUs of engines designed for use in professional equipment.*" (EUROMOT 2018f)

While the wording is simplified compared to the original exemption request, the equipment in scope may not necessarily differ. The formulation furthermore does not limit the applicability of the exemption to equipment with combustion engines, though the timeframe for compliance is understood to have been specified in relation to such equipment and its required compliance with the NRMM Regulation.

It is the consultant's understanding that engines are often designed with severe environmental conditions and/or high duty cycle in mind (for use in professional equipment), however, the same engines may also be used in equipment made available to consumers. Hence, potentially, all engines are "designed for use in professional equipment", including those employed in certain consumer equipment, such as hedge trimmers, leaf blowers, and chain saws. However, EUROMOT (2018c) further stated that "*Portable hedge trimmers, leaf blowers, chain saws, and other equipment carried by the user are different from the types of equipment that require this exemption. The types of equipment for which this exemption is requested are used at fixed positions for extended periods of time.*"

The current exemption 41 under RoHS Annex III[31] exempts hand-held combustion engines of the classes SH:1, SH:2 and SH:3 of Directive 97/68/EC (EU COM 1997) from the restriction on the use of lead in specific applications. Engine classes SH:1, SH:2 and SH:3 are defined as small engines with a net power ≤ 19 kW for hand-held machinery. The applicant of exemption 41 has applied for a renewal of the exemption on 30.06.2017. This exemption needs to be accounted for in order to avoid any overlap in the applications in scope of exemption 41 and the exemption request at hand.

In order to appropriately reflect these factors in the specification of the exemption wording, the consultants suggested the following formulation:

- Lead in sensors, actuators and ECUs of combustion engines installed in equipment used at fixed positions while in operation, which is designed for professionals, but also used by non-professional users and which is in the scope of Regulation (EU) 2016/1628 for internal combustion engines for non-road mobile machinery. Equipment benefiting from Ex. 41 of Annex III of this Directive shall be excluded from this exemption.

10.5.6. Conclusions

Article 5(1)(a) provides that an exemption can be justified for materials and components of EEE for specific application, if at least one of the following criteria is fulfilled:

[31] "Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council (2))"

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

From the available information it is observed that substitutes for lead-based solders are available on the market. However, the above described supply chain limitations lead to an insufficient availability of RoHS-compliant components with lead-free solders for the engine systems in scope of this request. In the consultants' view, the provided information sufficiently shows that additional time is needed to perform the testing for reliability of alternatives on the level of the engine systems and on the level of the finished equipment, where long life and resistivity against harsh environmental conditions (incl. extreme temperature, vibration, drop shock, etc.) play an important role in the operation of equipment. Additional time is also understood to be needed before RoHS compliant equipment could be placed on the market, to allow for recertification according to the NRMM Regulation and for the planning of the preparation of manufacturing capacities.

The consultants conclude that even though substitution of lead-based solder is in principle scientifically and technically viable in sensors, actuators and ECUs, that the reliability of these substitutes still needs to be ensured for the specific uses in the engine systems designed for use in professional equipment in the scope of this requested exemption. An exemption can therefore be justified based on the Article 5(1)(a) criteria.

10.6. Recommendation

The applicant has provided detailed information, which plausibly describes issues related to achieving RoHS-compliance in the relevant industry sector. In the consultants' understanding, the second criterion provided under RoHS Article 5(1)(a) is fulfilled for some of the components (sensors, actuators and ECUs) in scope of this exemption request. According to the applicant, engines can only be tested for reliability and certified to comply with the NRMM Emissions Regulation when all components are available as RoHS-compliant versions. Although the consultants do not agree with this approach in general, in this case it can be followed that the sector is still in the first years of the compliance process and the will to commence testing on engine level, once the first screening is completed, is given.

The consultants suggest the following wording of the exemption:

- Lead in sensors, actuators and ECUs of combustion engines installed in equipment used at fixed positions while in operation, which is designed for professionals, but also used by non-professional users and which is in the scope of Regulation (EU) 2016/1628 for internal combustion engines for non-road mobile machinery.

