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

Report for the European Commission DG Environment under Framework Contract No ENV.C.2/FRA/2011/0020

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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

Eunomia Research & Consulting, Öko-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 Eunomia Research & Consulting, Öko-Institut and Fraunhofer IZM are not responsible for decisions or actions taken on the basis of the content of this report.

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1.0 Background and Objectives

The RoHS Directive 2011/65/EU entered into force on 21 July 2011 and effectively leads 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 old Directive) and RoHS 2 (the new Directive).

Under Framework Contract No. ENV.C.2/FRA/2011/0020, a consortium led by Eunomia Research & Consulting 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 Öko Institut with support from Franhofer Institut IZM, and has been peer reviewed by Eunomia Research & Consulting.

The approach to adjudicating on the case for exemptions has to take into account some new aspects under the RoHS 2 regime as compared to that of RoHS 1:

- The scope covered by the Directive is now broader as it covers all EEE (as referred to in Articles 2(1) and 3(a));
- 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) 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 Ordinance (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 with-

out 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, now has to 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 upon its entry into force (21.7.2011), the consultants have undertaken evaluation of a range of exemptions in this work (new exemption requests, renewing existing exemptions, amending exemptions or revoking exemptions).

The Report includes the following Sections:

Section 2.0 Project Set-up

Section 3.0 Scope

Section 4.0 Overview of the Evaluation Results

Section 5.0 Links from the Directive to the REACH Regulation

Sections 6.0 through 14.0 – Evaluation of the requested exemptions handled in the course of this project.

2.0 Project Set-up

Assignment of project tasks to Öko-Institut and Fraunhofer IZM started 2 May 2012. The overall project has been led by Carl-Otto Gensch. At Fraunhofer IZM the contact person is Otmar Deubzer. The project team at Öko-Institut consists of the technical experts Yifaat Baron, Markus Blepp and Andreas Manhart. Eunomia, represented by Dominic Hogg, have the role of ensuring quality management.

3.0 Scope

Eleven new RoHS exemption requests have been evaluated – 10 requests submitted under this service contract, and an additional request submitted under a subsequent contract (service contract ENV/2012/620308/ETU/C2, or 'Pack 2'). An overview of the exemption requests is given in Table 4-1 below.

In the course of the project, a stakeholder consultation was conducted. The stakeholder consultation was launched on 26 June 2012 and ran until 4 September 2012. It covered all 11 exemption requests.

A specific project website was also set up 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 mailings about new steps within the project.

Information concerning the consultation was provided on the project website, including a general guidance document, the applicant's documents for each exemption request, or results of earlier evaluations where relevant, a specific questionnaire and the link to the EU CIRCA website, where all non-confidential stakeholder comments submitted during the consultations were made available (EU CIRCA website)[1].

The evaluation of the stakeholder contributions led to further consultation including, *inter alia*, engaging with stakeholders in further discussion, further exchanges in order to clarify remaining questions, cross-checking with regard to the accuracy of technical arguments, and checks in respect of confidentiality issues. Where this was deemed necessary, stakeholder meetings were held.

In the course of the project, two requests were withdrawn by the applicant, shortly after the stakeholder consultation closed, for the purpose of reformulation with a similar request withdrawn from the previous RoHS exemption request review project.

The remaining requests were evaluated according to the various criteria (Cf. Section 1.0 for details). The evaluations appear in the following chapters. The information provided by the applicants and in some cases also by stakeholders is summarized for each request in the first sections. This includes a general description of the application and requested exemption, a summary of the arguments made for justifying an exemption, information provided concerning possible alternatives and additional aspects raised by the applicant and other stakeholders. In some cases, reference is also made to information submitted by applicants and stakeholders in previous evaluations, in cases where a similar request has been reviewed or where a renewal has been requested of a request reviewed in the past. The Critical Review follows these sections, in which the submitted information is discussed to clarify how the consult-

[1] EU CIRCA website (Browse categories > European Commission > Environment > RoHS 2012 Exemptions Review, at top left, click on "Library")

ants 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.[2]

[2] Cf. under:
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Project_Description_II_.pdf

4.0 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 summarized in Table 4-1. The reader is referred to the corresponding sections of this report for more details on the evaluation results.

The final – not legally binding – recommendations for exemption request no. 1 through 11 (excluding no. 8 and no. 9) were submitted to the EU Commission by Öko-Institut and Fraunhofer IZM and have already been published at the EU CIRCA website on the 12th of April 2013. So far, the Commission has not adopted any revision of the Annex to Directive 2011/65/EU based on these recommendations.

Table 4-1: Overview of the Exemption Requests, Associated Recommendations and Expiry Dates

No.	Wording	Applicant	Recommendation	Expiry date
1	**Hexavalent chromium** in alkali dispensers for in-situ production of photocathodes	COCIR: European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry	*Hexavalent chromium in alkali dispensers used to create photocathodes* - *in X-ray image intensifiers until 31 December 2019,* - *and in spare parts for X-ray systems placed on the EU market before 1 Jan 2020*	31 December 2019 1 January 2020
2	Reuse of parts from medical devices including X-ray tube components in new X-ray tube assemblies	COCIR	*Lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before July 22 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer*	21 July 2021.
3	**Lead** in solders for Positron Emission Tomography detectors and data acquisition units installed in Magnetic Resonance Imaging equipment	COCIR	*Lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment.*	31 December 2019
4	**Lead** in solders used in mobile medical equipment	COCIR	*Lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices others than portable emergency defibrillators:* - *used in Class IIa – mobile medical devices –* - *used in Class IIb – mobile medical devices –* *Where mobile medical devices are defined as medical devices which are designed and approved by a notified body, according to Directive 93/42/EEC, to be hand carried, or to be transported on own wheels, on a cart or trolley or in a vehicle, aircraft or vessel during and/or between operations.*	Class IIa: 30 June 2016 Class IIb: 31 December 2020

No.	Wording	Applicant	Recommendation	Expiry date
5	Decorative ceramic lamp bases or other ceramic components of luminaires containing **lead** and/or **cadmium** in the glaze/colouring	CELMA - Federation of National Manufacturers Associations for Luminaires and Electrotechnical Components for Luminaires in the European Union	Denied	
6	Decorative lamp shades and bases (luminaires) containing **lead** in the solder used to join/coat the copper foil mounting strips for the glass/shell/other material used in tiffany (like stained glass windows), capiz shell and similar products	CELMA	Denied	
7	**Mercury** in single capped (compact) fluorescent lamps not exceeding (per burner): 1(a)(1) For long-life lamps <30W (specified with a lifetime of >15 khrs) 3.5 mg may be used after 31 December 2011.	ELCF - European Lamp Companies Federation	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):	
			For general lighting purposes < 30 W: < 20.000h lifetime: 2.5 mg ≥20.000h lifetime: 3.5 mg	31 December 2017
8	**Mercury** in cold cathode fluorescent lamps for general lighting purposes (Category 5)	Federazione ANIE - Italian Federation of Electrotechnical and Electronic Industries	Withdrawn	
9	**Mercury** in cold cathode fluorescent lamps for luminous sign for advertising or decorative purposes (Category 5)	Federazione ANIE	Withdrawn	

No.	Wording	Applicant	Recommendation	Expiry date
10	**Lead** in micro-channel plate	JBCE - Japan Business Council in Europe	*Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is required:* *a) A compact size of the detector for electrons or ions where the space for the detector is limited to* *- to a maximum of 3 mm/MCP (detector thickness + space for the installation of the MCP); and* *- to a maximum of 6 mm in total;* *and an alternative design yielding more space for the detector is scientifically and technically impracticable.* *b) A two-dimensional spatial resolution for detecting electrons or ions* *- Where a response time shorter than 25 ns is required; or* *- Where a sample detection area larger than 149 mm^2 is required; or* *- Where a multiplication factor larger than 1.3 x 10^3 is required.* *c) A response time shorter than 5 ns for detecting electrons or ions* *d) A sample detection area larger than 314 mm^2 for detecting electrons or ions* *e) A multiplication factor larger than 4.0 x 10^7* *This exemption does not cover the uses of micro-channel plates in exemption 3 of Annex IV.*	- 21 July 2021 for medical equipment (cat. 8) and for monitoring and control instruments (cat. 9) - 21 July 2023 for in-vitro diagnostics (cat. 8) - 21 July 2024 for industrial monitoring and control instruments (cat. 9)
11	**Lead** as an activator in the fluorescent powder of discharge lamps when used as photophoresis lamps containing phosphors such as BSP (BaSi2O5:Pb)	Therakos Photopheresis	"Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi2O5:Pb) phosphors"	22 July 2021

5.0 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 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 authorization 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,[3] as well as for the evaluation of a range of requests assessed through a previous project in respect of RoHS 2.[4] Furthermore, substances for which an authorisation or restriction process is already underway are also reviewed, so that future developments may be considered where relevant.

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

- on the list of substances proposed for the adoption to the Candidate List (the Registry of Intentions);
- 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 Authorization List); or
- listed in REACH Annex XVII (the List of Restrictions).

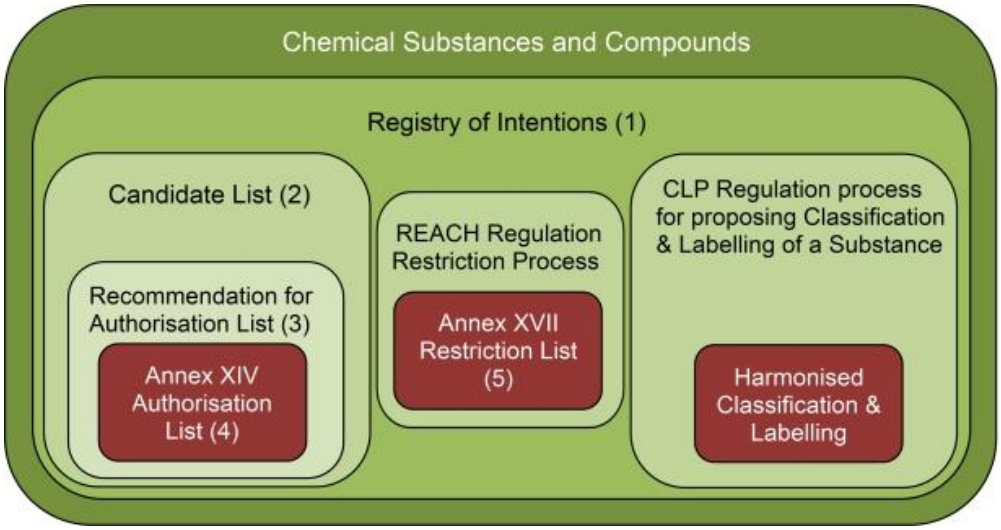
As the European Chemicals Agency (ECHA) is the driving force among regulatory authorities in implementing the EU's chemicals legislation, the ECHA website has been used as the reference point for the aforementioned lists, as well as for the exhaustive register of the Amendments to the REACH Legal Text.

Figure 5-1 shows the relationship between the two processes and categories. Substances included in the red areas may only be used when certain specifications and or conditions are fulfilled.

[3] 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 2011/65/EU, Final Report, Öko-Institut e.V. and Fraunhofer IZM,Freiburg, February 17, 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Re-evaluations_transfer_RoHS_I_RoHS_II_final.pdf

[4] 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 December 2012 http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/RoHS_V_Final_report_12_Dec_2012_final.pdf

Figure 5-1: Relation of REACH Categories and Lists to Other Chemical Substances



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 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: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/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 http://echa.europa.eu/web/guest/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 ECHA recommendations for inclusion in the Authorisation List are available at the ECHA website at http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list;

- 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 the last amendment of the REACH Legal Text is dated from 15 May 2012 (Commission Regulation (EU) No 494/2011), the consolidated version of the REACH Legal Text, dated 1 June 2012, was used to check Annex XIV and XVII: The consolidated version is presented at the ECHA website: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20120601:EN:PDF.

Table 5-1 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 5-1: Relevant Entries from Annex XIV: The 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)	
10. **Lead chromate** EC No: 231-846-0 CAS No: 7758-97-6	21 November 2013	21 May 2015	-
11. **Lead sulfochromate yellow** (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2	21 November 2013	21 May 2015	-
12. **Lead chromate molybdate sulphate red** (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8	21 November 2013	21 May 2015	-

For cadmium, hexavalent chromium, lead, mercury and their compounds covered in the exemption requests that were evaluated in this project, we have found that some relevant entries are listed in Annex XVII. The conditions of restriction of hexavalent chromium, lead, mercury and their compounds are presented in Table 5-2 below. Additionally, some amendments have been decided upon, and are still to be included in the concise version. These may be seen in Table 5-3.

Table 5-2: Conditions of restriction in REACH Annex XVII for mercury, cadmium and its compounds, cadmium oxide and specific lead compounds.

Designation of substance, group of substances or mixture	Conditions of restriction
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 Organisation (ILO) Convention 13 on the use of white lead and sulphates of lead in paint, 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.
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 ILO Convention 13 on the use of white lead and sulphates of lead in paint, 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.
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 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. 4. By 3 October 2009 the Commission shall carry out a review of the availability of reliable safer alternatives that are technically and economically feasible for mercury containing sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses. On the basis of this review or as soon as new information on reliable safer alternatives for sphygmomanometers and other measuring devices containing mercury becomes available, the Commission shall, if appropriate, present a legislative proposal to extend the restrictions in paragraph 1 to sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses, so that mercury in measuring devices is phased out whenever technically and economically feasible.
23. **Cadmium** and its compounds CAS No 7440-43-9 EC No 231-152-8	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. Shall not be used in mixtures and articles produced from synthetic organic polymers (hereafter referred to as plastic material) such as: — 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]

Designation of substance, group of substances or mixture	Conditions of restriction
	— 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] — high-density polyethylene (HDPE) [3901 20] — acrylonitrile butadiene styrene (ABS) [3903 30] — poly(methyl methacrylate) (PMMA) [3906 10]. Mixtures and articles produced from plastic material 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 (**) and acts adopted on its basis. 2. Shall not be used in paints [3208] [3209]. For paints 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

Designation of substance, group of substances or mixture	Conditions of restriction
	indelibly marked as follows: '*Contains recovered PVC*' or with the following pictogram:  In accordance with Article 69 of this Regulation, the derogation granted in paragraph 4 will be reviewed, in particular with a view to reducing the limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e), by 31 December 2017. 5. For the purpose of this entry, 'cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface. Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications: (a) equipment and machinery for: — food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] — agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] — cooling and freezing [8418] — printing and book-binding [8440] [8442] [8443] (b) equipment and machinery for the production of: — household goods [7321] [8421 12] [8450] [8509] [8516] — furniture [8465] [8466] [9401] [9402] [9403] [9404] — sanitary ware [7324] — central heating and air conditioning plant [7322] [8403] [8404] [8415] In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited. 6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below: (a) equipment and machinery for the production of: — paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] (b) equipment and machinery for the production of: — industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431]

Designation of substance, group of substances or mixture	Conditions of restriction
	— 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. 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 under- taken 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. Carcinogen category 1A or 1B or carcinogen category 1 or 2 According to Appendices 1 and 2: **Cadmium oxide** **Cadmium chloride** **Cadmium fluoride** **Cadmium Sulphate** **Cadmium sulphide** **Cadmium (pyrophoric)** **Chromium (VI) trioxide** **Zinc chromates including zinc potassium chromate**	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,

Designation of substance, group of substances or mixture	Conditions of restriction
Compounds containing Chromate and Di-Chromate **Chromium III chromate; chromic chromate** **Chromium (VI) compounds**, with the exception of barium chromate and of compounds specified elsewhere in Annex VI to Regulation (EC) No 1272/2008 **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**	- the relevant concentration specified in Directive 1999/45/EC. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: - motor fuels which are covered by Directive 98/70/EC, - mineral oil products intended for use as fuel in mobile or fixed combustion plants, - fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC.
29. Mutagens: category 1B or category 2 According to Appendices 3 and 4: **Cadmium chloride** **Cadmium fluoride** **Cadmium Sulphate** **Chromium (VI) trioxide** **Compounds containing Chromate and Di-Chromate**	
30. 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** **Compounds containing Chromate and Di-Chromate** **Lead acetate** **Lead alkyls** **Lead azide** **Lead Chromate** **Lead di(acetate)** **Lead hydrogen arsenate** **Lead(II) methane- sulphonate** **Trilead bis- (orthophosphate)** **Lead hexa-fluorosilicate** **Lead nickel salt** **Lead compounds** with the exception of those specified elsewhere in this Annex, [...] **Lead acetate** [...] **Lead 2,4,6-trinitroresorcinoxide, lead styphnate** **Mercury**	

Designation of substance, group of substances or mixture	Conditions of restriction
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.

Table 5-3: Summary of relevant amendments to annexes that came into force after the last concise version of the REACH Regulation was finalized

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction	Amended Annex	Amendment date
Mercury	(1) paragraph 4 is deleted; (2) the following paragraphs 5 to 8 are added: 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 § 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.'	Annex XVII, entry 18a	20 September 2012

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction	Amended Annex	Amendment date
Lead **CAS No 7439-92-1** **EC No 231-100-4** **and its compounds**	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05% by weight. 2. For the purposes of paragraph 1: (i) "jewellery articles" shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; (ii) "any individual part" shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*); (b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C. 5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961. 6. By 9 October 2017, the Commission shall re-evaluate 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.	Annex XVII, entry 63	19 September 2012

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction	Amended Annex	Amendment date
Cadmium	In the second column of entry 23, the first and second subparagraphs of paragraph 1 are replaced by the following: 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.'	Annex XVII, entry 23	18 September 2012

Additionally, on 19 April 2012, Sweden registered the intention at ECHA[5] to propose the restriction (Annex XVII) of "Lead and lead compounds in articles intended for consumer use". The proposal for restriction must be submitted by 19 April 2013. This proposal stems from the recent findings deeming lead to be a toxic substance with no

[5] European Chemicals Agency (ECHA), *Registry of intentions to propose restrictions*: http://echa.europa.eu/registry-of-current-restriction-proposal-intentions/-/substance/1402/search/+/term (last accessed 22 August 2012)

threshold below which it has no neurotoxic effects, particularly for children. As earlier decisions concerning restrictions on the use of lead were based on the belief that there is a threshold below which no effect occurs, Sweden considers there is a rationale for imposing restrictions on the use of lead in additional applications.

Since at present, it cannot be foreseen if, or when, new restrictions might be implemented as a result of this proposal; its implications have not been considered in the review of the exemption requests dealt with in this report. In future reviews, however, on-going research into processes and the results of on-going proceedings shall be followed and carefully considered where relevant.

On the 3rd of September, ECHA launched a consultation for contributions concerning the proposal of 54 substances for the candidate list for Substances of Very High Concern (SVHC). This list refers among others to 21 lead compounds. Decisions should be reached concerning these substances towards the end of 2012.

As at the time of writing (late 2012), this procedure only addresses the inclusion of these substances in the candidate list of substances of very high concern (SVHC) and since it cannot yet be foreseen how this process will conclude, it is not possible at this time to determine if the protection afforded by REACH Regulation would consequently be weakened by approving the exemption requests dealt with in this report. For this reason, the implications of these decisions have not been considered in the review of the exemption requests dealt with in this report. However for the sake of future reviews, process results shall be followed and carefully considered where relevant.

Table 5-4 shows the check of substitutes and alternative materials of relevance to the exemption requests evaluated in the course of this project for specific provisions under REACH, e.g. conditions of restriction in REACH Annex XVII and Annex XIV. The evaluation and recommendations of each exemption request that are presented in the following chapters will only briefly refer to the relationship to the REACH Regulation, indicating the results of the REACH check described below.

Table 5-4: In Progress: Check of conditions of restriction and authorisation in REACH Annex XVII and Annex XIV, for possible substitutes

Request No.	Substance or compounds	Specific provisions etc. under REACH
1	Cadmium Zinc Telluride	None - Cadmium and its compounds are mentioned in items 23, 28 and 29, however these items are not relevant in the case of the items mentioned in the course of this request.
	Thallium doped Cesium Iodide & Cesium Iodide	None

6.0 Exemption Request No. 1: "Hexavalent Chromium in Alkali Dispensers for In-situ Production of Photocathodes"

Abbreviations

CrVI	Hexavalent Chromium
CZT	Cadmium Zinc Telluride
II	Image Intensifiers used with x-ray equipment
PMT	Photomultiplier Tubes used for measurement of electromagnetic radiation

The applicant, COCIR (2011)[6], explains that image intensifiers, photomultipliers and other similar devices use a component known as a photocathode which converts visible light (from an input phosphor) into electrons. According to the applicant (COCIR 2011)[7], the fabrication process of these photocathodes is through a chemical reaction between a layer of antimony and an alkali metal vapour that is generated from alkali dispensers. The alkali dispenser contains a mixture of an alkali metal chromate and a reactive metal which, when heated, emits the alkali metal as a gas. The fabrication of these photocathodes must be done in-situ, that is, within the device, under vacuum conditions, due to the chemical reactivity of the alkali metals. Some of the hexavalent chromium (CrVI) from the process remains inside the product that is placed on the market.