Equipment benefiting from Ex. 41 of Annex III of this Directive shall be excluded from this exemption.

Five years should suffice to substitute most parts with RoHS-compliant versions. Additionally, the industry is expected to prepare a detailed roadmap for all other components and the steps to be taken together with actors from the supply chain to achieve full compliance with the requirements under RoHS. This roadmap may be used as a benchmark in case a renewal of the exemption is requested upon expiration of the exemption.

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Appendix

Aspects relevant to the REACH Regulation

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

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

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

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

Table A-1: Relevant entries from Annex XIV: List of substances subject to authorization

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
4. Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	21 August 2013 (*)	21 February 2015 (**)	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/ 2004, Directive 2001/82/EC, and/or Directive 2001/83/EC
5. Benzyl butyl phthalate (BBP) EC No: 201-622-7 CAS No: 85-68-7	21 August 2013 (*)	21 February 2015 (**)	
6. Dibutyl phthalate (DBP) EC No: 201-557-4 CAS No: 84-74-2	21 August 2013 (*)	21 February 2015 (**)	
7. Diisobutyl phthalate (DIBP) EC No: 201-553-2 CAS No: 84-69-5	21 August 2013 (*)	21 February 2015 (**)	
10. Lead chromate EC No: 231-846-0 CAS No: 7758-97-6	21 Nov 2013 (*)	21 May 2015 (**)	-
11. Lead sulfochromate yellow (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2	21 Nov 2013 (*)	21 May 2015 (**)	-

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
12. Lead chromate molybdate sulphate red (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8	21 Nov 2013 (*)	21 May 2015 (**)	-
16. Chromium trioxide EC No: 215-607-8 CAS No: 1333-82-0	21 Mar 2016 (*)	21 Sep 2017 (**)	-
17. Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid EC No: 231-801-5 CAS No: 7738-94-5 Dichromic acid EC No: 236-881-5 CAS No: 13530-68-2 Oligomers of chromic acid and dichromic acid EC No: not yet assigned CAS No: not yet assigned	21 Mar 2016 (*)	21 Sep 2017 (**)	-
18. Sodium dichromate EC No: 234-190-3 CAS No: 7789-12-0 10588-01-9	21 Mar 2016 (*)	21 Sep 2017 (**)	-
19. Potassium dichromate EC No: 231-906-6 CAS No: 7778-50-9	21 Mar 2016 (*)	21 Sep 2017 (**)	-
20. Ammonium dichromate EC No: 232-143-1 CAS No: 7789-09-5	21 Mar 2016 (*)	21 Sep 2017 (**)	-
21. Potassium chromate EC No: 232-140-5 CAS No: 7789-00-6	21 Mar 2016 (*)	21 Sep 2017 (**)	
22. Sodium chromate EC No: 231-889-5 CAS No: 7775-11-3	21 Mar 2016 (*)	21 Sep 2017 (**)	
28. Dichromium tris(-chromate) EC No: 246-356-2 CAS No: 24613-89-6	22. Jul 2017 (*)	22 Jan 2019 (**)	
29. Strontium chromate EC No: 232-142-6 CAS CAS No: 7789-06-2	22 Jul 2017 (*)	22 Jan 2019 (**)	
30. Potassium hydroxyoctaoxodizincatedichromate EC No: 234-329-8 CAS No: 11103-86-9	22 Jul 2017 (*)	22 Jan 2019 (**)	

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
31. Pentazinc chromate octahydroxide EC No: 256-418-0 CAS No: 49663-84-5	22 Jul 2017 (*)	22 Jan 2019 (**)	

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

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

For the substances currently restricted according to RoHS Annex II: cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls and polybrominated diphenyl ethers and their compounds, we have found that some relevant entries are listed in Annex XVII of the REACH Regulation. The conditions of restriction are presented in Table A-2 below.

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

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

Designation of the substance, group of substances, or mixture	Conditions of restriction
18a. Mercury CAS No 7439-97-6 EC No 231-106-7	1. Shall not be placed on the market: (a) in fever thermometers; (b) in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers). 2. The restriction in paragraph 1 shall not apply to measuring devices that were in use in the Community before 3 April 2009. However Member States may restrict or prohibit the placing on the market of such measuring devices. 3. The restriction in paragraph 1(b) shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007; (b) barometers (except barometers within point (a)) until 3 October 2009. 5. The following mercury-containing measuring devices intended for industrial and professional uses shall not be placed on the market after 10 April 2014: (a) barometers; (b) hygrometers; (c) manometers; (d) sphygmomanometers; (e) strain gauges to be used with plethysmographs; (f) tensiometers; (g) thermometers and other non-electrical thermometric applications. The restriction shall also apply to measuring devices under points (a) to (g) which are placed on the market empty if intended to be filled with mercury. 6. The restriction in paragraph 5 shall not apply to: (a) sphygmomanometers to be used: (i) in epidemiological studies which are ongoing on 10 October 2012; (ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers; (b) thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers until 10 October 2017; (c) mercury triple point cells which are used for the calibration of platinum resistance thermometers. 7. The following mercury-using measuring devices intended for professional and industrial uses shall not be placed on the market after 10 April 2014: (a) mercury pycnometers; (b) mercury metering devices for determination of the softening point. 8. The restrictions in paragraphs 5 and 7 shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007; (b) measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.

Designation of the substance, group of substances, or mixture	Conditions of restriction
23. Cadmium CAS No 7440-43-9 EC No 231-152-8 and its compounds	For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87 (1). 1. Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material): • polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21] • polyurethane (PUR) [3909 50] • low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] • cellulose acetate (CA) [3912 11] • cellulose acetate butyrate (CAB) [3912 11] • epoxy resins [3907 30] • melamine-formaldehyde (MF) resins [3909 20] • urea-formaldehyde (UF) resins [3909 10] • unsaturated polyesters (UP) [3907 91] • polyethylene terephthalate (PET) [3907 60] • polybutylene terephthalate (PBT) • transparent/general-purpose polystyrene [3903 11] • acrylonitrile methylmethacrylate (AMMA) • cross-linked polyethylene (VPE) • high-impact polystyrene • polypropylene (PP) [3902 10] Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material. By way of derogation, the second subparagraph shall not apply to articles placed on the market before 10 December 2011. The first and second subparagraphs apply without prejudice to Council Directive 94/62/EC (13) and acts adopted on its basis. By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be

Designation of the substance, group of substances, or mixture	Conditions of restriction
	restricted. 2. Shall not be used or placed on the market in paints with codes [3208] [3209] in a concentration (expressed as Cd metal) equal to or greater than 0,01 % by weight. For paints with codes [3208] [3209] with a zinc content exceeding 10 % by weight of the paint, the concentration of cadmium (expressed as Cd metal) shall not be equal to or greater than 0,1 % by weight. Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,1 % by weight of the paint on the painted article.' 3. By way of derogation, paragraphs 1 and 2 shall not apply to articles coloured with mixtures containing cadmium for safety reasons. 4. By way of derogation, paragraph 1, second subparagraph shall not apply to: — mixtures produced from PVC waste, hereinafter referred to as 'recovered PVC', — mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0,1 % by weight of the plastic material in the following rigid PVC applications: — (a) profiles and rigid sheets for building applications; (b) doors, windows, shutters, walls, blinds, fences, and roof gutters; (c) decks and terraces; (d) cable ducts; (e) pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC in compliance with paragraph 1 above. Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: '*Contains recovered PVC*' or with the following pictogram:  In accordance with Article 69 of this Regulation, the derogation granted in paragraph 4 will be reviewed, in particular with a view to reducing the limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e), by 31 December 2017. 5. For the purpose of this entry, 'cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface. Shall not be used for cadmium plating metallic articles or components of the articles used in the following