As substitutes and alternative designs are currently not sufficiently available, an exemption has been applied for.

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) has therefore applied for an exemption for "*Hexavalent chromium in alkali dispensers used to create photocathodes in X-ray image intensifiers until 31 December 2019, and in spare parts for X-ray systems placed on the EU market before 1 Jan 2020*."

[6] COCIR (2011) Original exemption request no. 1, Submitted by COCIR, 30 September 2011; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_1/COCIR-Exemption_request_1-Alkali_dispensers.pdf

[7] Ibid.

6.1 Description of Requested Exemption

The applicant (COCIR 2011)[8] explains that image intensifiers (II), photomultiplier tubes (PMT) and other similar devices use a component known as a photocathode which converts visible light into electrons. X-ray image intensifiers were first used for X-ray imaging in 1948. They are gradually being replaced by digital semiconductor detectors, which are discussed below (cf. Section 6.2.2.4). Nowadays, image intensifiers are used in two main types of X-ray imaging equipment:

- Mobile X-ray C-arc – these are smaller systems that are moved around hospitals to examine patients who cannot be moved, for example, if they are receiving emergency treatment or during surgery. These are relatively simple, low priced systems, but they are robust and less sensitive to damage inflicted as a result of mobile use. In some cases, digital detectors can be used. These are, however, more sensitive and so in most cases, replacement is impracticable.
- Nearby controlled C-arc – these are stationary systems where the patient is brought to the equipment. As these are stationary, they can be larger and more complex, and may therefore be replaced with digital detectors more frequently.

COCIR (2011)[9] explains that image intensifiers use the following steps to amplify X-radiation to generate bright visible light images.

- X-radiation that has passed through the patient strikes an input phosphor with a photo emissive layer. This converts the weak input X-radiation into a weak visible light image that is projected and focussed onto a photocathode.
- The photocathode is a layer consisting of compounds of alkali metals, such as caesium with antimony and arsenic, and typically, caesium antimonide is used, although more complex mixtures are also used. The photocathode is charged to a high voltage so that where light from the input phosphor strikes it on one side, this is converted and amplified into electrons that are emitted from the other side, and travel to the output phosphor screen which converts the electron image into a bright visible light image.

According to COCIR (2011)[10] the best performing photocathodes are complex mixtures of compounds of alkali metals such as potassium and caesium with Group V elements such as antimony and arsenic. Alkali metals are very reactive and will react extremely rapidly with minute traces of oxygen and moisture vapour and so the alkali antimonide photocathode coating layer must be fabricated in-situ in the absence of air and moisture and kept permanently within a high vacuum. The fabrication procedure used is to first assemble the II or PMT with a thin coating of antimony metal on the photocathode support. The alkali dispenser is inserted inside the assembled II or PMT with electrical connections to the alkali dispenser's heaters and then the II or

[8] Ibid.

[9] Ibid.

[10] Ibid.

PMT is evacuated to remove all traces of air and then sealed. It is normal to bake the equipment while pumping under vacuum to desorb moisture and other contamination from internal surfaces that would react with alkali metals or degrade the performance. Internal parts, including the alkali dispenser, must, therefore, be stable at baking temperature, which is typically ~200°C. Once evacuated and sealed, the alkali dispenser is electrically heated, causing the mixture of substances inside the dispenser to chemically react and release the alkali metal as a vapour. This vapour then reacts with the layer of antimony on the photocathode support to create the photocathode, e.g. caesium antimonide, (as in the reaction below):

$$Cs + Sb = CsSb$$

The alkali dispenser is a sealed tube containing a mixture of an alkali metal dichromate with a reducing agent, usually zirconium/aluminium (Zr/Al) alloy powder. This mixture is heated electrically (via the electrical connections) and reacts to generate the alkali metal vapour, and in some designs the gas pressure created also opens the dispenser.

$$Cs_2CrO_7 + Zr/Al = ZrO_2 + Al_2O_3 + Cr_2O_3 + Cs\ (vapour)$$

The alkali metal vapour reacts with a thin antimony coating on a support structure to produce the alkali antimonide photocathode. The chemical reaction with the dichromate salt is usually incomplete and some hexavalent chromium remains in the dispenser device that remains inside the finished image intensifier, or photomultiplier tube. The dispenser device is only used in the manufacturing process, and plays no part in the operation of the device.

The applicant[11] estimates that about 14 grams of hexavalent chromium is placed on the EU market annually through this application.

The following assumptions have been made:

- Figures are based on one representative manufacturer's products, which are assumed to have ~12% market share.
- The EU is estimated to have one third of the global market.

The figures in the table below represent CrVI content of products of the above mentioned manufacturer of image intensifiers:

[11] COCIR (2012a) Information provided by the applicant in response to first round of clarification questions, submitted on 19 June 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_1/Request_1_1st_Clarification_Questions_Answers.pdf

Table 6-1: Data concerning CrVI content of various Image Intensifiers placed on the EU market (Source: COCIR, 2012a)

Size Image intensifier*	Weight CrVI per II (g)	Annual quantity (pcs)	Total weight (g)
23 cm	0.00228	1200	2.74
31 cm	0.00342	500	1.71
38 cm	0.00342	300	1.03
		Total (global)	5.48

** Note that 15 cm IIs are supplied only for repair of existing systems and so are excluded from RoHS.*

The estimated annual global consumption of CrVI in this application is ~45.7 grams. Therefore the total EU quantity of CrVI for this application is 13.7 grams.

6.2 Applicant's Justification for Exemption

This exemption is required since, according to COCIR (2011)[6], potential substitute designs and materials are not sufficiently reliable or available to cover the full product demand range. Potential alternative designs for use with II and PMT are:

1. Alternative substances to hexavalent chromium salts;
2. External alkali dispensers; and
3. The use of digital semiconductor detectors instead of image intensifiers for X-ray imaging.

The reasons provided by the applicant as for why each of these cannot be used to replace hexavalent chromium are detailed in the next sections.

6.2.1 Possible Substitute Alternatives

The applicant[12] contends that alternative substances, that emit alkali metals in a controlled way, are at this time not available. The applicant goes on to argue that although research into alternative substances has been undertaken, to date, suitable alternatives are yet to be developed. The applicant argues that none of the potential alternatives looked into in the past has proven to be an option that will allow the fabrication of photocathodes with suitable performance.

[12] Op. cit. COCIR (2011)

6.2.2 Possible Design Alternatives

6.2.2.1 Location of Alkali Dispensers

According to the applicant (COCIR, 2011)[13], most current II designs use internal alkali dispensers, although it is possible to connect an external alkali dispenser to the II or PMT and then to remove the dispenser after fabrication of the photocathode and creation of the vacuum seal. This, however, requires a significant design change and current designs cannot be adapted to use this approach[14]. Since current production lines would still be required to provide spare parts for systems already in use, altering the design of newly manufactured systems would require building separate production lines. As the market for II is declining, manufacturers would not invest in redesigning their IIs, nor are they likely to build new production lines, and so the availability of IIs would very significantly decline. This would leave only a few models from one supplier, who would then dominate the market, removing competition. With very little competition, prices of II would inevitably rise and this would consecutively have an impact on healthcare providers in the EU.

6.2.2.2 Alternative Alkali Dispensers

COCIR [15] states that research has been carried out concerning alternative types of alkali dispensers for many years, partly to avoid using hazardous hexavalent compounds but also because the alkali dispenser mixture can release detrimental impurities as well as the alkali metal. These include hydrogen gas released from the Zr/Al alloy which must be removed from the vacuum by a separate "getter". The applicant further elaborates on some of the problems with the various alternatives that have been looked into:

- In some of these cases the application is unstable and so can either not be used or results in unreliable results;
- In PMT applications, the alternatives use Indium for sealing the dispenser, which consequently is often melted in the process of sealing the PMT (made of glass and having a higher melting point). The dispenser is then open and some of the alkali metal may escape before it can be used, resulting in an insufficient amount for forming the photocathode;
- Another problem in PMT alternatives is that a current, passed through a wire, is used to activate the alkali dispenser mixture. The wire is bound to the glass of the PMT, so that as its temperature may rise due to the current, it expands

[13] Ibid.

[14] In other words photocathodes produced with ex-situ dispensers are not interchangeable with those produced with in-situ dispensers, due to different design of the final product in which the photocathode is located.

[15] Op. cit. COCIR (2011)

and sometimes causes the glass to crack, destroying the vacuum needed within the application; and

- In some of the alternative dispensers, the alkali metal is produced at a different rate to that of the CrVI dispenser, resulting in a poor image and often in loose particles remaining in the II and appearing randomly in images, sometimes leading to misleading or incorrect diagnosis.

The applicant therefore concludes that research by manufacturers has not yet resolved all technical issues to enable any of the CrVI-free substitutes to be used commercially (i.e., substitutes for the dispensers used for in-situ fabrication).

6.2.2.3 Alternative image intensifier and photomultiplier design

The applicant[16] explains that there is an option of locating the alkali dispenser in a separate "side-arm" attached to the photomultiplier or image intensifier. In order to do this, it must be possible to disconnect the separate alkali dispenser, after dispensing the alkali vapour needed to create the photocathode, while maintaining the high vacuum inside the device. Such mechanisms are not problem free, however, even if solutions were to be found, the main technical disadvantage of using an external alkali dispenser, remains the distance that the alkali metal needs to travel before reaching the photocathode. During this "journey" the alkali metal coats other parts of the image intensifier where condensed metal can degrade the performance. A correspondingly larger amount of hexavalent chromium is required, therefore, to ensure that a sufficient amount reaches the photocathode. In other words, using an external alkali dispenser may result in a RoHS compliant product, but it does not avoid the use of hexavalent chromium, but rather requires a larger quantity be used over the life cycle of the device.

In light of this argumentation, Toshiba, who supplies applications with photocathodes produced with ex-situ dispensers, was contacted and asked as to the differences between the ex-situ and in-situ produced photocathodes. The information they supplied confirms that their products are supplied to the European market. As for the amounts of CrVI used, Toshiba contend that the "quantity of required CrVI is essentially the same… CrVI remains in the cell (i.e. dispenser, and) is disposed by industrial waste disposers". When asked if the reliability of applications using cathodes produced with ex-situ dispenser is impaired due to the production process and the need to separate the dispensers from the end product, Toshiba replied that the "technology of connecting and separating (the) cell is a common technology for vacuum-tube manufacturers. There is no effect on the integrity of its performance and reliability"[17].

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[16] Ibid.

[17] Toshiba (2012) Answers provided by Toshiba in response to clarification questions sent by the consultants, submitted per e-mail on 24 September 2012

6.2.2.4 Digital Detectors

The applicant[18] puts forward that image intensifiers can be replaced by digital array detectors. Although these have a few advantages, disadvantages also apply in some areas, making them impracticable at present as an application that could replace all II's and PMT's.

First of all, digital detectors are considerably more expensive than image intensifiers and are therefore used mainly in "high-end" systems, although their share in the market is increasing. Typically, an image intensifier based imaging system[19] costs from less than €100,000 to up to ~€200,000, whereas a digital detector based system ranges from €200,000 - 300,000 or more. [20]

Second of all, the best performing digital semiconductor detectors contain Cd, Pb or Hg and so, where substitution is to be considered; environmental aspects must also be reviewed see Table 6-2 below.[21]

Another aspect concerns devices used for mobile applications. Mobility is a potential risk to the more fragile digital detectors which are difficult to repair and so, usually, II's will be preferred in these cases. That said, a few mobile digital C-arc systems were sold in the EU in recent years, and it may be assumed that this trend may grow as digital detectors are developed, which can address this concern. [22]

Finally, although for some treatments, II systems and digital systems use similar X-ray doses, there are also treatments where digital detectors require slightly higher doses which will have a negative health impact on patients. In these cases, substituting II's with digital detectors would not be justified. [23]

The applicant[11] further elaborated that procedures, requiring continuous real-time imaging, subject patients to higher radiation doses if digital detectors are used, than with image intensifiers. "This is because a higher noise level is acceptable with analogue image intensifiers than with digital detectors. Higher doses are needed with digital detectors to ensure that electronic noise is insignificant and do not hide important features. Continuous imaging is used, for example for angiography where the patient's blood vessels are viewed while stents etc. are fed through to reach blockages (see http://en.wikipedia.org/wiki/Angiography). The additional X-ray dose that patients are exposed to where digital detectors are used is extremely varied and is not possible to quantify as this is controlled to a large extent by medical staff. For many procedures, no additional dose is needed by digital detectors but this depends on the image quality that can be tolerated. Doctors try to use the lowest dose possible

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[18] Op. cit. COCIR (2011)

[19] Note that the price of image intensifiers is much less at about €7,000 but image intensifiers and digital detectors are not interchangeable in x-ray system designs.

[20] Op. cit. COCIR (2011)

[21] Ibid.

[22] Ibid.

[23] Ibid.

to achieve an acceptable image. The dose depends on the type of procedure, the type of X-ray system, the patient and what the doctor is trying to see. Under some circumstances, image intensifier systems can require lower X-ray doses than digital systems but this cannot be quantified". [24]

In light of the various aspects mentioned above, digital detectors do not sufficiently cover the full application range, as is demonstrated by the fact that at present, in the EU, about 45% of new X-ray systems sold, still use image intensifiers[25].

The applicant[26] contends that the continued availability of low-end image intensifier systems will be needed until digital detectors do not require higher radiation doses for all applications, and also until the prices of digital detectors can be reduced to an extent that all health care providers in the EU are able to afford them. Image intensifier technology will still be needed for new equipment after medical devices are included in the scope of the RoHS Directive on 21 July 2014, but should not be needed in new systems after 2020 when it is expected that research into silicon digital detectors has resolved the technical issues that exist (such as reducing the radiation dose needed and supplying systems sufficiently reliable for mobile applications) and enabled digital systems to be sold at lower prices. After this date, image intensifiers will be needed as spare parts to be used as replacements for faulty units in older X-ray systems.

6.2.3 Environmental Arguments

The applicant[27] has provided some information concerning the dangerous materials used in some digital detectors, in comparison to the CrVI requirement of II's and PMT's.

Various types of semiconductors are used depending on the type of imaging technique and the performance that is required, but types based on silicon were the first to be introduced and are the most common. Amorphous silicon photodiode or CMOS detectors are used, but as silicon is a light element, it adsorbs X-radiation inefficiently. Silicon detectors, therefore, usually have a coating of an X-radiation sensitive phosphor, based on heavy metals that efficiently adsorb radiation and convert it into visible light that is detected by the silicon. Thallium doped caesium iodide is the most common type of phosphor used to convert X-radiation into visible light that can be detected by silicon. Thallium is very toxic and this type of phosphor is used only in digital silicon detectors.[28]

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[24] Ibid.

[25] Ibid.

[26] Ibid.

[27] Ibid.

[28] Ibid.

Recently, more efficient types of digital detector such as cadmium zinc telluride (CZT) have been developed. These are more sensitive than silicon detectors so that lower radiation doses can be used, but they contain cadmium which is a RoHS restricted substance. However, cadmium in digital X-ray detectors is covered by an existing RoHS exemption (item 1 of Annex IV of the recast).

Other types of digital detectors based on silicon but without thallium do not efficiently adsorb radiation because silicon is a low atomic mass element. Gallium arsenide detectors are used for non-medical applications only, but arsenic is toxic and a carcinogen and it also has a lower sensitivity than heavy metal semiconductor detectors such as CZT detectors. Some types of silicon detectors require cooling and so consume more energy. Overall silicon detectors have lower sensitivity than CZT and so require higher radiation doses than CZT.

The applicant further puts forth information concerning life cycle assessment (LCA) of materials used for digital detectors as compared to those used in image intensifiers, provided in Table 6-2 below.

Table 6-2: Comparison of materials used in image intensifiers and in digital detectors

Design and materials	Abundance and toxicity	Extraction, refining and production	Other comments
Image intensifiers			
Steel, aluminium	Very abundant, low toxicity		Metals are always recovered at end of life
Lead seal	Very abundant, less toxic than thallium and cadmium	Straightforward, no risk at well regulated modern facilities	Pure lead is easy to recycle with very high yield
Input phosphor – caesium iodide	Iodine is widely available but caesium occurs at useful concentrations at only a few locations. Both have low toxicity	Caesium is produced on a relatively small scale and iodine on a larger scale using sequences of chemical process steps	
Silicon detectors			
Silicon	Common and non-toxic	High purity silicon semiconductors production is very energy intensive	Silicon is not recovered at end of life
Thallium doped caesium iodide	Thallium is moderately abundant but occurs at low concentrations in ores. Thallium is very toxic, similar to cadmium	Usually recovered as a by-product from lead, zinc and copper production. See above for caesium and iodine	
CZT detectors			
CZT	Cadmium is toxic and a carcinogen but widely available	High purity CZT semiconductors production is very energy intensive	Modern efficient recycling processes are able to recover cadmium, zinc and tellurium

Source: Op. cit. COCIR 2011

The applicant later provided some insight as to the amounts of hazardous materials present in various digital detectors. According to COCIR[29], "*the most commonly used digital detectors are based on silicon with a thin layer of scintillator material that contains thallium. We estimate that one silicon detector will contain only a few tens of milligrams of thallium (this depends on the size of the detector)… Less common but having the advantage of requiring lower radiation doses are new cadmium telluride and cadmium zinc telluride detectors. For example, one detector of 20 x 20 x 6mm typically will contain 6.5 grams of cadmium. Image intensifiers contain besides*

[29] Op. cit. COCIR (2012a)

0.00228–0.00342 grams of CrVI, 0.0051–0.011 grams Cadmium in the phosphor layer, depending on the size".

It should be noted that the use of lead, cadmium and mercury, in ionising radiation detectors, is already covered by exemption 1 of Annex IV in the RoHS Directive 2011/65/EU. In the consultants understanding this exemption covers the use of cadmium both in digital detectors, as well as in II'S and PMT'S.

6.2.4 Stakeholder Contributions

Contributions were not made during the stakeholder consultation concerning this request. However, Toshiba who confirmed production of a CrVI free product after the consultation closed submitted some information in response to the consultants' questions. Information provided by Toshiba is discussed in Section 6.2.2.3 above.

6.2.5 Road Map for Substitution

The applicant[30] provides some insight as to the time frame required for full substitution of hexavalent chromium-containing alkali dispensers. An assumption is put forward that by 2018, most new X-ray systems sold in the EU will use digital detectors if the current technical issues can be resolved. Manufacturers estimate that this work may be completed by ~2017 or possibly a few years later, so after this date, image intensifiers will no longer be used in new x-ray imaging systems although image intensifiers will continue to be used for up to 20 years more as replacement spare parts in systems placed on the EU market before this date. As research cannot guarantee results, 2017 may be optimistic and 2020 may be a more realistic date.

In later correspondence with the applicant[31] it was further stated that "*the use of image intensifiers is declining and their use in new equipment will end by the end of 2019*"

Further support for the foreseen phase-out of image intensifiers with innovative digital detectors can be found in the 2006 ERA report, reviewing the need for exemptions for category 9 and 9 applications[32]. It should be noted that in this report it can be understood that phase-out is likely to occur earlier, but seems to have not materialized. A further ERA study prepared in 2009 on behalf of COCIR to review additional exemptions from the RoHS Directive needed by the medical sector, states that the research

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[30] Op. cit. COCIR (2011)

[31] COCIR (2012b) Information provided by the applicant in response to a second round of clarification questions, submitted on 23 November 2012

[32] Goodman, P. (2006) *Review of Directive 2002/95/EC (RoHS) categories 8 and 9 – Final Report*. ERA Report 2006-0383, July 2006, amended September 2006, http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf

efforts of manufacturers carried out after the 2006 report did not manage to resolve all technical issues to allow for the development of commercial substitutes[33].

6.3 Critical Review

6.3.1 REACH Compliance - Relation to the REACH Regulation

Chapter 5.0 of this report lists entries 28 and 47 of the REACH Regulation Annex XVII, restricting the use of hexavalent chromium and its compounds in various articles.

In the consultants' understanding, entry 28 of Annex XVII does not apply to the use of CrVI in alkali dispensers used to create photocathodes since the regarded substance is part of an application, and so, would not be placed on the market, or used as a substance, a constituent of a substance or as a mixture for supply to the general public. Entry 47 regards the CrVI contents of cement and cement mixtures placed on the market and so does not correspond to the use of CrVI referred to in this request for exemption. In other words, the use of CrVI in question is not subject to any restrictions by REACH.

The consultants conclude that the use of CrVI in alkali dispensers used to create photocathodes does not weaken the environmental and health protection afforded by the REACH Ordinance. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

Consequently, the mentioned substances used in digital detectors have also been checked where REACH Regulation is of concern;

As for digital detectors using Cadmium Zinc Telluride – though the use of cadmium is restricted in item 23, 28 and 29 of Annex XVII of the REACH Directive, in the consultants view, the application of cadmium in CZT digital detectors is not addressed by these restrictions.

As for Thallium doped Cesium Iodide and Cesium Iodide; the consultant did not find restrictions relevant to the use of these substances in the REACH Regulation.