Designation of the substance, group of substances, or mixture	Conditions of restriction
	sectors/applications: (a) equipment and machinery for: — food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] — agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] — cooling and freezing [8418] — printing and book-binding [8440] [8442] [8443] (b) equipment and machinery for the production of: — household goods [7321] [8421 12] [8450] [8509] [8516] — furniture [8465] [8466] [9401] [9402] [9403] [9404] — sanitary ware [7324] — central heating and air conditioning plant [7322] [8403] [8404] [8415] In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited. 6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below: (a) equipment and machinery for the production of: — paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] (b) equipment and machinery for the production of: — industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431] — road and agricultural vehicles [chapter 87] — rolling stock [chapter 86] — vessels [chapter 89] 7. However, the restrictions in paragraphs 5 and 6 shall not apply to: — articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. 8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C. 9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons. 10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in: (i) metal beads and other metal components for jewellery making; (ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including: — bracelets, necklaces and rings, — piercing jewellery, — wrist-watches and wrist-wear, — brooches and cufflinks. 11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011.
28. Substances which are classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2, respectively: Cadmium carbonate Cadmium chloride Cadmium dihydroxide Cadmium dinitrate Cadmium fluoride Cadmium hydroxide Cadmium (pyrophoric) Cadmium nitrate Cadmium oxide Cadmium Sulphate Cadmium sulphide	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'. 2. By way of derogation, paragraph 1 shall not apply to:

Designation of the substance, group of substances, or mixture	Conditions of restriction
Chromium (VI) trioxide Zinc chromates including zinc potassium chromate Nickel Chromate Nickel dichromate Potassium dichromate Ammonium dichromate Sodium dichromate Chromyl dichloride; chromic oxychloride Potassium chromate Calcium chromate Strontium chromate Chromium III chromate; chromic chromate Sodium chromate Lead Chromate Lead hydrogen arsenate Lead Nickel Salt Lead sulfochromate yellow; C.I. Pigment Yellow 34; Lead chromate molybdate sulfate red; C.I. Pigment Red 104;	(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.
29. Substances which are classified as germ cell mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 3 or Appendix 4, respectively: Cadmium carbonate Cadmium chloride Cadmium dihydroxide Cadmium dinitrate	

Designation of the substance, group of substances, or mixture	Conditions of restriction
Cadmium fluoride Cadmium hydroxide Cadmium nitrate Cadmium Sulphate Chromium (VI) trioxide Potassium dichromate Ammonium dichromate Sodium dichromate Chromyl dichloride; chromic oxychloride Potassium chromate Sodium chromate	
30. Substances which are classified as reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or Appendix 6, respectively.'Toxic to reproduction: category 1A or 1B or toxic to reproduction category 1 or 2 According to Appendices 5 and 6: Cadmium chloride Cadmium fluoride Cadmium Sulphate Potassium dichromate Ammonium dichromate Sodium dichromate Sodium chromate Nickel dichromate Lead compounds with the exception of those specified elsewhere in this Annex Lead Arsenate	

Designation of the substance, group of substances, or mixture	Conditions of restriction
Lead acetate Lead alkyls Lead azide Lead Chromate Lead di(acetate) Lead hydrogen arsenate Lead 2,4,6-trinitroresorcinoxide, lead styphnate Lead(II) methane- sulphonate Trilead bis- (orthophosphate) Lead hexa-fluorosilicate Mercury Silicic acid, lead nickel salt	
47. Chromium VI compounds	1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002 %) soluble chromium VI of the total dry weight of the cement. 2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1. 3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin. 4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1. 5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather. 6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.
51. The following phthalates (or other CAS and EC numbers covering the substance): (a) Bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 EC No 204-211-0 (b) Dibutyl phthalate (DBP) CAS No 84-74-2 EC No 201-557-4 (c) Benzyl butyl phthalate (BBP) CAS No 85-68-7 EC No 201-622-7	1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles. 2. Toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market. 4. For the purpose of this entry 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.
62. (a) Phenylmercury acetate EC No: 200-532-5 CAS No: 62-38-4 (b) Phenylmercury propionate EC No: 203-094-3 CAS No: 103-27-5 (c) Phenylmercury 2-ethylhexanoate EC No: 236-326-7 CAS No: 13302-00-6 (d) Phenylmercury octanoate EC No: - CAS No: 13864-38-5 (e) Phenylmercury neodecanoate EC No: 247-783-7 CAS No: 26545-49-3	1. Shall not be manufactured, placed on the market or used as substances or in mixtures after 10 October 2017 if the concentration of mercury in the mixtures is equal to or greater than 0,01 % by weight. 2. Articles or any parts thereof containing one or more of these substances shall not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than 0,01 % by weight.