In this sense, partial, or full substitution are not perceived by the consultant to weaken the protection afforded by the REACH Regulation.

6.3.2 Scientific and Technical Practicability of Substitution of In-situ Alkali Dispensers using CrVI

COCIR[34] puts forward information, explaining the complexity of substituting in-situ alkali dispensers containing CrVI, used for photocathode fabrication.

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[33] Goodman, P. (2009) Additional Exemptions from the RoHS Directive needed by the Medical Industry. ERA Report on behalf of COCIR, September 2009, http://www.cocir.org/uploads/documents/38-1248-8-1100-cobham_era_report_on_rohs_exemptions_for_medical_devices_sept_2009.pdf

[34] Op. cit. COCIR (2011)

Though it is clarified that substitutes do exist for this application, it remains unclear to what extent these could be used to substitute the full range of applications needed by the medical sector in the next few years. Upon being asked to provide specific information as to what substitutes exist for what medical applications (digital detectors or applications produced with ex-situ dispensers) the applicant[35] stated that:

> *"There are four manufacturers of image intensifiers and of these only one has designs with external dispensers. This manufacturer has an estimated market share of ~20% so they could not replace the image intensifiers used by the other three manufacturers. If image intensifiers from only this one manufacturer could be used the impact would be one or several of the following:*
>
> - *The manufacturer of image intensifiers with external dispensers would not increase production to meet the shortfall by the other three producers because the use of image intensifiers is declining and their use in new equipment will end by the end of 2019. Increasing capacity would require new production lines and medical equipment manufacturers will not invest very large sums on production lines with such short lifetimes.*
> - *Similarly for the same reasons, those manufacturers who currently use internal dispensers will not build new production lines using technology licensed from the manufacturer of image intensifiers with external dispensers*
> - *All image intensifier designs are different and are specific to X-ray equipment and so it is usually not possible to use a different model of image intensifier in X-ray imaging equipment.*
> - *The result will be that the availability of new X-ray equipment with image intensifiers will decrease by ~80% from July 2014. EU hospital demand for image intensifier systems will not change and so many will not be able to buy new systems with image intensifiers and so will either be forced to continue to use old equipment or pay much more for digital systems and as explained in the exemption request this will have an effect on the hospitals ability to buy other equipment. As explained in the exemption request, this would affect the health of patients."*

Though the exact market share of the CrVI-free image intensifiers was not further affirmed to represent 20% of the image intensifier applications provided to the EU market, the consultant believes it is reasonable to assume that the supplier does not dominate the market for these products to an extent that would allow sufficient supply of the full image intensifier product range. As image intensifiers are said to still be required for 45% of these applications (see Section 6.2.2.4 above), the consultants find the argumentation that failure to supply full demand may have an effect on patients health, reasonable, especially in areas where;

[35] Op. cit. COCIR (2012b)

- Insufficient supply of image intensifiers will result in continuous use of older applications or;
- in a shortage in applications in some departments, prolonging waiting times and impacting the availability of certain procedures;
- Digital detectors are used to fulfil remaining need for image intensifiers, resulting in some cases in higher radiation doses and in others in shorter application lifetime (mobile applications).

Furthermore, the consultants find it likely that the scenario prohibiting the use of photocathodes produced with in-situ dispensers may result;

- either in a supply of image intensifiers insufficient to fulfil European demand;
- or in a need to develop further production lines;

It is less relevant if the latter mentioned production lines shall be set up by the ex-situ dispenser photocathode supplier or following redesign efforts of the in-situ dispenser photocathode suppliers. In any case, assuming that phase-out is indeed foreseen before 2020, the set-up of production lines for the period between 2014 and 2020 for which the exemption is required is perceived as a waste of resources in respect of the ability of existing production lines to manufacture the full demand range.

Additionally, from the consultants' experience, as new medical products usually require more time for product reliability testing and for product registration according to medical devices Regulation, if products are to be redesigned, a few years can be expected to go by before new products can come on the market. Assuming that phase-out is indeed underway this further supports the perception of new production-lines as wasteful in terms of resources.

6.3.3 Environmental Arguments

COCIR[36] presents environmental data and statements comparing the life cycles of in-situ alkali dispensers containing CrVI, used for photocathode fabrication, with potential substitutes.

In light of the various scientific and technological argumentations, it is clear that a key issue remains in the comparison of the magnitude of hazardous substance aspects between image intensifiers and photomultipliers and between digital detectors. As stated by the applicant, digital detectors make use of a few heavy metals and so the substitution of one application for the other has various environmental aspects that are of importance when considering elimination. Though the applicant emphasizes this issue and provides some detailed examples, data allowing a comprehensive comparison was provided in the submitted information regarding this issue.

[36] Op. cit. COCIR (2011)

When compared to silicon based digital detectors, it seems that though these often contain thallium, this substance usually amounts to only a few tens of milligrams per application whereas II's and PMT'S usually contain 0.00228–0.00342 grams of CrVI, as well as 0.0051–0.011 grams of Cadmium in the phosphor layer. Without going into the discussion of which substances hold more risks, it was clarified that silicon based digital detectors often require higher doses of radiation. It seems that the potential risk associated with higher radiation doses is more probable to occur in relation to the risk of substance emissions during regular operation, for either thallium, CrVI or cadmium, as all of these are located in the application within sealed areas and so emissions would be likely to occur during set-up or maintenance and not during on-going operation of the applications.

As for CZT based digital detectors, an example is given of a 20 x 20 x 6mm detector which would typically contain 6.5 grams of cadmium. Assuming that the maximum concentrations tolerated according to Annex II of RoHS 2, reflect to some degree the relation between risks associated with CrVI and Cadmium (0.1 and 0.01% weight respectively), it can be understood that substituting a devices with the highest substance contents (0.00342 grams of CrVI 0.011 grams of Cadmium) with a device containing 6.5 grams could be regarded as less favourable in terms of the risks associated to these substances.

Against this background, it seems that further acceleration of the on-going phase out of image intensifiers would lead to more risk in terms of hazardous substance emissions or in terms of radiation dose effects on health. Additionally, in some cases higher energy consumption is expected, where digital detectors require cooling. Against this background, the consultants believe that further acceleration of the phase-out process already in motion would not be recommended.

6.3.4 Conclusions

As for substitution with digital detectors, the applicant implies that the applications for which this exemption has been requested shall probably be phased out by the end of this decade by digital detector applications. This is substantiated with information submitted concerning the market share of digital detectors, corresponding to 85% of Nearby C-arc systems but only to 15% of mobile X-ray C-arc systems (see Section 6.1 above).

Earlier reports prepared by ERA for the European Commission (2006) as well as for the applicant (2009) also mention the on-going phase-out.

Both sources support the argumentation that production of photocathodes with CrVI-free in-situ dispensers has not sufficiently developed to allow for the marketing of a commercial application. In light of possible environmental and health impacts, it is unclear if the acceleration of this phase-out through a prohibition of II's and PMT's containing CrVI would be recommended.

Concerning substitution with CrVI-free II's and PMT's, the argumentation that the available supply of photocathodes produced with ex-situ dispensers would not fully cover the demand for II's and PMT's in Europe is reasonable, i.e. the possible substi-

tute is not available for full substitution. It is therefore assumed that prohibiting CrVI containing products would either:

- Result in a failure to cover the full product demand range of II's and PMT's, indirectly leading to negative health impacts.
- Result in the assembly of new production lines, consequently contributing to inefficient use of resources against the background of on-going phase-out.

6.4 Recommendation

Against the various risks tied with accelerated elimination and full range substitution of CrVI containing II's and PMT's, it is recommended to grant the exemption.

As in the last correspondence[37], COCIR stated that phase out is assumed to be complete by the end of 2019, the consultants recommend the exemption remain valid until this time. Furthermore, article 4 (4) (f) of the 2011/65/EU RoHS Directive excludes

> "*the use of spare parts for repair, reuse, updating of functionalities or upgrading of capacities" of "EEE which benefited from an exemption and which was placed on the market before that exemption expired".*

In this sense the second part of the proposed wording, regarding the validity of the requested exemption for spare parts for X-ray systems placed on the market before 1 January 2020 would also be in line with the RoHS 2 Directive.

The applicant[38] states that:

> *"The types of image intensifiers used in medical devices require this type of alkali dispenser but non-medical image intensifiers can use different technology".*

As no further information has been submitted to demonstrate that the exemption is required for additional categories, the consultants recommend adding the following exemption to Annex VI of Directive 2011/65/EU:

> *"Hexavalent chromium in alkali dispensers used to create photocathodes in X-ray image intensifiers until 31 December 2019, and in spare parts for X-ray systems placed on the EU market before 1 Jan 2020."*

[37] Op. cit. COCIR (2012b)

[38] Ibid.

6.5 References Exemption Request 1

COCIR (2011) Original exemption request no. 1, Submitted by (COCIR), 30 September 2011; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_1/COCIR-Exemption_request_1-Alkali_dispensers.pdf

COCIR (2012a) Information provided by the applicant in response to first round of clarification questions, submitted on 19 June 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_1/Request_1_1st_Clarification_Questions_Answers.pdf

COCIR (2012b) Information provided by the applicant in response to a second round of clarification questions, submitted on 23 November 2012

Goodman, P. (2006) *Review of Directive 2002/95/EC (RoHS) categories 8 and 9 – Final Report*. ERA Report 2006-0383, July 2006, amended September 2006, http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf

Goodman, P. (2009) *Additional Exemptions from the RoHS Directive needed by the Medical Industry.* ERA Report on behalf of COCIR, September 2009, http://www.cocir.org/uploads/documents/38-1248-8-1100-cobham_era_report_on_rohs_exemptions_for_medical_devices_sept_2009.pdf

Toshiba (2012) Answers provided by Toshiba in response to clarification questions sent by the consultants, submitted per e-mail on 24 September 2012

7.0 Exemption Request No. 2: Reuse of Parts from Medical Devices Including X-ray Tube Components in New X-ray Tube Assemblies"

Abbreviations

Cr Hexavalent Chromium

7.1 Description of Requested Exemption

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) has put forward a request an exemption for reuse of parts from medical devices including X-ray tube components in new X-ray tube assemblies.

The applicant therefore puts forward the following main arguments: [39]

- Most used X-ray assemblies are returned to manufacturers who reuse as many parts as possible but some of these, including the housing, contain RoHS-restricted substances and so, without an exemption, would not be reusable in new equipment after 21st July 2014;
- The applicant claims that the reuse of parts from used assemblies will have a smaller negative impact on the environment than if there was no re-use of parts;
- All medical equipment manufacturers will stop using hexavalent chromium before 21st July 2014 for new housings, and so allowing reuse of existing housings after this date will not pose a risk to health or the environment because the only significant risk from this substance is during the production life-cycle phase; and
- Many other medical equipment parts are refurbished and are used to repair medical equipment. These would become waste earlier if they cannot be used to repair medical devices placed on the EU market after 22 July 2014.

Therefore, the applicant proposed three new exemptions for chemicals implicated in the reuse of various items of medical equipment):[40]

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[39] COCIR (2011) Original exemption request document no 2, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), September, 2011, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/COCIR_-_Exemption_request2_-_X_ray_and_other_parts_reuse.pdf

[40] Ibid.

a) Lead, cadmium and hexavalent chromium in refurbished parts from professional medical devices that are reused within a closed loop business to business return system used for the repair of medical equipment placed on the EU market after 21 July 2014 until 22 July 2026;

b) Hexavalent chromium in housings from X-ray tube assemblies that are reused within a closed-loop business to business return system until 22 July 2026; and

c) Lead in component parts from X-ray tube assemblies that are reused within a closed-loop business to business return system until 22 July 2026.

7.2 Applicant's Justification for Exemption

According the applicant the exemption request consists of two separate parts, reuse of parts from medical devices and X-ray assemblies. The most commonly re-used medical parts are[41]

- X-ray tubes;
- MRI coils;
- printed circuit boards from many different types of equipment; and
- detectors and components of detectors (e.g. radiation detectors).

Some of these will contain small amounts of lead, cadmium and hexavalent chromium.[42]

Article 4 (b) of the RoHS 2 Directive permits the use of spare parts containing Annex II substances, for the repair, the reuse, the updating of functionalities or the upgrading of capacities of medical devices that will be placed on the EU market before 22 July 2014. This article does not apply to equipment placed on the market after this date.

The applicant argues that implementing this Article will lead to more waste (from scrapped devices) on the one hand and to a larger demand for (the production of) new parts needed to replace re-usable parts (that would otherwise be used) on the other hand. [43]

Moreover the applicant claims that re-use of refurbished parts has a smaller environmental impact than disposal of re-usable parts and the use of new parts as re-

[41] Ibid.

[42] COCIR (2012a) Answers to first clarification questions submitted by the applicant, by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), June 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/Request_No2_1st_Clarification-Answers.pdf

[43] Op. cit. COCIR (2011)

placements. In general, most used parts are removed from medical devices for repair or refurbishment, and are then reused. Thus only a very small amount enters the waste stream directly[44].

An X-ray tube, as used as part of a specialist medical device, is a vacuum tube used for the production of X-rays. COCIR[45] explains that X-ray imaging equipment consists of many sub-assemblies including those used for supporting the patient, holding and moving the X-ray tube and the X-ray detector into the required positions, as well as the x-ray tube assembly itself and the detector assembly.

One of the largest parts of the assembly that is reused is the external housing. This is constructed from aluminium alloys, or sometimes brass, some steel parts, lead sheeting (as radiation shielding) and a few other materials. The X-ray housing has some component parts which are protected against corrosion by chromate passivation. Thus, the housing contains a small quantity of hexavalent chromium.[46]

According to the applicant[47] all medical equipment manufacturers will stop using hexavelent chromium before 2014 when medical devices are included in the scope of the RoHS Directive. In the past, at present and in the future, housings that contain hexavalent chromium could be re-used many times unless they are damaged. This is the reason why COCIR has requested the exemption mentioned in Section 7.1, bullet point b). Moreover the applicant states that the reuse of housings in refurbished systems and reusable products in medical equipment has a smaller environmental impact than the production of new medical assemblies.

Additionally, the applicant[48] asserts that re-use of equipment is encouraged by the EU in waste legislation such as the WEEE Directive as this has a smaller environmental impact than allowing it to become waste sooner. This is recognised by the RoHS Directive recast (2011/65/EC) in Article 4.5 which allows the reuse of spare parts, but only if these are recovered from EEE placed on the market before 1 July 2006 when the original RoHS Directive 2002/95/EC came into force. The Article 4.5 exclusion ends on 1 July 2016, i.e. 10 years later. These dates do not take into account that medical devices will be included in scope from 21st June 2014 so that this exclusion cannot be utilised for x-ray tube housings and other medical equipment parts removed from equipment that will have been placed on the EU market between 1 July 2006 and 21 June 2014, during which time they were still excluded from scope. Without an exemption, all of the parts from medical devices placed on the EU market in this period will become waste, and will have to be replaced by new parts. In principal, only parts that contain RoHS substances could not be used but it will be very difficult to determine whether an old part does or does not contain RoHS substances,

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[44] Ibid.

[45] Ibid

[46] Ibid.

[47] Ibid.

[48] Ibid.

and so, to ensure RoHS compliance is maintained, relatively few old parts could be used.

One criterion required for the exclusion in Article 4.5 is that the parts should be part of a closed loop business-to-business return system. According to the applicant[49], X-ray tubes are supplied only through business-to-business services and their return to suppliers is guaranteed through binding contracts agreed upon in correlation with supplying new imaging equipment. Furthermore many types of defective, used parts removed from medical devices are also returned to manufacturers who provide refunds upon return. The result is that approximately 95% of assemblies are returned to the original manufacturer.

The applicant[50] assumes a time schedule until 2026 regarding the re-use of parts (see also Section 7.2.3). It is explained that as these assemblies have average lives of 5 years, three re-uses each of 5 years totalling 15 years from 2011 will require this exemption until 2026.

It is foreseen that by 2026, most of these repairable parts will be at the end of product life; the rest will be scrapped, therefore COCIR assume the exemption shall be needed until 2026[51].

7.2.1 Possible Substitute Alternatives and Possible Design Alternatives

From the applicant's[52] argumentation, it is suggested that substitution would only be possible through the production of new parts. The applicant states that the goal of this exemption is to save resources. A complete substitution of products using Cr should already be possible in July 2014, when medical devices come in to the scope of the RoHS Directive. This would apply to new products. However, if the exemption is not granted, as the affected parts in current medical devices are already on the market, these would have to be scrapped, because it is impossible, or economically unattractive, to remove the RoHS substances from the parts (e.g. soldering on PCBs) (2012a). That is to say, parts from RoHS non-compliant devices, brought onto the market before 2014, could no longer be reused, even though the practice of using refurbished parts instead of manufacturing new ones is common, and shall probably remain common in the future.

[49] Ibid.

[50] Ibid.

[51] Ibid.

[52] Ibid.

7.2.2 Environmental Arguments

The applicant[53] has submitted information concerning life cycle assessment aspects, to further enhance the argumentation. Information includes reference to energy consumption, carbon dioxide emissions and information concerning the re-use and recycling of waste. In general, the information submitted concerning these aspects also supports the re-use of parts to be the most suitable alternative, noting that:

- Production Phase: The parts are already available: reuse would have a smaller impact as new parts would be needed only to replace those that are damaged;
- Use Phase: There is no evidence that handling of products with passivation coatings poses a risk to users and workers. Risk is relevant only for the production phase, whereas the coating process with hexavalent chromium salt solutions is already being phased out and replaced by safer processes;
- End of Life: Parts may be reused at least five times. Recycling systems [it can be followed that take-back systems are meant– consultants comment] are guaranteed by contracts, the process is straightforward and illegal export for recycling is currently not widespread. Re-used parts entail the use of less energy in comparison to replacement with new parts.

COCIR[54] states that:

> *"the environmental benefit of reusing parts in terms of avoiding waste, not consuming raw materials and lower energy consumption… will be the same irrespective of whether a part is used in equipment or in a new product. This will not affect the product's lifetime. Some used parts are types that are regularly replaced during the lifetime of equipment, such as X-ray tubes, and other parts are designed to last at least the product lifetime and so do not cause medical devices to reach end of life early".*

Moreover the applicant delivers a credible environmental impact comparison between re-used and new X-ray assemblies. COCIR[55] has estimated that parts from about 16,000 X-ray tube assemblies are reused in the EU annually to construct new assemblies used in both new equipment and as replacements for existing equipment. If these parts could not be re-used, then new parts would first need to be manufactured for up to 160,000 assemblies over 10 years, which will consume nearly four times more energy and create more waste than if the parts may be re-used. The same situation, described above for X-ray tube housings, is also relevant for parts from other medical equipment. That is, the possibility of re-using parts containing lead,

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[53] Ibid.

[54] COCIR (2012b) Answers to further clarification questions submitted per e-mail by the applicant, The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) on 09 November 2012

[55] Op. cit. COCIR (2011)

cadmium and hexavalent chromium would have a smaller overall impact on the environment than having to replace these with new parts.

The applicant estimates that only 2kg of hexavalent chromium is placed on the EU market annually by X-ray tube housings and this amount will decrease in the next years. The amounts in other medical equipment are estimated to be less than 200kg of lead, less than 0.1 kg cadmium and less than 5 kg of hexavalent chromium to be present in re-used parts per year. [56]

7.2.3 Road Map for Substitution

The applicant[57,58] mentions that research into substitutes for new products has been completed and all medical equipment manufacturers have developed alternative production processes. This is to say that substitution of new products has for the most part been resolved.

It is understood that the only "real" substitute for the use of refurbished parts would be to produce new ones, an alternative that is explained to be more wasteful in the applicant's argumentation (cf. Section 7.2.2).

Against this background the applicant requests this exemption solely for the reuse of the parts. Taking into consideration an average component life of 5 years along with a re-use of three times, starting 2011, the applicant assumes that the exemption shall be needed *until 2026*.

7.3 Stakeholder Contributions

No further contributions were received from other stakeholders.

7.4 Critical Review

7.4.1 REACH Compliance – Relation to the REACH Regulation

In the consultants' understanding, as the requested exemption would not apply to the use of new RoHS Annex II resources, nor to the use of potential substitutes for these, it is not subject to any restrictions by REACH.

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[56] Ibid.

[57] Ibid.

[58] COCIR (2012a) Answers to first clarification questions submitted by the applicant, by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), June 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/Request_No2_1st_Clarification-Answers.pdf

7.4.2 Scientific and Technical Practicability

Though substitution and elimination are for the majority of cases possible, they would apply to the production and placing on the market of new devices, whereas this exemption has been requested for the reuse of spare parts refurbished from products already on the market. Though reused spare-parts can be replaced with new spare parts, this issue has additional impacts that shall be discussed below.

The applicant provides sufficient evidence that the re-use of spare parts from medical devices including X-ray tube components (e.g. housings) would be environmentally beneficial as explained in the Section 7.4.3. The re-use of medical parts may reduce energy and material consumption as well as reducing emissions and waste.

The information provided for comparing the environmental impacts of using refurbished parts to that of substituting refurbished parts with new ones, demonstrates that the total negative environmental, health and consumer safety impacts of substitution would outweigh the total benefits thereof. Hence, an exemption would be justified according to Article 5 (1)(a) of the RoHS 2 Directive.

In this context, it can be understood that some parts can be used as replacements both in old equipment as well as in new equipment without affecting the product's lifetime. Against this background, as in both cases, the re-use of parts can be regarded as environmentally beneficial, the consultants would not recommend limiting this exemption to the re-use of parts in old equipment.

Moreover, COCIR[59] explains that all repairable assemblies in medical equipment have a good quality closed loop business to business system. According to the applicant the number of used assemblies going to landfill is believed to be negligible. This implies that the system is organized in a way that could support the collection, refurbishment and reuse of spare parts from medical devices, further avoiding waste produced once such parts are not reused.

7.4.3 Environmental Arguments

The applicant provides sufficient evidence that the re-use of spare parts from medical devices including X-ray tube components (e.g. housings) would be environmentally beneficial. The re-use of medical parts may reduce energy and material consumption as well as reducing emissions and waste.

The evidence submitted by the applicant regarding environmental impacts and statements comparing the life cycles of two options with and without granted exemption is adequate. In the consultants view it is reasonably supported that not granting the requested exemption would result in negative impacts to the environment in terms of consumption of resources and in terms of greater quantities of waste that would outweigh the positive impacts of restricting the reuse of refurbished medical parts containing RoHS substances.

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[59] Cf. footnote 1 (original)

The information provided for comparing the environmental impacts of using refurbished parts to that of substituting refurbished parts with new ones, demonstrates that the total negative environmental, health and consumer safety impacts of substitution would outweigh the total benefits thereof. Hence, an exemption would be justified according to Article 5 (1)(a) of the RoHS 2 Directive.

7.4.4 Conclusions

According to the consultants, the applicant's arguments can be followed and *the exemption is* scientifically and technically *justified.* Furthermore, the consultants view X-Ray assemblies to be included in the scope of medical equipment parts. In other words, an exemption permitting the use of Lead, cadmium and hexavalent chromium in refurbished parts from professional medical devices, would be applicable for parts from X-ray assemblies. Therefore we suggest reducing the wording of the three exemptions by the applicant to one singular wording applicable for all medical equipment.

Further support can be found in how this exemption request relates to the general approach apparent in the RoHS Directive, despite its limited applicability to medical products, in the explanation below:

RoHS Directive 2[60] addresses the use of spare parts under two circumstances:

- Article 4 (4) excludes the use of cables and spare parts for the repair, the reuse, the updating of functionalities or the upgrading of capacities of various product groups from the RoHS restrictions. Items (b) through (e) in this article make the exclusion available for:
  - medical devices placed on the market before 22 July 2014; and
  - in vitro diagnostic medical devices placed on the market before 22 July 2016.
- Article 4 (5) excludes the reuse of spare parts recovered from EEE placed on the market before 1 July 2006 and used in equipment placed on the market before 1 July 2016, provided that reuse takes place in auditable closed loop business-to-business return systems, and that the reuse of parts is notified to the consumer.

Article (3) (27) defines spare parts as separate parts of EEE:

> *"that can replace a part of an EEE…The functionality of the EEE is restored or is upgraded when the part is replaced by a spare part."*

[60] RoHS Directive (2011) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT

These two Articles provide that parts are excluded from RoHS provisions throughout the specified timeframes and when used in certain EEE. As the definition of spare parts addresses newly produced spare parts unless otherwise specified (as in Article 4 (5)), the *reuse* of spare parts will only be available for category 8 products when using parts recovered from products placed on the market before 2006, if they are to be installed in products placed on the market before 1.7.2016. Other reused parts containing Annex II substances will be scrapped, as will older parts after July 2016.

The consultants therefore agree with the applicant that the use of refurbished spare parts in EEE is, for the most part, prohibited where spare parts originating in medical products are concerned, as Article (4) (5) is only applicable under specific circumstances. Hence, to the extent that the exemption request is justified (on technical and environmental grounds) it also seems necessary.

7.5 Recommendation

Based on the submitted information, it is recommended that the exemption be granted and adopted to Annex IV of the RoHS Directive. The applicant's arguments are plausible, and an exemption could be justified in line with the requirements of Art. 5(1)(a). Additionally, it is suggested that the intentions of RoHS, apparent in Article 4, give further support to the view that this exemption would be in line with the intentions behind the RoHS 2 Directive. It is also recommended, therefore, that the wording be reformulated similarly to the wording of this Article.

Regarding the scope of this request for exemption, as parts b and c of the requested exemption are effectively covered in the wording of part a, it is assumed that these parts were requested to account for the scenario in which the more general exemption as requested in part a would not have been regarded as justifiable (cf. Section 7.1). It would therefore be sufficient to grant an exemption correlating only to the requested part a:

> *"Lead, cadmium and hexavalent chromium in refurbished parts from professional medical devices that are reused within a closed-loop business to business return system used for the repair of medical equipment placed on the EU market after 21 July 2014 until 22 July 2026"*

Regarding the timeline, the arguments brought forth by the applicant regarding the need for this exemption until 2026 are viewed by the consultants as adequate. However, according to Article 4 (2) of the RoHS 2 recast, the maximum period for which an exemption may be granted is 7 years.

Therefore, it is recommended that the exemption be granted with the following wording and validity:

> *Lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before July 22 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer.*

The exemption expires on 21 July 2021.

In principal, this exemption may also be relevant for category 9 and 11 as these categories have similar timeframes where inclusion in the RoHS scope is concerned. However as contributions were not received from representatives of other categories to this end, it could not be determined if, or to what extent, such an exemption would be needed. As the scope of any exemption should generally be well defined, and supported by a sound case in support of the exemption, opening the scope for other categories not specifically discussed is not considered appropriate.

7.6 References Exemption Request 2

COCIR (2011) Original exemption request document no 2, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), September, 2011, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/COCIR_-_Exemption_request2_-_X_ray_and_other_parts_reuse.pdf

COCIR (2012a) Answers to first clarification questions submitted by the applicant, by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) June 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/Request_No2_1st_Clarification-Answers.pdf

COCIR (2012b) Answers to further clarification questions submitted by the applicant, by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) personal communication e-mail November 2012.

RoHS Directive (2011) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT

8.0 Exemption Request No. 3 "Lead in solders for Positron Emission Tomography detectors and data acquisition units installed in Magnetic Resonance Imaging equipment"

Abbreviations

DAU	data acquisition unit
ENIG	electroless nickel-gold
g	acceleration of gravity (9.81 m/s^2)
MRI	magnetic resonance imaging
Ni	nickel
Pb	lead
PCB	printed circuit board
PET	positron emission tomography
RF	radio frequency

8.1 Description of Requested Exemption

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) has applied for an exemption for

"Lead in solders for Positron Emission Tomography detectors and data acquisition units installed in Magnetic Resonance Imaging equipment".

8.1.1 Summary of the Exemption Request

According to COCIR[61], MRI-PET is a relatively new technique which uses an array of complex high component density printed circuit boards that will experience severe vibration for long periods in use. Research has shown that lead-free solders that have been investigated for vibration susceptibility are more vulnerable to early failure under severe vibration conditions than bonds made with tin/lead solder. MRI-PET equipment could fail prematurely if lead-free alloys were used. Therefore this exemp-

[61] COCIR (2012a) Original application for exemption request no. 3, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_3/COCIR_-_Exemption_request3_-_PET_MRI_solder.pdf, last accessed 9 November 2012

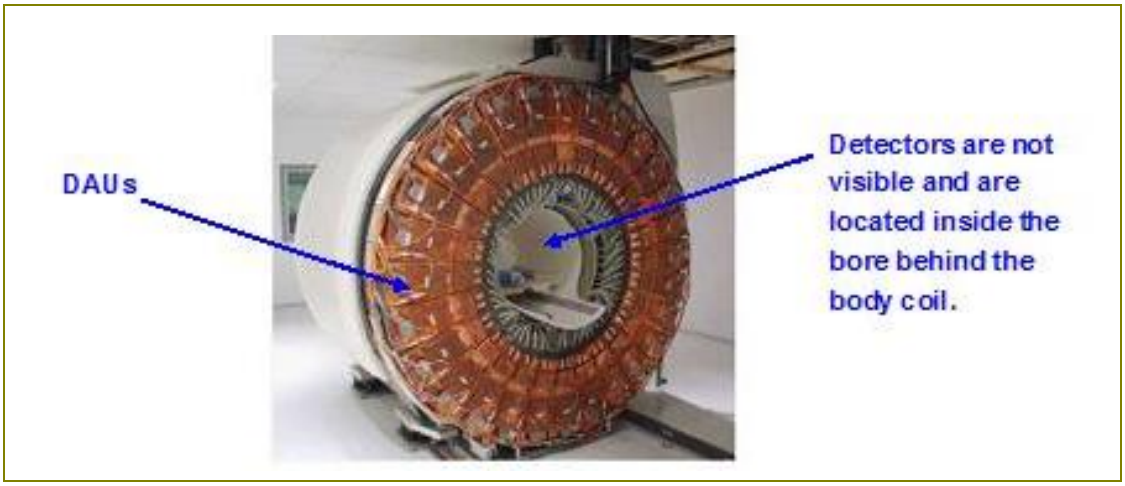
tion is requested to allow manufacturers sufficient time for research to identify suitable lead-free materials and designs.

8.1.1.1 Functionality and Construction of the MRI-PET Combination

Magnetic resonance imaging (MRI) is a medical technique used to obtain three dimensional images of soft tissue and organs of the human body. Positron Emission Tomography (PET) is also a three dimensional imaging technique which is used for viewing biological activity in the human body. An array of sensitive radiation detectors can image tumours, for neurology, cardiology, etc. using radioactive markers. More detailed and precise diagnostic information can be obtained by combining these techniques into one machine.[62]

The PET circuitry consists of many multilayer high component density printed circuit boards (PCBs). Inside the magnet and arranged around the patient is an array of detector PCBs. Each detector PCB is connected to a data acquisition unit (DAU). The DAUs are arranged in an array around one side of the magnet as shown in Figure 8-1[63].

Figure 8-1: Data acquisition units arranged around the magnet



Source: Op. cit. COCIR (2012a)

The array of detector PCBs and DAUs are arranged symmetrically around the patient. They consist of many small size components each of which contains a very small amount of nickel. It is not necessary to use non-magnetic components for the PET

[62] Ibid.

[63] Ibid.

circuits, as the total amounts of nickel are small, and the symmetrical installation around the patient avoids image distortions or allows the images to be corrected.[64]

Nickel cannot be used for PCB pad coatings (i.e. ENIG cannot be used) as the total amount of magnetic material must be limited. The content of magnetic nickel (Ni) in assemblies mounted to, or within, the MRI magnet/bore impacts upon both[65]:

- the magnetic field uniformity, which needs to be shimmed mechanically and electrically to a uniformity of 1ppm; and
- the ability to service the respective assemblies safely with the high-strength (3T) magnetic field present. It is a requirement that service technicians can safely remove system components when the 3T magnetic field is on. Any magnetic material within the component creates a hazard in that the component could be pulled from the service technician and accelerated into the magnet. The higher the field strength, the greater is the hazard. Objects flying at high speed through the air are a serious hazard to people and to the equipment.

The applicant notes that from an MRI perspective, the assemblies should, therefore, have zero Ni content. As a result, wherever possible, nickel is not used in the printed circuit boards. The DAU PCBs are fabricated using immersion silver deposited directly onto the copper pads with no intervening nickel layer. As these PCBs are located inside or close to the electromagnet, they will experience very intense vibration and high g-forces. They need to be assembled with materials that will be resilient to these forces during the normal life of this equipment, which is typically 25 years.[66]

The detector and DAU circuits have high component densities with 2,000 components on each detector PCB and 4,000 components on each DAU PCB. If a single one of the soldered connections to the majority of these components fails, at least one segment would cease to function. This would result in inferior PET image quality which could prevent diagnosis. Failure of several component connections would cause complete failure. In total, there are 336,000 connections in a typical PET system that is used as part of the MRI-PET. Solder bonds to simpler small components are relatively robust, but these PCBs have many large and complex ball grid array (BGA) devices including 112 with 780 ball connections and 28 with 1,152 connections. These BGAs are particularly susceptible to bond failure due to large stresses such as those that result from vibration. [67]

COCIR states that the PET detectors and data acquisition units in combined MRI-PET devices are exposed to high vibration levels and high voltage. Under these conditions, it states that the use of lead free solders does not ensure the necessary reliability over the product life time and therefore requests an exemption for the use of lead in

[64] Ibid.

[65] Ibid.

[66] Ibid.

[67] Ibid.

solders to achieve reliable interconnects on the detectors and data acquisition units of the PET part in combined MRI-PET devices.

8.1.1.2 Amount of Lead Used under the Requested Exemption

Table 8-1 shows that a DAU/detector pair uses around 10g of lead.

Table 8-1: Amount of Lead used in a DAU/Detector Pair

Model no. PCB	PCB name	PCB in comp.	Sum Pb-mass [g] PCB	Process step	Pb mass [g]	Printing area %	PCB area mm^2
10413384	**DAU-M**	1	3.50	SMD-Top	1.25	12.3%	54568
				SMD-Bot	0.63	6.2%	54568
				THT	1.61		
10413518	**DAU-I**	1	0.96	SMD-Top	0.25	5.0%	26767
				SMD-Bot	0.00		
				THT	0.72		
10413472	**DAU-C**	1	1.42	SMD-Top	0.00		
				SMD-Bot	0.00		
				THT	1.42		
10413504	**DAU-AIF**	6	0.15	SMD-Top	0.04	5.0%	4517
				SMD-Bot	0.00		
				THT	0.11		
10413506	**DAU-POF**	2	0.26	SMD-Top	0.09	10.0%	4744
				SMD-Bot	0.00		
				THT	0.17		
10413509	**DAU-I2CF**	1	0.16	SMD-Top	0.08	10.0%	4517
				SMD-Bot	0.00		
				THT	0.08		
10504163	**Triflex**	2	1.34	SMD-Top	0.89	10.0%	47775
				SMD-Bot	0.45	5.0%	47775
				THT	0.00		
	Component						
10414179	**DAU-M Assembly**		7.45				
	"+2*Triflex		10.12				

Source: COCIR, 2012c, Answers to second round of clarification questions concerning exemption request No. 3, submitted by COCIR via e-mail, November 2012

With around 50 systems sold per year, and 26 DAU/detector pairs per system, the total amount of lead that would be used under this exemption is around

$$10g * 26 * 50 = 13kg$$

Around 13kg of lead would be used under this exemption. It is not clear whether this is the amount of lead in MRI-PET equipment put on the market worldwide or only in the EU. [68]

8.2 Applicant's Justification for Exemption

8.2.1 Specific Operation Conditions

8.2.1.1 High Sound Pressure Levels

The applicant states that the MRI uses a very powerful circular electromagnet into which the patient is placed. The patient is exposed to a very powerful magnetic field. "Radio Frequency (RF) send and receive coils" are located around the patient and inside the magnetic field to transmit RF signals which excite magnetised protons in the patient's soft tissues and organs. The protons then emit characteristic signals that are received and measured by these coils. This process induces very large forces inside, and close to, the electromagnet which the patient perceives as a very loud noise. Ear protection is hence required during imaging. Manufacturers have measured acoustic pressure waves of 145dB which can impose severe mechanical stresses on the electrical circuitry. For comparison, 130dB causes aural pain and a jet engine at 30 m distance causes 150dB.[69]

8.2.1.2 High Voltages

Another characteristic of these PCBs that is different to most other types of electrical equipment is the combination of high component density with high voltage. On the detector boards as well as many components on the DAU PCBs 550V are present at over 700 components. A short circuit occurring at this voltage would cause arcing and severe damage. The combination of high component density and the inability to use PCB coatings such as ENIG results in an increased risk of tin whiskers, which, due to the high voltage present, could cause catastrophic failure.[70]

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[68] COCIR (2012c) Answers to second round of clarification questions concerning exemption request No. 3, submitted by COCIR via e-mail, November 2012

[69] COCIR (2012a) Original application for exemption request no. 3, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_3/COCIR_-_Exemption_request3_-_PET_MRI_solder.pdf, last accessed 9 November 2012

[70] Ibid.

8.2.2 Specific Effects of Lead-free Solders Affecting the Resistance against Vibrations

The only potential alternative to tin/lead (SnPb) solder for this application would be lead-free solders of which there are many types. The ERA report prepared for the Commission in 2006 concerning the inclusion of categories 8 and 9 in the scope of RoHS[71] concluded that temporary exemptions for lead in solders may be required. This report was published in 2006, and since then, research into substitutes has been carried out. The results show that lead-free substitutes are not yet technically viable for certain more demanding applications as they may be less reliable than SnPb, as is applicable in this case due to the very intense vibration experienced by these PCBs.[72]

Before describing the potential alternatives to SnPb, it is worth first explaining the reasons why failures occur as a result of severe vibration. Failures have been found to occur predominantly at the interface between brittle intermetallic phases[73] and solder, although failures as a result of damage to the PCB laminate can also occur. Intense vibration causes the PCBs to flex, and this imposes strain on solder bonds and the internal structures within the laminate.

8.2.2.1 Intermetallic Phase Formation with Solders

The following summarises information from the applicant.[74]

The applicant states that SnPb solder interacts with the substrate metals to create a layer of intermetallic phase. This phase is produced as a result of chemical reaction between the tin in the solder and the metal surface of the PCB pad or the component's terminals. With copper circuitry, a SnCu intermetallic is produced whereas - if the pads or components have a nickel coating - SnNi intermetallic is formed. SnCu forms more quickly and tends to be thicker than SnNi but both continue to grow after the solder bond has been produced due to "aging". The growth rate depends on temperature. At higher temperatures the intermetallic phase grows more quickly. This effect can be used to simulate accelerated aging.

With SnPb solders, the available tin close to the interface is depleted so that this zone becomes lead-rich, which retards intermetallic growth as tin is less accessible. Also, the residual lead is relatively flexible unlike tin/copper and tin/nickel intermetallic

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[71] Goodman, P. (2006) *Review of Directive 2002/95/EC (RoHS) categories 8 and 9 – Final Report*, ERA Report 2006-0383, July 2006, amended September 2006, retrieved from http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf; last accessed 9 November 2012

[72] Op. cit. COCIR (2012a)

[73] Di Maio, D. & Hunt, C. (2007) *High-frequency vibration tests of Sn-Pb and lead-free solder joints*, NPL Report MAT 2, August 2007, http://publications.npl.co.uk/npl_web/pdf/mat2.pdf

[74] Op. cit. COCIR (2012a)

phases. Lead-free solders contain mostly tin. A tin-depleted zone does not form and the structure and behaviour of the bond is different from SnPb bonds. [75]

A second effect also occurs with aging. SnPb solder consists of two phases, one tin-rich and the other lead-rich. These are separate grains, which gradually grow especially where there is high imposed stress. Grain growth within SnPb does not affect bond reliability unless they become particularly large in stressed regions when thermal fatigue failure can occur after many stress/relaxation cycles. [76]

Most lead-free solders consist of mainly pure tin with a dispersion of irregularly shaped SnAg and SnCu intermetallics. When a solder bond is formed on a copper substrate, SnCu forms at the interface and on nickel substrates, and a SnNi intermetallic is formed. These layers tend to be thicker than those produced with SnPb solder because of the higher soldering temperature and because tin is not depleted close to the interface. Sn_3Ag and SnCu intermetallic crystals form within the solder as soon as the bond is formed and grow in size due to thermal aging. Sn_3Ag crystals are a particular problem as they are needle shaped and can be quite long. In very small solder ball bonds used for micro-BGAs and CSP, large intermetallic crystals can occupy a significant proportion of the ball volume whereas this is not possible with SnPb as lead occupies half of the volume, and lead does not react with copper or nickel. [77]

An additional failure mode that has been found with lead-free ball bonds is where the solder is bonded to a copper PCB pad with a nickel barrier layer that is not completely non-porous. If a small amount of copper reaches the solder, the intermetallic that forms is SnNiCu, which has been found to be very brittle and fractures easily. This is a very uncommon failure mode with SnPb because of the lower soldering temperature, but has been frequently found with lead-free products. [78]

8.2.2.2 Kirkendall Voiding

As previously, this information is taken from the case made by the applicant.[79]

The use of lead-free solders has introduced other complicating factors. Lead-free processes have been shown to increase the risk of “Kirkendall voiding”. This is a process that creates many very small voids at the solder-substrate interface. It is believed to be related to the plating process although it is not fully understood.

Research has shown that Kirkendall voiding is more likely to occur with lead-free processes than with SnPb solders due to the higher soldering temperature. The latest theory is that electroplating processes trap organic substances within the metal coat-

[75] Ibid.

[76] Ibid.

[77] Ibid.

[78] Ibid.

[79] Ibid.

ing and these decompose, giving off gases during soldering which then create the small voids. Due to the higher melting point of lead-free solders, the 20 – 30 °C higher soldering temperature increases the risk that the organic substances will decompose to form gases. The higher temperature also increases the volume of the gases as they are hotter.