Designation of the substance, group of substances, or mixture	Conditions of restriction
63. Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight. 2. For the purposes of paragraph 1: (i) 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; (ii) 'any individual part' shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*); (b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C. 5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles articles produced before 10 December 1961. 6. By 9 October 2017, the Commission shall re-evaluate paragraphs 1 to 5 of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly. 7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm 2 per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	8. By way of derogation, paragraph 7 shall not apply to: (a) jewellery articles covered by paragraph 1; (b) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Directive 69/493/ EEC; (c) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/ 87) unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500 ° C; (e) keys and locks, including padlocks; (f) musical instruments; (g) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0,5 % by weight; (h) the tips of writing instruments; (i) religious articles; (j) portable zinc-carbon batteries and button cell batteries; (k) articles within the scope of: (i) Directive 94/62/EC; (ii) Regulation (EC) No 1935/2004; (iii) Directive 2009/48/EC of the European Parliament and of the Council (**); (iv) Directive 2011/65/EU of the European Parliament and of the Council (***) 9. By 1 July 2019, the Commission shall re-evaluate paragraphs 7 and 8(e), (f), (i) and (j) of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 7, including the requirement on coating integrity, and, if appropriate, modify this entry accordingly. 10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 1 June 2016. --- (*) OJ L 326, 29.12.1969, p. 36. (**) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1). (***) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).
67. Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE)	1. Shall not be manufactured or placed on the market as a substance on its own after 2 March 2019. 2. Shall not be used in the production of, or placed on the market in:

Designation of the substance, group of substances, or mixture	Conditions of restriction
CAS No 1163-19-5 EC No 214-604-9	(a) another substance, as a constituent; (b) a mixture; (c) an article, or any part thereof, in a concentration equal to or greater than 0,1 % by weight, after 2 March 2019. 3. Paragraphs 1 and 2 shall not apply to a substance, constituent of another substance or mixture that is to be used, or is used: (a) in the production of an aircraft before 2 March 2027. (b) in the production of spare parts for either of the following: (i) an aircraft produced before 2 March 2027; (ii) motor vehicles within the scope of Directive 2007/46/EC, agricultural and forestry vehicles within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council (*) or machinery within the scope of Directive 2006/42/EC of the European Parliament and of the Council (**), produced before 2 March 2019 4. Subparagraph 2(c) shall not apply to any of the following: (a) articles placed on the market before 2 March 2019; (b) aircraft produced in accordance with subparagraph 3(a); (c) spare parts of aircraft, vehicles or machines produced in accordance with subparagraph 3(b); (d) electrical and electronic equipment within the scope of Directive 2011/65/EU. 5. For the purposes of this entry 'aircraft' means one of the following: (a) a civil aircraft produced in accordance with a type certificate issued under Regulation (EU) No 216/2008 of the European Parliament and of the Council (***) or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation; (b) a military aircraft. (*) Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OL L 60, 2.3.2013, p. 1). (**) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24). (***) Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79 19.3.2008, p. 1).

As of 14 September 2018, the REACH Regulation Candidate list includes various substances of relevance for RoHS. Proceedings concerning the addition of these substances to the Authorisation list (Annex XIV) have begun and shall be followed by the evaluation team to determine possible discrepancies with future requests of exemption from RoHS (new exemptions, renewals and revocations)).