Normally these voids have little effect, but they increase the risk of failure when the equipment is dropped or subjected to stresses such as vibration.

8.2.3 Impacts of Intense Vibration Forces on Lead-free Solder Joints

8.2.3.1 Effects of Vibrations

COCIR[80] is concerned about the solder bond reliability with the PET DAUs and detectors because the circuits are exposed to very severe vibration for an extended period. There are several research publications which compare the vibration performance of SnPb solder with lead-free solder, although some of the results appear contradictory. The reasons for contradictory results were demonstrated by research carried out by JGPP[81], which according to COCIR showed that susceptibility depends on:

- the solder alloy composition;
- the type of component;
- the position on the circuit board; and
- g-force.

Later research, described below, also showed that vibration frequency is an important variable. [82]

The JGPP research used test boards having several types of components, each attached at several positions. SnPB solder and three lead-free solder types were compared. At lower g-forces, no failures occurred during the 7 hour period of the test. At moderate to high g-forces, there were many failures. The most susceptible type of component to fail was the ball grid array (BGA). Most of the BGAs on the test board had bond failures before other types of components, although the time to failure was strongly dependent on the location on the PCB. Results with BGAs showed that during the tests, failures were significant at g-forces above 9g, and that the lead-free solders tested failed before SnPb. In these tests, g-forces were increased once every hour. Results for two of the BGAs are shown in Table 8-2 below (BGAs U4 and U6 were of the same type).

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[80] Ibid.

[81] T. Woodrow, JCAA/JG-PP (2006) *Lead-free solder project: Vibration and Thermal Shock Tests*, April 2006, http://www.jgpp.com/projects/lead_free_soldering/April_4_Exec_Sum_Presentations/040406WoodrowVibThShock.pdf

[82] Op. cit. COCIR (2012a)

Table 8-2: BGAs with failed bonds (%) during vibration testing

g-force	BGA U4			BGA U6		
	SnPb	SAC	SACB	SnPb	SAC	SACB
9.9	40	80	100	0	20	0
12	80	100	100	20	60	40
14	100	100	100	40	100	60
16				60	100	100
18				60	100	100
20				80	100	100

SAC = Tin, silver and copper *SACB = Tin, silver, copper and bismuth*

Source: Op. cit, COCIR, 2012a

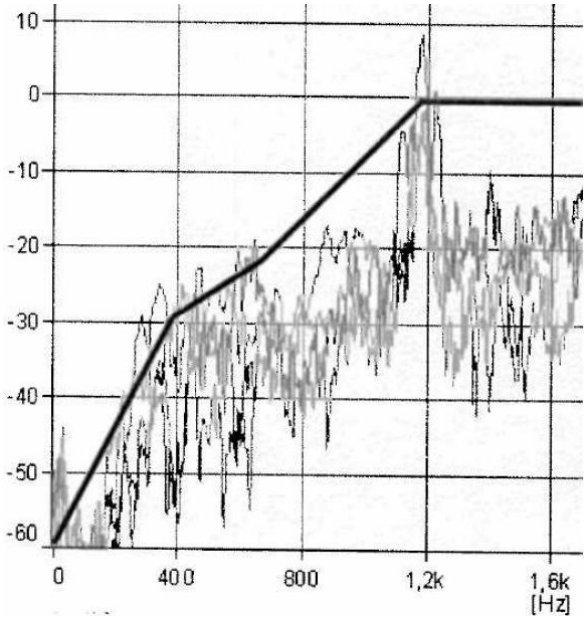
As component location affects vibration failures, it is difficult to compare the susceptibility of different types of components to vibrations. Most of the other types of components at locations adjacent to U4 and U6, also experiencing similar vibration force and amplitude, failed later than these BGAs. The applicant contends that this is a concern to manufacturers of MRI-PET medical devices because BGAs are commonly used.[83]

The test results reported from the JGPP research are from highly accelerated testing using very high g-forces. The test duration was only 7 hours whereas MRI-PET scanners have lifetimes of over 25 years and will be in use for a number of hours per day. Clearly if the MRI-PET or any other electrical device, irrespective of which type of solder was used, were to be exposed to 9.9 g or more, it would not survive 25 years. Accelerated testing is useful to identify potential failures during the normal lifetime of the equipment based on known characteristics of the equipment such as the level of vibration. The figure below shows the typical level and frequency of vibration experienced by a MRI-PET DAU PCB.[84]

[83] Ibid.

[84] Ibid.

Figure 8-2: Vibration Spectrum of PCBs in MRI-PET (vertical scale = dB/1.0 g)



Source: Op. cit. COCIR (2012a)

COCIR notes that the maximum vibration force experienced is equivalent to well over 2g, which is relatively large for electrical equipment, although much less than the value of 9.9g that was used in the JGPP tests. Figure 8–2 shows that the largest amplitude vibration occurs at about 1.1 kHz even though vibrations occur at all frequencies from < 200Hz to over 3 kHz.

Some electrical component bonds failed after less than 2 hours in the JGPP tests whereas MRI-PET PCBs must survive accelerations of more than 2g for 25 years. MRI manufacturers have many years of field experience with SnPb solders at high levels of vibration and so can expect that PCBs made with SnPb solder will survive 25 years. As the JGPP tests show that bonds made with lead-free solders will have shorter lifetimes, there can be no certainty that the same PCBs when made with SAC lead-free solders will survive the 25 years. Unexpected early failure of an MRI-PET scanner could be harmful to patients due to the equipment not being available when needed and early failure would also create more waste electrical equipment.[85]

COCIR references research published by the National Physical Laboratory (NPL) [86] NPL's research compared SnPb with four SAC alloys including SAC0305 having only 0.3% of silver (Ag), which has better drop shock resistance than SAC305. This investigation used piezoelectric actuators to impose controlled vibration forces and vibration

[85] Ibid.

[86] Di Maio, D. & Hunt, C. (2007) *High-frequency vibration tests of Sn-Pb and lead-free solder joints*, NPL Report MAT 2, August 2007, http://publications.npl.co.uk/npl_web/pdf/mat2.pdf

amplitude, and the frequency was controlled in these tests. The main result was that at all frequencies, SnPb had a lower probability of failure than any of the four SAC alloys. This was especially the case at higher frequencies as 400 and 800Hz were compared. The numbers of vibration cycles to 20% probability of failure from Weibull plots were as indicated in Table 8-3.

Table 8-3: Cycles to failure

Solder alloy	20% probability at 400Hz	20% probability at 800Hz
SnPb	200,000	20,000
SAC305	100,000	2,000
SAC387	60,000	8,000
SAC 0305	40,000	4,000
Annealed SAC305	9,000	-

Source: Op. cit. COCIR (2012a)

COCIR [87] points out that vibration tests with real PCBs can give misleading results. COCIR[88] explains that this is the reason why in the JGPP research[89] lead-free solders gave superior performance to SnPb for a few types of components. NPL's tests indicate that the superior performance found for those components soldered with lead-free solders is not due to the properties of the solder alloys. Solder joint shape, vibration amplitude, frequency, etc., all affect the time to failure for a specific type of component.

COCIR[90] explains that the NPL results are a real concern for medical device board designers as their results show that under severe vibration conditions, failures are more likely to occur with lead-free solders. The JGPP results show where on a PCB failure are most likely to occur but it is not always practical to design PCBs to avoid high g-forces.

Figure 8-2 shows that maximum vibration occurs at ~1,100 Hz, which indicates that the difference between SnPb and SAC solders would be even larger than at 800 Hz.

The JGPP research also compared Sn0.7Cu0.05Ni (often referred to as SN100C) wave soldering with the two SAC lead-free solders and with SnPb. This can only be

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[87] Op. cit. COCIR (2012b)

[88] Op. cit. COCIR (2012a)

[89] T. Woodrow, JCAA/JG-PP (2006) *Lead-free solder project: Vibration and Thermal Shock Tests*, April 2006, http://www.jgpp.com/projects/lead_free_soldering/April_4_Exec_Sum_Presentations/040406WoodrowVibThShock.pdf; source referenced in COCIR 2012 a

[90] Op. cit. COCIR (2012b)

used for some types of components and appears to give superior performance to SnPb with only one type of DIP (Dual Inline Package) component. The detector and DAU PCBs used for MRI-PET are all surface mount types with BGAs and so SN100C cannot be used. This is because BGAs are made using SAC balls and the solder used to attach these should have a similar melting temperature to avoid reliability problems. Standard SAC that is used for BGA balls melts at 217 °C whereas SN100C melts at 227 °C. This would result in the BGA ball melting before the SN100C and this would allow flux volatiles to form large voids inside the BGA balls before the SN100C melts. It has been shown that large voids inside BGA balls affect bond reliability.[91] For this reason, manufacturers always use solder pastes with similar alloys to the BGA ball alloy.

Another issue is that BGAs are temperature sensitive devices and so are more likely to be damaged by the higher reflow temperature needed for SN100C solder. Too high a reflow temperature can cause delamination or cracking of the circuits of the BGA package.

The applicants mention that SnCuNi was also assessed by Barry[92] (as well as SAC305) who tested solders in a more consistent way as was also performed by NPL (described above). This research showed that SnPb has superior vibration performance to both the SAC305 alloy and SnCuNi, with SnCuNi being inferior to SAC3055.

8.2.3.2 MRI PCB Vibration Comparative Test Results

One MRI manufacturer has evaluated a PCB that is used at a location close to the PET detector and DAU boards to compare the reliability of SnPb and lead-free solder bonds to RF screen chip capacitors in the conditions experienced in the MRI. These PCBs were tested using conditions appropriate to the MRI, although as an accelerated test. Three types of capacitors were tested with two lead-free solders, SAC305 and SnAgBi. At worst only 13% of the PCBs survived the vibration testing, and at best 63% survived. When capacitors were assembled using tin/lead solder, 100% survival was achieved after testing.[93]

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[91] M. Yunus et al. (2003) Effect of voids on the reliability of BGA/CSP solder joints, *Microelectronics Reliability*, 43 (2003), p. 2077, http://www.atv-tech.com/en/pdf/Effects%20of%20voids%20on%20the%20reliability%20of%20BGA%20and%20CSP%20solder%20joints.pdf

[92] N. Barry (2008) *Ph.D thesis*, University of Birmingham, UK, October 2008; source as referenced by COCIR 2012a

[93] Op. cit. COCIR (2012a)

8.2.4 Tin Whisker Formation Due to Bad Wetting of Lead-free Solders

Tin whiskers are thin rods of tin that grow from electroplated tin coatings. These are now very common on component terminations, but as often no alternatives are available, manufacturers have no choice but to use these. Tin whiskers have, however, been found to form on thicker electroless tin coatings that are used as protective coatings on PCB pads.[94] Thin electroless tin may not form whiskers, but as tin combines rapidly with copper to form an intermetallic phase, which does not wet to solder, thin coatings have too short a shelf-life. As a result, electroless tin pad coatings are rarely used, but due to the specific characteristics of MRI-PET PCBs, this is the only option for detector PCBs.[95]

Some additional coating alternatives and their specific properties are detailed below:

- Electroless nickel-gold (ENIG) cannot be used due to the ferromagnetic properties of nickel;
- Hot Air Solder Level (HASL) is a molten solder applied to the PCB and coats pads. It is unsuitable as the applied coatings are not perfectly flat which is required for the 780 and 1152 BGA devices;
- Organic Solderability Preservative (OSP - thin organic coatings) can impair solder wetting and are used predominantly for mass produced consumer products; and
- Immersion silver has a short storage life so it is unsuitable for detector PCBs. Immersion silver is, however, used for DAU boards. These are made and populated so that the shelf life of silver is not an issue. A long shelf life is needed for detector PCBs though, because these are made and part-populated at one location with additional components added later at another location.

Electroless tin is non-magnetic, and thicker coatings have a longer shelf-life than silver. It is perfectly flat and so is suitable except for the risk of tin whiskers. Tin whiskers will only form on areas of pads that are not wetted by molten solder during the soldering process. With tin/lead, this is not a concern as wetting is good so that none of the pad areas are left without a solder coating. Lead-free solders, however, are well known to wet surfaces, unlike SnPb. There is a tendency for the corners of pads to remain unwetted, which result in locations where whiskers can form. Various methods are used to improve pad coverage such as decreasing pad size and the use of more unusual solders that have better wetting properties. Each of these options will require additional time for research to ensure that a very high reliability is achieved, which is essential for medical devices.

Tin whiskers are a particular concern due to the high component density, which results in very small gaps between the edges of adjacent pads so that fairly short

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[94] *Electroless tin*: http://www.p-m-services.co.uk/electroless_tin.htm, source referenced in (COCIR 2012a)

[95] Op. cit. COCIR (2012a)

whiskers could cause a short circuit in this application. High voltage is also an issue because short circuits at high voltages can cause arcing and catastrophic failure.

One method used to reduce the risk from whiskers is to use conformal coatings, but these cannot be used underneath BGA devices.

8.2.5 Thermal Fatigue Risk Related to Lead-free Solders

COCIR explains that thermal fatigue failure can occur after many stress cycles as a result of temperature fluctuations such as those caused by powered components.[96] Research has shown that lead-free solders have a greater risk of thermal fatigue failure than SnPb only if stress levels are high. It is not yet known if this would be a significant risk for lead-free soldered MRI-PET and more research is planned to investigate. However, the following is known:

- MRI-PET can experience one thermal cycle per day and be used for at least 25 years. This would impose 9,000 stress cycles, which is a significant number;
- DAU PCB temperature rises by up to 35°C when powered. Although not very large, this would result in large stresses if the thermal expansion coefficient (TCE) of a component were very different to the PCB laminate; and
- The TCE of components is not usually measured or published, but the TCE of complex BGAs can be relatively small in comparison with FR4 laminate. This is because FR4 is mostly glass reinforced epoxy which has a fairly large TCE (typically ~15 x 10^{-6} / °C) whereas complex BGAs with large silicon die have much smaller TCE due to the very low TCE of silicon (2.6 x 10^{-6} / °C)

Therefore, MRI-PET scanners could experience a significant number of stress cycles. There are indications that stress levels may not be small so that thermal fatigue could be an issue. More research will be needed, which will require several years of testing to complete. (COCIR 2012 a)

8.2.6 Alternative Designs and Technologies for Elimination of Lead

COCIR has not indicated design alternatives that would allow the elimination of lead in this application.

[96] Ibid.

8.2.7 Road Map for Substitution

Table 8-4 shows the roadmap COCIR presents to achieve RoHS compliance.

Table 8-4: Roadmap to elimination of lead in requested exemption (COCIR 2012a, b)

No.	Step	Time
1	Manufacture lead-free PCBs	0.75 to 1 year
2	Accelerated testing and redesign to optimise vibration performance	0.75 to 1 year
3	Long term PCB testing	2.5 to 3 years
4	MRI-PET testing	1.5 to 2 years
5	Reliability testing to collect data for Medical Device Directive approval	0.75 to 1 year
6	Apply for approval under the Medical Device Directive	0.75 to 1 year
	Total	**7 to 9 years**

COCIR[97] states that the above steps cannot be conducted in parallel. Steps 1 and 2 are required subsequently first to enable step 3 to begin. Steps 1, 2 and 3 are at the component level. It is critical that parametric performance is established at the component level prior to integration into the hybrid system in step 4. Steps 5 and 6 are regulatory in nature with 5 required before 6 and also cannot start until 4 is completed satisfactorily.

According to COCIR[98] , timescales in the above table assume that an alternative design or solder is available, but at present none are known. Trials are currently being carried out with lead-free solders. COCIR[99] reports that the most recent results of soldering detector PCBs with lead-free alloys were a failure as severe board delamination occurred. These boards are an uncommon flex-rigid construction. If a suitable substitute were available for evaluation then the minimum timescales, indicated in the above table, would be possible.

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[97] COCIR (2012b) Answers to First Round of Clarification Questions concerning Exemption Request No. 3, submitted by COCIR, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_3/Request_3_1st_Clarification_Questions_Answers_non-confidential.pdf

[98] Ibid.

[99] Ibid.

8.3 Critical Review

8.3.1 REACH Compliance – Relation to the REACH Regulation

As this request concerns lead in solders and not a specific compound, Annexes XIV and XVII were reviewed for entries concerning lead. Chapter 5.0 of this report lists 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 restriction for substances under entry 30 of Annex XVII does not apply to the use of lead in this application. Putting lead in a solder used in a medical device on the market does not constitute 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 would not apply. Additionally, the MRI-PET equipment is a product that is not provided to the general public, but rather to specialist uses, notably, hospitals.

No other entries relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status 12th December 2012).

The review of related restriction and authorization processes, revealed one process underway concerning lead and lead compounds (see Chapter 5.0 above). This concerns the use of lead and lead compounds in articles intended for consumer use, for which Sweden has notified the intention to propose a restriction. The article in the focus of this exemption request, the MRI-PET equipment, is, however, not intended for consumer use. In the current proposed wording, this intended restriction proposal would not affect the exemption for the use of lead in solders on PCBs of PET detectors and DAUs in MRI-PET equipment.

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.

8.3.2 Scientific and Technical Practicability of Lead Substitution

8.3.2.1 Thermal Fatigue Risk

COCIR argues that the use of lead-free solders might result in thermal fatigue. The reviewers do not see this as a unique situation for this type of equipment. Thermal fatigue is a general issue related to all solder joints, even though the failure mechanisms change if lead-free solders are used. Producers of other long-life equipment under the scope of the RoHS Directive, for example professional music equipment, have solved this problem for lead-free solder joints as well.

8.3.2.2 Whiskers

COCIR[100] states that whiskers can grow to lengths of several millimeters referring to a NASA database[101] showing a tin whisker short-circuiting an 8 mm gap. In particular, whiskers induced by high humidity have no limit on the maximum length, and the longest whiskers are believed to form as a result of this mechanism. Therefore whiskers are often longer than the 0.4 mm gap between pads.

The referenced NASA source illustrates, however, only photos of whiskers without specifying details such as thicknesses of coatings, test specifications, soldering and (electro-) plating conditions, etc. It is a well-established fact that tin surfaces are in principle more prone to whisker growth compared to tin-lead surface finishes. Nevertheless, the question remains as to whether there is evidence that whiskers grow under the conditions that are realistic for the environmental and use conditions of MRI-PET devices, and why whisker mitigation techniques might not provide sufficient application reliability.

COCIR[102] states that MRI-PET will be used in all parts of the EU and at some hospitals; the equipment will not be kept in air-conditioned rooms in all cases. High humidity will occur from time to time at some locations due to the local weather conditions. COCIR[103] claims that many publications including the NASA website state that whiskers may grow in high humidity conditions, and there is evidence that under these conditions, whisker length can be longer than the 0.4 mm gap between pads. COCIR cites work by Hillman[104] as supporting evidence for the view that there is no "stop-mechanism" with humidity, which means that whiskers can grow to great lengths. COCIR further cites test results of Reynolds[105], published by iNEMI, where from extensive testing of components under accelerated conditions, high temperature and humidity and whiskers were found after less than one year under the most extreme conditions, even though the longest test was only 10,100 hours (less than 1.2 years). According to COCIR, it is impossible to find published research with data on whisker growth in high humidity conditions for the much longer periods that will be experi-

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[100] Ibid.

[101] NASA Metal Whisker Photo Gallery, http://nepp.nasa.gov/WHISKER/photos/index.html; referenced in (COCIR 2012a)

[102] COCIR (2012c) Answers to second round of clarification questions concerning exemption request No. 3, submitted by COCIR via e-mail, November 2012

[103] Ibid.

[104] Hillman, C., Kittlesen, G., & Schueller, R. (2011) *A New (Better) Approach to Tin Whisker Mitigation*, DfR Solutions 2011, retrieved from http://www.dfrsolutions.com/uploads/white-papers/WP_SnWhisker.pdf; paper referenced in Op. cit. COCIR (2012c)

[105] Reynolds, H. L., Osenbach, J. W., Henshall, G., Parker, R. D., & Su, P. (2010) Tin Whisker Test Development—Temperature and Humidity Effects Part I: Experimental Design, Observations, and Data Collection, *IEEE Transactions on Electronics Packaging Manufacturing*, Vol. 33, No. 1, January 2010; http://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=05361410; paper referenced in (COCIR 2012c)

enced by MRI-PET, i.e. more than 15–20 years.[106] The NASA images of very long whiskers are thus the only evidence available that very long whiskers may form under certain conditions after many years.

As mentioned before, the NASA picture database proves that whiskers may grow, but it does not relate the images to conditions of electroplating, storage, soldering conditions, tin plating thicknesses etc. In this sense, the source does little more than confirm what has been known for quite some time.

OCIR reference Hillman et al.[107] as evidence that there is no stop mechanism for humidity-induced whisker growth.

However, according to Hillman et al., this is true if when no techniques are applied to prevent or at least to mitigate whisker growth. However, various mechanisms may be applied in order to reduce the risk for whisker growth under various circumstances. Table 8-5 summarizes different techniques and approaches that Hillman et al. detail[108] as methods for controlling the various whisker growth mechanisms in order to prevent actual growth associated with specific circumstances.

[106] Op. cit. COCIR (2012c)

[107] Op. cit. Hillman et al. (2011)

[108] Ibid.

Table 8-5: Whisker mechanisms and mitigation/prevention techniques (based on Hillman et al.[109])

Whisker mechanism	Mitigation/prevention technique
Formation of intermetallics with base metal	• Annealing (150°C for an hour within 24 hours of plating • use of an underplate (nickel, silver, etc.) • treatment of the base metal to limit anisotropic intermetallic growth (i.e., surface roughening)
Differences in the coefficient of thermal expansion	• use copper as base metal • coefficient of thermal expansion is greater than or equal to nickel (13 ppm)
Tin plating conditions	• supplier only uses low carbon/organic content tin plating • plating is subjected to reflow temperatures that melt the tin
Oxidation/corrosion due to humidity or other corrosive impacts	• device will be used in a vacuum • application has sufficient power dissipation to drop the humidity below 40%RH • the application is always on • the device is covered with conformal coating or potting material

Source: Hillman, C., Kittlesen, G., & Schueller, R. (2011), A New (Better) Approach to Tin Whisker Mitigation; DfR Solutions 2011, retrieved from http://www.dfrsolutions.com/uploads/white-papers/WP_SnWhisker.pdf;referenced in COCIR 2012a

The above list may not be complete, but the approach presented shows that whisker growth is not an inevitable fate that necessarily occurs when tin surfaces are applied on components or PCB pads. There are techniques available to control whiskers, even though not every technique is appropriate for every device, and a zero-risk-situation may not be achievable. To demonstrate that whiskers grow and how dangerous they may be, COCIR mentions whisker induced failures of accelerator pedal position sensors in Toyota vehicles, which had resulted in the unintended acceleration of such vehicles.

In the consultants opinion this information raises the question why whiskers had only caused failures in Toyota cars and not in other cars, which also have pedals with accelerator position sensors. However the information provided by the applicant does not provide insight on this matter. Thus the Toyota case may be viewed as an example that whiskers may grow under certain circumstances and cause damage, however

[109] Ibid.

it does not verify that whisker growth cannot be prevented, therefore requiring an exemption.

In the specific case of the MRI-PET device, the DAU boards are, for example, coated with immersion silver, and COCIR describes that the small components in the detectors and the DAU carry nickel underlayers.[110] Both measures reduce the risk of whiskers. Conformal coatings cannot be used underneath BGAs to reduce whiskers, but underfillers may be an appropriate measure to help this situation. COCIR says that due to incomplete wetting of the PCB pads by lead-free solder, there is an increased risk of whisker growth. Geometrical adaptations of the pads, e.g. using rounded pads instead of rectangular ones or adapting the soldering profiles, and other measures, might help to solve, or at least mitigate, this problem. The work by Hillman et al describes more measures to prevent whisker growth (see Table 8-5).

The fact that tin-plated surfaces are more prone to whisker growth does not necessarily justify an exemption due to available mitigation and prevention techniques. The prevention of whiskers requires measures that are adapted to the particular equipment and its conditions of use. In the case of the MRI-PET device, it must be taken into account that some of these techniques require time to be tested and qualified. This alone may well require time beyond 2014. As mitigation techniques, as well as experience with whisker avoidance is available (and becoming more so over time, due to the substance bans in the RoHS Directive being in force since 2006), new measures should not take until 2020, which is the validity period requested by COCIR[111].

Other conditions such as strong vibrations are, however, more unique to MRI-PET, and as little experience is available for lead-free solutions, overcoming the specific problems related to vibrations is likely to take more time to overcome. Therefore there was no further assessment on how long it would actually take to implement and qualify sufficiently reliable solutions to prevent failures due to whisker growth.

8.3.2.3 Vibrations

COCIR justifies the exemption request mainly with the effects of the strong vibrations due to the strong magnetic field from the MRI equipment under which the PET DAU and detectors operate. In a previously recommended exemption request for "*Lead in solders and solderable coatings, used on non-magnetic components and circuits that are used in magnetic fields or are associated with circuits used inside strong magnetic fields*"[112], the main argument justifying the use of lead solders was the necessity to use non-magnetic components. As in both cases, strong magnetic fields occur, COCIR

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[110] Op. cit. COCIR (2012a)

[111] Ibid.

[112] See http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_9/9_COCIR_-_Exemption_request_-_Lead_solder_magnetic_field.pdf;

was asked to explain why vibration only plays a role for this exemption request, but not for the previous one.

COCIR responded that the MRI application uses lead solders together with non-magnetic components within the body coil and patient local coil assemblies. The MRI assemblies are exposed to vibrations, generated by the gradient coil, that are mainly acoustically and mechanically coupled.[113]

In the MRI-PET application, COCIR adds, the detectors and DAUs are high-density large assemblies with integrated RF shielding. In addition to acoustically and mechanically coupled vibration, Lorenz force induced vibrations are coupled to the detectors and DAUs due to gradient field Eddy currents induced within the integrated shielding and acting against the static high field strength of the MRI magnetic field. The DAUs are located on the back of the magnet where the static field lines return to the magnet so the field strength in the DAU location can be up to 2.5 times larger than the field strength in the MR bore.

8.3.2.4 Mechanical Measures to Mitigate Vibration Effects

The applicant was asked why mechanical and other measures may not be applied to protect the PET detectors and DAUs from these strong vibrations. In response, COCIR listed several measures that could, in principle, be applied:[114]

- Mechanical support by chassis/housing;
- Compliant thermal/mechanical gasket between PCB and chassis/housing;
- Compression of PCB by clam-shell chassis/housing interface;
- Location of PCB assembly relative to gradient field/static magnetic field;
- Minimizing distance between PCB support to reduce/control resonant frequencies;
- Air bladder between gradient coil and detector housing to apply continuous normal force along the detector length to keep the detector within the gantry pocket; and
- Rigid gantry structure to hold the DAU and detector assemblies.

COCIR argues that it is not possible to apply these measures in the MRI-PET equipment for two reasons:[115]

- The DAU location is governed by maximum system length and patient tunnel length requirements and has been optimized to the design boundary condi-

[113] COCIR (2012d) Answers to third Round of Clarification Questions Concerning Exemption Request No. 3, submitted to consultants via e-mail on 10 December 2012

[114] Ibid.

[115] Ibid.

tions. Detector location must be within the MRI bore, centred within the MRI field of view; and

- PCB free lengths are also governed by the area required for the respective circuit components within the volume formed by the housing/chassis interface.

The specific conditions and geometrical restrictions of MRI-PET equipment thus, COCIR argues, restrict the applicability of mechanical measures that could eliminate or sufficiently mitigate the effects of the intense vibration on the PCBs of PET detectors and DAUs.

8.3.3 Environmental Arguments

COCIR submitted environmental arguments intended to support the request. As substitution or elimination of lead is currently scientifically and technically impracticable, these arguments were not reviewed.[116] The consultants would like to point out, however, that this neither indicates agreement nor disagreement with the applicant's environmental arguments.

8.3.4 Conclusions

The applicant's arguments, that thermal fatigue and whiskers require the use of lead solders in MRI-PET equipment, in the reviewers' opinion does not justify an exemption. Manufacturers of other equipment have been able to solve these problems, and there is no justification that in MRI-PET equipment they cannot be solved, albeit possibly not until mid-2014. This aspect was not further evaluated, as the main justification for the exemption request are the strong vibrations.

The applicant plausibly explains why strong vibrations occur on the DAUs and detectors in MRI equipment, and why the possibilities for protecting the DAUs and detectors from the strong vibration forces by mechanical means are limited. The very strong vibrations combined with long life time and high reliability requirements may demand time to implement, and have fulfill requalification according to required regulation of sufficiently reliable lead-free soldered solutions. This seems all the more likely to be the case since experiences with such strong vibrations are not available from other electrical and electronic equipment which has been under the scope of the RoHS Directive since 2006. The strong vibration effects are therefore deemed to justify the exemption. According to the applicant's roadmap (see Section 8.2.7), the development and approval of a RoHS-compliant solution would require seven to nine years.

[116] Op. cit. COCIR (2012a)

8.4 Recommendation

Based on the information submitted, it is recommended to grant the exemption. The PCBs in the PET detectors and DAUs are exposed to very intense vibration forces. In combination with the long lifetime and high reliability requirements, granting an exemption would be in line with the stipulations of Art. 5 (1) (a).

The reviewers' recommend adopting an exemption with the following wording to Annex IV of the RoHS Directive:

> *Lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment.*

The exemption expires on 31 December 2019.

8.5 References Exemption Request 3

COCIR (2012a) Original exemption request no. 3, document "COCIR - Exemption request - PET MRI solder.pdf", COCIR 2012, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_3/COCIR_-_Exemption_request3_-_PET_MRI_solder.pdf, last accessed 9 November 2012

COCIR (2012b) Stakeholder document "Request_3_1st_Clarification Questions_Answers_non-confidential.pdf" submitted by COCIR 2012 on exemption request no. 3 in 2012 within the consultation, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_3/Request_3_1st_Clarification Questions_Answers_non-confidential.pdf; last accessed 9 November 2012

COCIR (2012c) Stakeholder document "Request_III_2nd COCIR final answer.docx" submitted to consultants via e-mail in November 2012

COCIR (2012d) Stakeholder document "Request_3_3rd-Questionnaire docx Final 12-10-2012-rev.docx" submitted to consultants via e-mail on 10 December 2012

Goodman (2006) Goodman, Paul: *Review of Directive 2002/95/EC (RoHS) categories 8 and 9 – Final Report*. ERA Report 2006-0383, July 2006, amended September 2006, retrieved from http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf; last accessed 9 November 2012

Hillman et al. (2011) Craig Hillman, Gregg Kittlesen, and Randy Schueller: *A New (Better) Approach to Tin Whisker Mitigation*; DfR Solutions 2011, retrieved from http://www.dfrsolutions.com/uploads/white-papers/WP_SnWhisker.pdf; paper referenced in (COCIR 2012c)

Reynolds (2010), Heidi L. Reynolds, John W. Osenbach, Gregory Henshall, Richard D. Parker, Peng Su: Tin Whisker Test Development—Temperature and Humidity Effects Part I: Experimental Design, Observations, and Data Collection*; IEEE Transactions On Electronics Packaging Manufacturing*, Vol. 33, No. 1, January 2010; http://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=05361410; paper referenced in (COCIR 2012c)

9.0 Exemption Request No. 4 “Lead in solders used in mobile medical equipment”

Abbreviations

BGA	ball grid array, a specific electronic component
CSP	chip size package, a specific electronic component
EEE	electrical and electronic equipment
MD	medical device
MDD	Medical Device Directive (Directive 93/42/EEC)
MMD	mobile medical device
SAC alloy	tin (Sn) - silver (Ag) - copper (Cu) alloy

9.1 Description of Requested Exemption

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) has applied for an exemption for

“Lead in solders used in Directive 93/42/EEC Class IIa and IIb portable and mobile medical devices where the medical devices need to be transported on a cart or trolley, hand-held diagnostic devices, hand carried devices such as portable ventilators, those transported in a vehicle such as an ambulance or helicopter to the designated location of use and medical devices that are operated while being carried such as patient worn devices”.

The requested exemption is related to exemption 17 in Annex IV of the RoHS Directive:

Lead in solders in portable emergency defibrillators

9.1.1 Summary of the Exemption Request

Medical equipment must have high reliability as unexpected failures can be fatal. Many types of medical devices can be constructed using lead-free solders. Some of the mobile medical devices are life-critical pieces of equipment that are transported in ambulances, helicopters or around hospitals. They may, therefore, suffer from high g impacts, severe vibration and experience frequent large temperature changes. Tin/lead (SnPb) solder has been found to be reliable under these conditions.

The applicant argues that research has shown that there is no lead-free substitute alloy that has the same or better reliability under all of these environmental conditions. Therefore a temporary exemption to allow the continued use of lead solders is needed until further research has been carried out to identify alloys that are reliable for the normal life of mobile medical devices.[117]

9.1.2 Specific Risks for Mobile Medical Devices

COCIR[118] explains that most of the safety-critical medical equipment used in hospitals is not designed to be carried, or routinely transported, although many items are moved from one location to another within a hospital. In such cases, the levels of vibration are not high and there is little risk that the devices are dropped. A number of safety-critical products are, however, regularly carried by patients and medical staff both within hospitals and elsewhere. These mobile medical devices (MMD) will experience at least one of the following impacts, which can cause solder joints to fail:

- high levels of vibration;
- large temperature fluctuations; and
- high risk of being dropped.

The biggest risk is where MMD are exposed to all three impacts.

9.1.3 Classification of Medical Devices

COCIR[119] states that manufacturers classify their equipment according to Annex IX of the Medical Device Directive 93/42/EEC.

9.1.3.1 EU Class IIB Mobile Medical Devices

If Class IIB products do not function due to a fault, there is a severe and immediate risk to the patient (i.e. irrevocable harm within minutes). Unexpected faults with Class IIA equipment can also have serious consequences although in general, these may not be as severe as for Class IIb. One exception could be patient-carried, or worn, devices used outside of the usual clinical environment where no medical professional is present for periodic bedside checks, such as with home monitoring. Some conditions can go on for hours before there is irreversible damage but others, such as a

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[117] COCIR (2012 a) Original exemption request no. 4, submitted 22.2.2012 by COCIR, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_4/COCIR_-_Exemption_request4_-_Lead_in_mobile_MD_V2.pdf, last accessed 20 November 2012

[118] Ibid.

[119] Ibid.

heart attack, can be fatal if not treated quickly. If the patient is alone, the equipment failure could prove fatal if the condition goes undetected for an extended period.

COCIR[120] lists products, for which the exemption would be relevant, included under the EU Class IIb Mobile Medical Devices classification:

- Automated Cardio Pulmonary Resuscitation (CPR)
- Ventilators
- Infant Apnea Monitors
- Carbon Dioxide-(CO2) Sensors

Further detail concerning devices classified as Class IIb equipment, is provided in Annex 3 in Section A.3.0. This includes detail of the critical medical situations and procedures in which devices are used as well as information as to the environmental conditions under which equipment is used.

9.1.3.2 EU Class IIA Mobile Medical Devices

Patient worn devices (PWD), portable ultrasound and portable monitors are less safety critical than portable defibrillators and so are classified as class IIA "non-life sustaining and diagnostic tool devices" according to the Medical Device Directive 93/42/EEC. In some circumstances another device will be available if one fails and failure will not always be life threatening unlike portable defibrillators. However there will be circumstances where defects or complete failure would be life threatening. For example, if a patient with a PWD suffers heart failure while out of sight, no alarm would be sent. If the monitor being used for a patient in an ambulance fails, any changes to the patient's condition would be missed. At best, equipment failure will delay diagnosis or treatment and this can have serious implications.

COCIR[121] lists products, for which the exemption would be relevant, included under the EU Class IIa Mobile Medical Devices classification:

- Patient-Worn Devices (PWD)
- Mobile Ultrasound Equipment
- Patient monitors

Further detail concerning devices classified as Class IIa equipment, is provided under Annex 3 in Section A.3.0.

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[120] Ibid.

[121] Ibid.

9.1.4 Amounts of Lead Used in the Requested Exemption

COCIR[122] indicates the total amount of lead used in the EU in the scope of this exemption request is around 1.9 tonnes, and 5.7 tonnes worldwide.

COCIR[123] calculates these amounts based on the quantity of lead used in MMDs from the estimated quantity of solder used on printed circuit boards of MMDs[124], the number of these PCBs used in each device and annual EU sales of each device.

According to COCIR[125], the quantity of solder used on each PCB normally is not measured, and so a contract manufacturer has estimated that each mobile medical device PCB will on average consume about 11 grams of SnPb during processing. This also includes the amount of SnPb plating for the components on the PCB. There is, of course, considerable variation with some very small PCBs having much less and some very large high density boards containing substantially more solder.

The number of assemblies is multiplied by 11 grams of SnPb and by the EU sales volume, then divided by 1000 to obtain kilograms of lead solder used in MMD placed on the EU market annually. The mass of solder is multiplied by 37% (SnPb 63/37) to obtain the amount of lead which will give us the total consumption of Pb in EU.[126]

The mass of lead used in MMD sold in the EU annually is estimated, through this approach, at 1.9 tonnes. It is estimated that the EU accounts for about a third of global MMD sales (so the quantity of lead used globally in this way is 5.7 tonnes).[127]

9.2 Applicant's Justification for Exemption

Lead-free solders are the potential substitute for the lead-containing solders. COCIR[128] puts forward that MMD products can experience severe vibration, large temperature changes, high humidity and shock from being dropped. These impacts can cause severe strains on solder joints, which lead-free solders are less likely to tolerate.

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[122] COCIR (2012 b), Stakeholder document "Request_4_1st_Clarification.pdf" submitted by COCIR 2012 on exemption request no. 4 in 2012 within the consultation, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_4/Request_4_1st_Clarification.pdf; last accessed 20 November 2012

[123] Op. cit. COCIR (2012a)

[124] Remark of the consultants: Even though not indicated in the proposed exemption wording, it was later clarified that the exemption is only required for lead in solders used on printed circuit boards.

[125] Op. cit. COCIR (2012b)

[126] Ibid.

[127] Ibid.

[128] Op. cit. COCIR (2012a)

9.2.1 Specific Impacts on MMD

COCIR[129] describes the specific impacts MMDs are exposed to as follows:

- Severe Vibration
  MMDs may experience severe vibration, especially equipment, which is carried in ambulances, emergency helicopters, the vehicles of doctors who are 'on call' and equipment, which is mounted on trolleys that are moved around hospitals and between hospital buildings.
- Large Temperature Fluctuations
  Mobile equipment is transported outside of buildings between locations, for example in ambulances and in helicopters and so will experience large temperature changes. Some parts of Europe can exceed 40°C in summer, and temperatures in excess of 60°C are possible inside parked vehicles. The equipment can be transported to other locations where at night or in mountains, the ambient temperature can be well below zero. An extreme situation would be transporting from southern Europe in summer by helicopter to an Alpine location.
- High Humidity
  High humidity increases the risk of tin whiskers growing on tin electroplated tin coatings, corrosion and the formation of dendrites on PCBs, especially if solders with silver are used. High humidity is a particular problem especially when cold equipment, e.g. after overnight storage in a vehicle) is moved to a warm humid environment causing condensation.
- Shocks from Being Dropped or from Striking Objects
  Shock impacts are possible for any type of equipment designed to be carried such as portable ultrasound, patient-worn devices, or when attached to equipment that is carried, such as stretchers. Manufacturers test their equipment using drops from 1 m onto concrete because this is a fairly common occurrence. Shock also occurs with trolley mounted equipment if this strikes a wall or door frame.

9.2.2 Field Failures

9.2.2.1 Field Failure Rates in Consumer Products

There is recent field failure rate data for some types of consumer products but this does not differentiate SnPb and lead-free products. For example, the insurer "Square-trade" reported in 2009 that 31% of laptop PCs fail within the first three years and 10.6% was attributed to accidental damage, e.g. from being dropped. Laptop PCs are

[129] Ibid.

relatively complex products and so are comparable to medical devices, but this high rate of failures would not be acceptable for safety critical products.[130]

This data is for computers made since 2006 and so would be produced using lead-free solders, showing that complex equipment using lead-free solder is susceptible to accidental damage. In order to justify this exemption request, a thorough search for field data that compares tin/lead and lead-free versions has been made, but no data could be found, and such data may not exist. There is evidence of poor reliability of lead-free products such as the case of the Microsoft X-Box. The failures appear to be due to poor design, and selection of an unsuitable lead-free solder, but not due solely to the choice of lead-free solders.[131,132]

Gartner[133] found that tin-lead soldered laptop PC reliability improved between 2003 and 2005 (pre-RoHS directive). They found that in 2005–2006, laptop failures were 22% over four years. These figures are for all failures (hardware and accidental) and are lower than the 31% over three years published by Squaretrade in 2009 which corresponds to lead-free laptop PCs. This difference could be due to the change from SnPb to lead-free, but other variables such as design (complexity will have increased) and the way the data in the two studies were collected were different (Gartmore data is from mainly business users whereas Squaretrade is all users). However there do appear to be more failures with lead-free than SnPb laptop PCs from this data.[134]

9.2.2.2 Whisker-induced Failures

There have been many incidents where failures have occurred due to tin whiskers, including in Toyota vehicles, which has recently been discovered and studied by NASA engineers.[135] Although the cars that failed were built in 2003, research since RoHS was adopted has not found solutions that guarantee that no whisker failures will occur. Commercial component tin coatings provide a small, but not insignificant, risk for equipment with long field lives, particularly where this may be used in humid environments. Tin/lead solders reduce this risk by providing better wetting than SAC alloys so that less exposed tin plating remains.[136]

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[130] Ibid.

[132] Ibid.

[133] Gartmore press release, 2006 from http://www.gartner.com/press_releases/asset_154164_11.html, referenced in (COCIR 2012a)

[134] Op. cit. COCIR (2012a)

[135] H. Leidecker, L. Panashchenko and J. Brusse, Electrical Failure of an Accelerator Pedal Position Sensor Caused by a Tin Whisker and Discussion of Investigative Techniques Used for Whisker Detection, 5 th International tin Whisker Symposium, 2011, referenced in (COCIR 2012a); http://nepp.nasa.gov/whisker/reference/tech_papers/2011-NASA-GSFC-whisker-failure-app-sensor.pdf

[136] Op. cit. COCIR (2012a)

9.2.2.3 Confidentiality of Field Failures

Whilst a lot of research into lead-free solders highlights their limitations, COCIR[137] argues that evidence of field failures is very limited for certain specific reasons:

- Most lead-free products sold in the EU since RoHS was adopted have been lower value IT, consumer and household appliances. If failures due to the reliability of lead-free solders were tohave occured, this would be after the warranty had expired and so would not have been investigated.
- Manufacturers never publicise reliability issues because it could harm their business. Reliability is important to all manufacturers and so they would never admit publically to defects in their products, unless forced by regulatory requirements for full disclosure.[138]
- Most consumer products are not exposed to severe environments and have fairly short lives, and so solder failures are not an issue.
- If a lower priced product fails after 3 years, failure investigations are rarely carried out and so the cause is not identified.

Very large numbers of electrical products have been constructed since RoHS was adopted in 2006, and gross reliability problems have not been encountered. However medical devices need to be much more reliable than consumer and office equipment. They can be relatively complex, have lives of over 20 years and mobile types are exposed to severe conditions that impose significant stresses on solder bonds. COCIR[139] reports that a manufacturer of mobile medical devices has collected field data showing that the likelihood of failure of mobile products used outside hospitals is double that of products used only within hospitals). Models used outside hospitals are more likely to be hand carried, and are more often dropped and knocked over, and also suffer from vibration when carried in vehicles (i.e. in ambulances). This data is routinely collected by the manufacturer's field service engineers, but is not available for public disclosure purpose and no study or reports exist.

The use of lead-free solders in MMD would therefore raise reliability concerns, and reduced reliability would cause a greater negative impact on human health (patients' health).[140]

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[137] Ibid.

[138] In 2009, the FDA forced Physio-Control portable defibrillators to disclose the root cause of four field failures. In each case it was found to be a tin whisker associated with a lead-free tin coated component finish (COCIR 2012a)

[139] Op. cit. COCIR (2013a)

[140] Op. cit. COCIR (2012a)

9.2.2.4 Unknown Relation between Testing and Field Conditions for Lead-free Solders

COCIR[141] claims that this exemption is required because the reliability of these types of equipment produced with lead-free solders could be inferior to those made with SnPb solder when exposed to the above impacts during use. The effect of these impacts on equipment reliability is well understood for SnPb solders as a result of many decades in use but there is much less field data for lead-free products. An issue for medical devices is that before a new product or one with a modified design can be sold in the EU, it must be approved by a Notified Body under the Medical Devices Directive. In order to gain approval, the manufacturer must prove that the equipment is reliable. The only way to do this is by extensive reliability trials which involve accelerated testing to simulate field conditions. To further confound these difficulties, before meaningful testing can begin, the grain boundaries must be allowed to rearrange themselves and reach an equilibrium condition. It is not clear how or if isothermal aging accurately simulates the normal aging process. According to research by Dr Werner Engelmaier, much worse test results can be expected from an assembly that has been aged for 12-months than from an assembly that has been freshly assembled.[142]

Unfortunately for lead-free solders, it is still unclear how field reliability can be predicted accurately from accelerated test results. So far there has been very little electrical equipment built with lead-free solders and used in the relatively severe environmental conditions experienced by MMD for sufficient periods of time in the field, i.e. more than 10 years.[143]

All medical devices must be approved by a Notified Body in the EU before they can be used and one way of assessing reliability is to use industry standard accelerated test data. As this is not reliable for lead-free equipment, this creates a problem obtaining approval. COCIR[144]

9.2.3 Intermetallic Phase Formation with Solders

COCIR[145] suggests that failures have been found to occur predominantly at the interface between brittle intermetallic phases[146] and solder, although failures as a result of damage to the printed circuit board (PCB) laminate can also occur.

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[141] Ibid.

[142] Opening remarks at the IPC Conference on Lead-Free Reliability in 2005

[143] Op. cit. COCIR (2012a)

[144] Ibid.

[145] Ibid.

[146] Di Maio, D. & Hunt, C. (2007) *High-frequency vibration tests of Sn-Pb and lead-free solder joints*, NPL Report MAT 2, August 2007, retrieved from http://publications.npl.co.uk/npl_web/pdf/mat2.pdf

COCIR[147] explains that SnPb solder interacts with the substrate metals to create a layer of intermetallic phase. This phase is produced as a result of chemical reaction between the tin in the solder and the metal surface of the PCB pad or the component's terminals. With copper circuitry, a SnCu intermetallic is produced whereas – if the pads or components have a nickel coating – SnNi intermetallic is formed. SnCu forms more quickly, and tends to be thicker than SnNi but both continue to grow after the solder bond has been produced due to "aging". The growth rate depends on temperature. At higher temperatures the intermetallic phase grows more quickly. This effect can be used to simulate accelerated aging.

According to COCIR[148], with SnPb solders, the available tin close to the interface is depleted, so that this zone becomes lead-rich, which retards intermetallic growth as tin is less accessible. Also, the residual lead is relatively flexible (unlike tin/copper and tin/nickel intermetallic phases). Lead-free solders contain mostly tin. A tin-depleted zone does not form, and the structure and behaviour of the bond is different to that of SnPb bonds.

As a second effect, COCIR[149] explains aging of solders. SnPb solder consists of two phases, one tin-rich and the other lead-rich. These are separate grains, which gradually grow, especially where there is a high level of stress imposed. Grain growth within SnPb does not affect bond reliability unless the grains become particularly large in stressed regions, such as when thermal fatigue failure occurs after many stress/relaxation cycles.

Most lead-free solders are mainly pure tin with a dispersion of irregularly shaped SnAg and SnCu intermetallics. When a solder bond is formed on a copper substrate, SnCu forms at the interface and on nickel substrates, SnNi intermetallic is formed. These layers tend to be thicker than those produced with SnPb solder because of the higher soldering temperature and because tin is not depleted close to the interface. Sn_3Ag and SnCu intermetallic crystals form within the solder as soon as the bond is formed and grow in size due to thermal aging. Sn_3Ag crystals are a particular problem as they are needle shaped and can be quite long. In very small solder ball bonds, used for micro-BGAs and CSP, large intermetallic crystals can occupy a significant proportion of the ball volume, whereas this is not possible with SnPb as lead occupies half of the volume, and lead does not react with copper or nickel.[150]

An additional failure mode that has been found with lead-free ball bonds is where the solder is bonded to a copper PCB pad with a nickel barrier layer that is not completely non-porous. If a small amount of copper reaches the solder, the intermetallic that forms is SnNiCu, which has been found to be very brittle and fractures easily. This is a

[147] Op. cit. COCIR (2012a)

[148] Ibid.

[149] Ibid.

[150] Ibid.

very uncommon failure mode with SnPb because of the lower soldering temperature, but has been found frequently in the case of lead-free products.[151]

9.2.4 Kirkendall Voiding in Lead-free Solder Joints

COCIR explains that the use of lead-free solders has introduced other complicating factors. [152] Lead-free processes have been shown to increase the risk of "Kirkendall voiding". This is a process that creates many very small voids at the solder-substrate interface. It is believed to be related to the plating process although it is not fully understood.

Research has shown that Kirkendall voiding is more likely to occur with lead-free processes than with SnPb solders due to the higher soldering temperature. The latest theory is that electroplating processes trap organic substances within the metal coating and these decompose to give off gases during soldering, and it is these gases that create the small voids. Due to the higher melting point of lead-free solders, the 20–30°C higher soldering temperature increase the risk that the organic substances will decompose to form gases. The higher temperature also increases the volume of the gases as they are hotter.[153]

Normally these voids have little effect, but they increase the risk of failure when the equipment is dropped, or subjected to stresses such as vibration.[154]

9.2.5 Lacking Resistance against Vibrations

COCIR[155] is concerned about solder bond reliability in MMDs because the circuits are exposed to very severe vibration for a very long period. There are several research publications which compare the vibration performance of SnPb solder with lead-free solder, although some of the results appear contradictory. The reasons for contradictory results were demonstrated by research carried out by JGPP, which showed that susceptibility depends on: [156]

- the solder alloy composition;
- the type of component;

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[151] Ibid.

[152] Ibid.

[153] Ibid.

[154] Ibid.

[155] Ibid.

[156] T. Woodrow, JCAA/JG-PP *Lead-free solder project: Vibration and Thermal Shock Tests*, April 2006, http://www.jgpp.com/projects/lead_free_soldering/April_4_Exec_Sum_Presentations/040406WoodrowVibThShock.pdf; source referenced in (COCIR 2012a)

- the position on the circuit board; and
- g-force.

Later research described below also showed that vibration frequency is an important variable.

The JGPP[157] research used test boards, having several types of components, each attached at several positions. Three lead-free solders and SnPb solder were compared. At lower g-forces, no failures occurred during the 7 hour period of the test. At moderate to high g-forces, there were many failures. The most susceptible type of component to fail was the ball grid array (BGA). Most of the several BGAs on the test board had bond failures before other types of components although the time to failure was strongly dependent on the location on the PCB. Results with BGAs showed that during the tests, failures were significant at g-forces above 9 g, and that the lead-free solders tested failed before SnPb. In these tests, g-forces were increased once every hour. Results for two of the BGAs are shown below (BGAs U4 and U6 were of the same type). [158]

Table 9-1: BGAs with failed bonds (%) during vibration testing

g-force	BGA U4			BGA U6		
	SnPb	SAC	SACB	SnPb	SAC	SACB
9.9	40	80	100	0	20	0
12	80	100	100	20	60	40
14	100	100	100	40	100	60
16				60	100	100
18				60	100	100
20				80	100	100

SAC = Tin, silver and copper *SACB = Tin, silver, copper and bismuth*

Source: Op. cit. COCIR (2012 a)

As component location affects vibration failures, it is difficult to compare the susceptibility of different types of components to vibrations. Most of the other types of components at locations adjacent to U4 and U6, and so experiencing similar vibration force and amplitude, failed later than these BGAs. However, of some concern to manufacturers of MMD is that BGAs are commonly used.[159]

The test results reported from the JGPP[160] research are from highly accelerated testing using very high g-forces. The test duration was only 7 hours whereas many types of medical devices have lifetimes of over 25 years and will be in use many hours per

[157] Ibid.

[158] Op. cit. COCIR (2012a)

[159] Ibid.

[160] Ibid.

day. Clearly if the electrical device, irrespective of which type of solder was used, were to be exposed to 9.9 g or more, it would not survive 25 years. Accelerated testing is useful to identify potential failures during the normal lifetime of the equipment based on known characteristics of the equipment such as the level of vibration.[161]

The maximum vibration force experienced in service is relatively large for MMD. Some electrical component bonds failed after less than 2 hours in the JGPP tests whereas medical device PCBs must survive for 25 years and may regularly experience severe vibration for long periods. Medical device manufacturers have many years of field experience with SnPb solders at high levels of vibration and so can expect that PCBs made with SnPb solder will survive 25 years. As the JGPP tests show that bonds made with lead-free solders will have shorter lifetimes, there can be no certainty that the same PCBs when made with SAC lead-free solders will survive the 25 years.[162]

NPL's research compared SnPb with four SAC alloys including SAC0305 having only 0.3% of silver (Ag), which has better drop shock resistance than SAC0305. This investigation used piezoelectric actuators to impose controlled vibration forces and vibration amplitude, and the frequency was controlled in these tests. The main result was that at all frequencies, SnPb had a lower probability of failure than any of the four SAC alloys. This was especially the case at higher frequencies as 400 and 800Hz were compared. Table 9-2 shows the results for vibration cycles to 20% probability of failure from Weibull plots.[163]

Table 9-2: Cycles to failure

Solder alloy	20% probability at 400Hz	20% probability at 800Hz
SnPb	200,000	20,000
SAC305	100,000	2,000
SAC387	60,000	8,000
SAC 0305	40,000	4,000
Annealed SAC305	9,000	-

Source: Op. cit. COCIR (2012a)

9.2.6 Lacking Drop/Shock Resistance of Lead-free Solders

Besides vibration, JBCE puts forward the lacking drop/shock resistance of lead-free solders as a reason to continue using leaded solders.[164]

[161] Ibid.

[162] Ibid.

[163] Ibid.

[164] Ibid.

COCIR explains that manufacturers carried out research into the reliability of equipment when dropped onto hard surfaces. The performance of SnPb solders has been established over many years so that mobile medical devices do not fail in normal use which includes being repeatedly dropped.[165]

9.2.6.1 Drop Tests with CO_2 Sensors

According to COCIR, CO_2 sensors are carried in ambulances, helicopters and on hospital trolleys and so suffer from vibration and are frequently dropped. [166] COCIR reports that lead-free soldered versions were also drop tested and preliminary test results with a mobile medical CO_2 sensor indicate that lead-free solder joints are more susceptible to damage when dropped[167].

COCIR describes the test methodology of the new CO_2 sensor designs: [168]

- Vibration was tested using the test method in IEC TR 60721-4-7 Class 7M3 and IEC 60068-2-64 Random Vibration;
- Shock resistance – IEC TR 60721-4-7 Class 7M3 and IEC 60068-2-27 Shock;
- Operational drop – testing ability to withstand repeated six foot drops onto tiles floor while operating; and
- Free fall (drop test) – TR 60721-4-7 Class 7M3 and IEC 60068-2-32 Free fall defined as less than 1 kg, 1 m drop height, 2 falls in each attitude.

COCIR[169] reports that the lead-free designs have not yet been fully evaluated because preliminary tests showed that lead-free versions had a higher failure rate:

- Tin/lead soldered CO_2 sensors – all pass criteria of above tests
- Lead-free soldered CO_2 sensors – above drop tests only carried out. All samples failed to meet the criteria specified by the above drop tests (i.e. ceased to function correctly).
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[165] Ibid.

[166] COCIR (2012c) COCIR Answers to 2nd Round of Clarification Questions, submitted by COCIR on 10 December to consultants via e-mail

[167] Op. cit. COCIR (2012a)

[168] Op. cit. COCIR (2012c)

[169] Ibid.

9.2.6.2 Drop Test Research Comparing SnPb and SAC Solders

COCIR[170] references research published by Heaslip et al.[171] in 2005. The researchers compared SnPb with SAC305 solders. They used printed circuit boards (PCBs) having ball grid array (BGA) devices that are similar to those used in mobile defibrillators, PWDs and many other types of mobile device. Drop performance of PCBs made with SnPb and Sn3.8Ag0.7Cu BGA balls and solder pastes were compared using drop heights of 406 and 610 mm. Two types of failure were noted:

- "hard", where permanent open circuits occurred; and
- "soft", where brief periods of high electrical resistance occurred.

Brief periods of high electrical resistance are sufficient to prevent some types of medical device from functioning, and as a result, posing a health risk to patients. This is often due to the significant functionality that is provided by embedded CPUs where even a momentary loss of communications can result in the system locking up or spontaneously rebooting. This could have serious implications with a portable ventilator or the types of equipment used by patients away from medical staff. Heaslip's research showed that there were failures after the following numbers of drops. See Table 9-3 and Table 9-4.

Table 9-3: Soft failure results of Heaslip's[171] drop test COCIR[172]

Drop height mm.	Number of drops until soft failure	
	SnPb	SAC
406	Best 200, worst 70	Best ~40, worst 10
610	Between 30 – 70 drops + one test after only 10 (solder defect?)	All failed after <20 drops

Table 9-4: Hard failure results of of Heaslip's[171] drop test COCIR[173]

Drop height mm.	Number of drops until hard failure	
	SnPb	SAC
406	One data point at ~120 drops	Between 10 and ~80 drops
610	Between 25 and 70 drops	Between <10 and ~20 drops

[170] Op. cit. COCIR (2012a)

[171] Heaslip, Ryan, Rodgers & Punch Stokes Research Institute and University of Limerick, *Board Level Drop Test Failure Analysis of Ball Grid Array Packages,* referenced by COCIR (2012a)

[172] Op. cit. COCIR (2012a)

[173] Op. cit. COCIR (2012c)

COCIR[174] concludes from the above results that SAC305 solders have significantly inferior drop performance than SnPb. If mobile medical devices were to be made with SAC305 solder, they would be significantly more likely to fail than SnPb versions. As a result of this finding, which has been confirmed by other workers, alternative types of lead-free alloys have been evaluated and compared with SnPb.

9.2.6.3 Good Drop Test Performance of Low-silver SAC Solder Alloys

COCIR[175] references other research published in 2007[176], which compared the drop performance of simulated BGA assemblies soldered with 17 different lead-free solders including three with ~3% silver, the rest with lower amounts and SnPb solder. All of the SAC alloys with ~3%Ag gave significantly inferior performance to SnPb confirming Heaslip's results. COCIR[177] admits that several of the SAC alloys containing ~1% silver plus certain additives gave slightly superior drop performance to SnPb when tested in the "as reflowed" condition. COCIR,[178] however, judges this condition as unrepresentative of medical devices as all solders "age" in use, which changes their microstructure so that they perform differently. This research also compared drop test performance of aged samples and this showed that only one lead-free solder was superior to SnPb. This alloy contained 1.1% Ag and 0.13% manganese (Mn) which survived after a minimum of ~15 drops whereas SnPb survived a minimum of 10 drops in these tests. It would appear therefore that if drop performance were the only important criteria, Sn1.1Ag0.64Cu0.13Mn could be used. According to COCIR[179], the melting temperature of such a solder paste is in the range of 217- 227 °C. COCIR[180] states that the upper end of this range of 227 °C is 10 °C hotter than standard tin-silver-copper solder so that the required reflow temperature will be too hot for some types of heat sensitive components. The high temperatures will cause more PCB distortion during reflow, which may prevent solder bonds forming, and increases the risk of PCB delamination and conductive anodic filaments (CAF). For these reasons, and because such solders are, according to COCIR, not commercially[181], these solder alloys cannot be used.

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[174] Op. cit. COCIR (2012a)

[175] Ibid.

[176] Weiping Liu and Ning-Cheng Lee, "The Effects of Additives to SnAgCu Alloys on Microstructure and Drop Impact Reliability of Solder Joints", Journal of Materials, July 2007, retrieved from http://link.springer.com/content/pdf/10.1007%2Fs11837-007-0085-5; source referenced in (COCIR 2012 a)

[177] Op. cit. COCIR (2012a)

[178] Ibid.

[179] Ibid.

[180] Op. cit. COCIR (2012c)

[181] Op. cit. COCIR (2012a)

According to COCIR[182], some manufacturers use commercially available SAC105 solders in applications where being dropped is likely, such as for mobile phones. It is clear that these have superior drop performance to SAC 305 solder.[183] Solders with low silver content have, however, been found in comparative testing to give inferior thermal fatigue performance (cf. section "Increased Temperature Fatigue of Lead-free Solder Joints" on page 89).

9.2.6.4 Applicant's Conclusions on Drop Resistance

COCIR[184] concludes that equipment which is dropped and experiences significant thermal fluctuations is at a high risk of failure if lead-free solders are used. Low silver content SAC alloys are now widely used for mobile phones because they are often dropped but due to the small component size and limited temperature changes, strain is too small for rapid thermal fatigue failures to occur.

Because of these findings, these solders would not be suitable for use in mobile medical devices that experience significant temperature fluctuations. Mobile phones may occasionally experience large temperature fluctuations such as when left in an automobile. As their expected life is relatively short, thermal fatigue failure is, nevertheless, not a concern as this type of failure within normal lifetimes is unlikely. Medical devices however need to function for over 20+ years and so thermal fatigue does need to be taken into account when selecting a suitable solder alloy.[185]

9.2.7 Increased Temperature Fatigue of Lead-free Solder Joints

COCIR[186] says that a considerable amount of research has been carried out into the effects of temperature fluctuations on solder reliability. Temperature increase causes materials to expand and PCB laminate expansion on heating is different and usually larger than component expansion, especially for ceramic components. This differential expansion imposes strain on solder joints. Where temperature increases and decreases repeatedly, failure can occur as a result of the cyclical strain causing thermal fatigue cracking of the solder joints. Thermal fatigue failures occur with both SnPb and lead-free solder joints. The time to failure depends on many variables including the size of the temperature variation, the rate of temperature change, the stress level and the solder alloy composition. Research has shown that where strain is low, lead-free solders are superior to SnPb whereas at high strain levels, lead-free

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[182] Ibid.

[183] Zhang, Cai, Suhling & Lall (2009) Aging effects on the mechanical behaviour and reliability of SAC alloys, *Proceedings of the ASME 2009*, July 19-23, 2009, San Francisco, California, USA

[184] Op. cit. COCIR (2012a)

[185] Ibid.

[186] Ibid.

solders are inferior to SnPb. This rather complex result means that PCB designers try to avoid using components that will suffer from large strain such as large ceramic components. This is not always possible. Some of the large BGAs used on mobile medical device PCBs will suffer from large strains when temperatures fluctuate. This difference in performance is a concern for mobile medical device producers as this equipment can experience many repeated large temperature changes. The field life of SnPb PCBs can be reliably predicted from the results of accelerated thermal cycling tests because many decades of field behaviour is available. The designers of SnPb PCBs can therefore predict product lifetimes and so can be certain that they will survive the expected lifetime of the equipment but this is not yet possible with lead-free solders. If high strain is likely, lead-free solder product lifetime will be shorter than the SnPb equivalent, but there can be no certainty of how much shorter the lifetime might be because no field data exists over the relevant time period to validate theoretical prediction models. [187]

COCIR[188] expects that in the near future, prediction models for lead-free solder will be developed that can be trusted, and so, will be used, but currently this is not possible. One dilemma for mobile medical equipment manufacturers is that to achieve good drop resistance, research has shown that SAC alloys with low silver content are superior as described above. However, low silver content lead-free solders (e.g. with <1% silver) have inferior thermal fatigue resistance to SAC alloys with 3 or 4% silver.[189] For example, Terashima[190] carried out comparative thermal cycling tests with SAC alloys having 1–4%Ag on flip-chip devices. Solders with the lowest silver contents had the highest failure rates. Research showed that failures occur with SAC having 1% silver after less than half the number of thermal cycles than can be withstood using SAC with 3% silver. These results have been confirmed by other researchers.[191]

9.2.8 High Copper Dissolution Rates and Impaired Repairability

When a printed circuit board is soldered by wave soldering, the copper pads and through-holes are in contact with liquid solder for a fairly short time, but some of the copper dissolves in the solder. This is not usually a problem unless rework or repairs are needed in which case the copper will be in contact with liquid solder for much longer. Research has shown that the rate of copper dissolution is much faster with SAC alloys than with SnPb solder although SnCuNi solder appears to be viable. Measurements by NPL (UK) show the difference in copper dissolution rates. See Table 9-5.

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[187] Ibid.

[188] Ibid.

[189] S. Terashima, et al., *Journal of Electronic Materials*, Vol. 32, No. 12, p. 1527 (2003); Abstract available via http://link.springer.com/article/10.1007%2Fs11664-003-0125-z?LI=true; source referenced in (COCIR 2012a, c)

[190] Ibid.

[191] Op. cit. COCIR (2012a)

Table 9-5: Comparison of copper dissolution rates of lead and lead-free solders

Solder alloy	Rate of dissolution of copper immersed in solder bath*	Copper dissolution rate (wave soldering) at specified temperature**
SnPb	1.8µm/sec at 275°C	~1.38µm/sec at 255°C (72°C above m.pt.)
SnCu	2.7µm/sec at 275°C	3.28µm/sec at 275°C (~48°C above m.pt.)
SnAg	4.4 µm/sec at 275°C	3.28µm/sec at 275°C (~54°C above m.pt.)
Sn3.7Ag0.7Cu	-	2.3µm/sec at 275°C (~58°C above solidus.) or 3.3µm/sec at 300°C (~80°C above solidus.)

** D. Di Maio, C. P. Hunt and B. Willis, "Good Practice Guide to Reduce Copper Dissolution in Lead-Free Assembly", Good Practice Guide No. 110, 2008, National Physical Laboratory, UK.*
*** C. Hunt and D. Di Maio, "A Test Methodology for Copper Dissolution in Lead-Free Alloys", National Physical Laboratory, UK.*

Source: Op. cit. COCIR 2012a

These results show that the risk of complete loss of copper is higher with lead-free solders than with tin/lead solder. This issue implies that the potential for rework and repairs are impaired so that additional waste would be created.

9.2.9 Whisker Formation and Corrosion due to High Humidity

COCIR[192] puts forward an argument that high humidity increases corrosion rates of materials and this could affect the reliability of mobile devices. Corrosion of most types of lead-free solder is not a concern as most types are less susceptible to corrosion than SnPb. The only exception is Sn-Zn alloys, which corrode and fail after fairly short periods. High humidity can, however, have the following effects:

- Tin whiskers of electroplated tin coatings;
- Corrosion of edges of solder pads and tracks; and
- Corrosion of metallic parts, e.g. of components on the PCB, due to corrosive flux residues.

[192] Ibid.

9.2.9.1 Humidity-induced Whisker Growth

COCIR[193] explains that surface corrosion affects the grain boundaries at the surface, imposing strain on these grains. This has been shown to grow long tin whiskers with no mechanism for this stopping (unless the tin is consumed). Many off-the shelf components are available only as lead-free versions, usually with tin plated terminations so that manufacturers have no other choice. However, the risk of tin whiskers can be limited with tin/lead solder by ensuring that it coats as much of the coating as possible. Lead-free solders wet tin less well so that it is common for a larger area of termination coating to remain uncoated.

COCIR[194] says that research has been carried out to determine whether conformal coatings can reduce the risk of tin whiskers causing short-circuits. COCIR[195] states that there are several types of conformal coating available and all have been evaluated. Research has shown, however, that they do not stop the formation of tin whiskers, they merely delay their formation, some types for longer than others.[196] Whiskers will eventually grow through many types of conformal coatings, but as they are flexible, once they emerge they cannot penetrate the coating over an adjacent termination.

COCIR[197] nevertheless describes three ways in which short circuits can occur with conformal coatings:

- Most types of conformal coating give fairly thick coatings and these tend to be more effective than thin coatings which can leave gaps. However, when used on fine pitch components, the coating bridges between terminals. If a whisker grows from one terminal, it is supported by the coating and will eventually reach the adjacent terminal (as there is no air gap) and cause a short circuit. This will take a longer time than without conformal coatings and to date no examples of failures due to this have been reported (although they would be very difficult to detect);
- Whiskers can grow beneath coatings across the surface of PCBs or components to the adjacent electrical conductor. Poor adhesion of the conformal coating will make this more likely to occur and no-clean soldering fluxes are known to cause inferior adhesion. No-clean fluxes are designed not to be removed and so poor adhesion occurs. As lead-free solders require higher temperature, this usually makes flux removal with solvents more difficult. Some types of components such as QFNs and vented BGAs (both of which are used in mobile medical devices) must be soldered with no-clean fluxes and they should not be cleaned; and

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[193] Ibid.

[194] Ibid.

[195] Ibid.

[196] http://nepp.nasa.gov/whisker/reference/tech_papers/2006-Woodrow-Conformal-Coating-PartII.pdf; document referenced in (COCIR 2012a)

[197] Op. cit. COCIR (2012a)

- If two whiskers grow through the coatings of two adjacent terminals into the air, they may touch each other causing a short circuit. This is likely to occur only if there are many whiskers formed although this is fairly common.

Tin whisker short circuits are less likely to occur with conformal coatings, but according to COCIR, the long term risk is not completely eliminated.[198]

9.2.9.2 Corrosion

According to COCIR,[199] lead-free solders wet less well than SnPb. Often, the solder does not fully wet the component solder pads. Corrosion of these uncoated areas has been observed in hostile environments when the PCBs have OSP or silver coatings. With ENIG or HASL coatings, these effects can, however, be avoided.

Some lead-free solder fluxes must be more aggressive than those used with SnPb solders due to the inferior wetting properties and the higher soldering temperatures resulting from higher lead-free solder melting points. This is alloy dependent with some fluxes being particularly corrosive. Ideally, no-clean fluxes are used to avoid the production of waste, but for many types of mobile medical devices, high surface insulation resistance (SIR) is essential for the equipment to function correctly. So these fluxes must be removed by washing. Lead-free flux residues tend to have a higher ionic content and are more difficult to dissolve due to the higher reflow temperature and so manufacturers can experience difficulties achieving the required level of cleanliness.[200]

High humidity combined with a higher ionic content of fluxes can also cause the Surface Insulation Resistance (SIR) between tracks and pads to decrease to a level that causes some types of equipment to malfunction. For example, biometric measurement circuits must have high impedance, and so humidity and higher lead-free ionic content fluxes can cause malfunctions resulting in false alarms or worse, no alarm when a serious incident occurs.[201]

Excessive ionic material with high humidity can also cause corrosion of metals and dendrite growth, which is an electrochemical corrosion process that causes short-circuits and is found to occur faster with solders containing silver. Therefore, overall, manufacturers find that using lead-free solders is more difficult than SnPb and so will need sufficient time to resolve these issues.[202]

Table 9-6 summarises the reliability performance due to the three main risk factors and reparability of the three main types of lead-free solder with SnPb.

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[198] Ibid.

[199] Ibid.

[200] Ibid.

[201] Ibid.

[202] Ibid.

Table 9-6: Comparison of solder properties COCIR[203]

Variable	SAC alloys with ≥3%Ag	Low Ag SAC alloys with <1%Ag	Sn100C, etc (no silver)
Temperature fluctuations	OK unless high strain	Inferior to SAC305 and SnPb	Inferior to SAC305 and SnPb
Vibration	Inferior to SnPb	Inferior to SnPb	Inferior to SnPb
Drop / shock	Unsuitable	Probably OK, used for mobile phones	Probably OK
Copper dissolution	Faster than SnPb	Faster than SnPb	Faster than SnPb but may be OK

9.2.10 Lacking Experience with the Use of Under-fills for Lead-free BGAs and CSPs

According to COCIR[204] research results prove that the resistance to drop failures of BGA and CSP bonds improves if these components are used with under-fill materials. These materials are types of adhesives that are injected between the device and PCB laminate and were used by Microsoft to resolve their high failure rates that were experienced with BGAs in their X-Box devices. Under-fills compatible with SnPb have been available for many years but lead-free compatible under-fills are newer. Drop-test performance of lead-free BGA and CSP is greatly improved by the use of suitable under-fill materials, but selection of the correct type of under-fill and how best to use it, is not yet routinely applied for lead-free assemblies. Research in the USA is being carried out to determine guidance on how to select and use under-fill with lead-free BGAs, CSP and QFN.[205] Research has shown that under-fill performance varies considerably with many under-fills providing little or no benefit. One reason for poor performance is the increased use of “no clean” fluxes. The residue interferes with the under-fill’s ability to adhere to the board which severely limits its effectiveness to support the component. [206]

To further complicate things, components such as QFNs nearly always mandate the use of “no clean” fluxes. Thermal coefficient of expansion (TCE) of the under-fill is important with low TCE materials appearing from research to give improved drop-test performance.[207]

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[203] Ibid.

[204] Ibid.

[205] For example http://www.inemi.org/project-page/advanced-si-node-pb-free-underfill-reliability; source referenced in (COCIR 2012a)

[206] Op. cit. COCIR (2012a)

[207] Ibid.

9.2.11 Roadmap to Substitution or Elimination

Manufacturers carry out research to find alloys and processes that give high reliability. It is likely that high reliability will be possible by means of a combination of selection of the correct alloy, and suitable design to minimise the risk from shock, vibration and temperature changes. This is time-consuming work because each type of equipment will need to be considered separately.[208]

Reliability testing of new alloys and designs must be thorough for medical devices as this data is needed before applying for approval under the Medical Devices Directive. Professor Cedar[209], has commented that in order to fully establish any new alloy or materials' characteristics and properties, it will take up to 18 years of effort and data collection, so that changes can be made appropriately to improve the materials, thus making the new materials close to problem-free, and more reliable when serving the industries. To gain approval, it will be necessary to show that the alternative alloy and every new design is not less reliable than with lead-based solders and so do not pose a risk to patients. Table 9-7 illustrates the likely time-scales. [210]

Table 9-7: Timescale to Substitution of Lead in Solders of MMD

Evaluation of alternative alloys and designs	up to 5 years
Reliability testing of new designs	at least 2 years
Submission for MDD approval	1 year
Total timescale	minimum 8 years

Source: Op. cit. COCIR (2012a)

This exemption is therefore likely to be needed until 2020 at least.

COCIR[211] claims that the 5 years for evaluation of alternative alloys and designs for all types of mobile medical equipment are needed to resolve technical issues connected with the use of lead-free solders, such as:

- COCIR[212] explains that in some types of mobile medical devices, printed circuit board assemblies are mounted onto a mother- board which could flex (bend) during reflow and use. Lead-free solders are less ductile than tin/lead solders

[208] Ibid.

[209] Private communication from Professor Cedar, MIT, Material Science Department; referenced in (COCIR 2012a)

[210] Op. cit. COCIR (2012a)

[211] Ibid.

and so a large board deflection is more likely to cause damage. Deflection of the circuit board creates stress to the solder-joints which can fail as a result. According to COCIR[213], lead-free processing (with SAC) limits the maximum allowable deflection of the circuit boards by about 35%. This is presumably the result of greater SAC erosion of copper plating especially at vias in pads in reflow processes. Through-hole components requiring wave soldering will cause even more copper erosion wherever copper sees the wave;

- Currently, the only solutions to copper dissolution are available for wave soldering of through-hole components. For surface mount components that utilize vias-in-pads, there is currently no solution to the erosion problem that we are aware of. SN100C solder reduces copper erosion, but is suitable only for wave soldering. For SMT it is still a problem (see section below on SnCuNi comparison);[214]
- ENIG can cause problems, most notable of which is "black pad" although this can also occur with SnPb. The electroless plating of nickel introduces phosphorus, which can collect and cause plating failure at the collection points. The solder dissolves the gold and bonds to the nickel, but the nickel is not secured to the copper. Therefore, time is required with any new design to ensure that reliability and quality issues do not occur;[215] and
- Some lead-free alloys such as SAC305 have been comprehensively studied and used for up to 10 years. For the reasons explained here, more research is needed but there has been a trend in recent years to use lower cost alloys with low silver content such as SAC0807 and SAC0307 (which have much higher melting temperature than SAC305). There has been much less research and field experience with these new alloys but they are cheaper and have a few technical advantages. Medical equipment manufacturers are able to select whichever alloy they need to ensure high reliability, but if most of the electronics industry switches to new alloys, this will severely limit the number of collaborative research studies into SAC305 and other alloys that medical equipment manufacturers have been evaluating and already have some experience with. Collaborative research is useful as a lot more research is carried out and shared than could be carried out by a single manufacturer in the same period of time. Switching to new alloys for consumer products which may not be suitable for mobile medical devices will mean that medical equipment manufacturers will need to carry out much more research themselves and this will require more time than if all of the electronics industry were investigating the same few alloys.[216]

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[212] Ibid.

[213] Ibid.

[214] Ibid.

[215] Ibid.

[216] Ibid.

9.2.12 Environmental Arguments

COCIR[217] claims that at end of life, most medical equipment is recycled as it often has a high value due to its metal content. Printed circuit boards (PCBs) are separated for separate recycling as required by Annex II of Directive 2002/96/EC before being recycled. In the EU and in many facilities elsewhere, PCB scrap is recycled using smelters which are large furnaces that melt some metals such as copper and convert others including lead into oxides which are collected and converted into metals for reuse. Lead is recovered with a very high efficiency and emissions are extremely low and meet EU environmental limits. PCB scrap is only one of manymaterials processed in large smelters and so removal of lead from solder will not affect this process as other materials including ores used may contain lead.

COCIR[218] admits that unsafe recycling of electrical and electronic equipment waste is carried out in some developing countries, but this is mostly with IT, telecom and consumer equipment. Waste from medical equipment is very unlikely to be recycled except by professional recyclers using well controlled safe processes.

COCIR[219] gives some more details for the recycling of lead and silver, which is one substitute of lead-free solders:

- Lead
  Large quantities of recycled lead are produced from lead scrap including printed circuit boards. No lead is released in the circuit board fabrication phase or the use phase of the life cycle. At end of life, PCBs in mobile medical devices contain some valuable metals and so they are nearly always recycled; and
- Silver
  If solders containing silver are used, recyclers will want to recover the silver from equipment at end of life. There are safe and efficient processes used by professional recyclers in the EU to recover silver with a high yield.
  If this equipment is exported to second users in developing countries, when it reaches end of life, unsafe recycling methods using very hazardous chemicals such as nitric acid and cyanide might be used and these chemicals are known to cause harm to local populations and the environment.

Other solder constituents including tin, bismuth, indium and zinc, according to COCIR[220] may also be recovered by modern efficient recycling processes, but are very difficult to recycle without suitable processes.

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[217] Ibid.

[218] Ibid.

[219] Ibid.

[220] Ibid.

9.2.13 Stakeholder Contributions

No contributions were made during the stakeholder consultation, concerning this request for exemption.

9.3 Critical Review

COCIR describes the specific conditions MMDs are exposed to. In combination with the high reliability requirements, long life times and the necessity to obtain approval of Medical Devices according to the Medical Device Directive, it is plausible that intermetallic phase formation, Kirkendall voiding, resistance against vibration and drop shocks are a challenge for lead-free soldered MMDs. The scientific and technical evidence COCIR submitted in principle is plausible, but some questions remained for which further efforts were made for clarification during the critical review of this exemption request.

9.3.1 REACH Compliance - Relation to the REACH Regulation

As this request concerns lead in solders and not a specific compound, Annexes XIV and XVII were reviewed for entries concerning lead. Chapter 5.0 of this report lists 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 restriction of substances under entry 30 of Annex XVII does not apply to the use of lead in this application. Putting lead in a solder used in a medical device on the market, 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 would not apply. Additionally, the medical equipment in the scope of this exemption request is a class of products that is not provided to the general public, but to other than private users, e.g. hospitals.

No other entries relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status 16 December 2012).

The review of related restriction and authorization processes revealed one process underway concerning lead and lead compounds (see Section 5.0 above). This concerns the use of lead and lead compounds in articles intended for consumer use, for which Sweden has notified the intention to propose a restriction. The articles in the focus of this exemption request, the mobile medical equipment, are, however, conceived for professional use and therefore in the consultant's understanding cannot be classified as consumer products. In the current proposed wording, this intended restriction proposal would not affect the exemption for the use of lead in solders of mobile medical equipment. Furthermore, as this request had not lead to the addition

of a restriction to Annex XVII at the time in which this restriction was evaluated, it could not provide a basis at that time for concluding that an exemption would weaken the environmental and health protection afforded by the REACH Regulation.

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.

9.3.2 Secondary Measures to Protect Equipment from Vibrations and Shocks

Exposure to vibration and shocks from dropping the equipment is a pillar of COCIR's justification. It is clear that such impacts are a challenge for lead-free, as well as, for lead-soldered joints. It would, therefore, be useful to protect the printed circuit boards and other sensitive parts from vibrations and shocks through appropriate measures.

COCIR[221] claims that manufacturers already do everything that is possible and are carrying out research into new designs that will be more resilient. There are, however, several limitations that prevent better protection being added to mobile devices. CO_2 monitors must fit onto the patient's neck and face. Ultrasound transducers' apertures must fit between patients' ribs. The small sizes leave limited space for secondary, additional protective measures.

Several other types, such as mobile ultrasound, portable monitors, automated CPR and mobile ventilators, are already fairly heavy and adding any additional weight might be unacceptable, as they need to be carried by hospital staff and paramedics, often with other equipment. Maximum weight is a severe limitation on adding additional features to give protection to delicate circuits.[222]

Devices worn by patients who are elderly or unwell must be as light as possible and so addition of substantial protection against shock from being knocked or dropped is not always feasible.[223]

Concluding from the applicant's information, it is possible to apply measures to protect the equipment from the effects of vibration, thermo-mechanical stress and dropping, but there are limits to how far this can be pursued depending on the intended use of the various MMDs.

[221] Op. cit. COCIR (2012b)

[222] Ibid.

[223] Ibid.

9.3.3 Actual Life Times of MMD

COCIR claims life times of 20 years and more for MMDs. Since, according to COCIR, MMDs are exposed to extreme stresses from vibrations, drops and temperature changes, the question arises whether such equipment can actually survive life times of 20 years and more as COCIR suggests. Additionally, COCIR had explained that the MMD life time depends on the type of equipment. It is hence logical to assume that not all equipment can have life times of 20 years and more. On further request, COCIR[224] said that many types of medical devices have several owners during their lifetimes and the owners are often located in different countries and continents. MMD service contracts are seldom longer than 15 years, but lifetimes in service can be longer with some in use for more than 20 years. COCIR[225] provided typical lifetime data for various types of MMDs as displayed in Table 9-8.

Table 9-8: Life times of MMDs COCIR[226]

MMD	Typical total lifetime – time between initial purchase by 1st user and disposal at end of life
• Infant Apnea Monitors • CO_2 sensors	~ 15 years
Ventilators (hospital and home use types)	~ 15 years with some in use for up to 20 years
• Automated CPR • Portable monitors • Devices worn by patients	> 15 years
Portable ultrasound	> 18 years

Source: Op. cit. COCIR (2012c)

COCIR[227] adds that MMD manufacturers design their products to have long and very reliable lifetimes since unexpected failures can be fatal to patients. Warranty periods vary depending on the type of product and can be up to 5 years, but most MMD warranties are 1–2 years.

According to COCIR,[228] manufacturers also offer their customers service contracts where they provide assistance to users; upgrade software and maintain and repair if

[224] Op. cit. COCIR (2012c)

[225] Ibid.

[226] Ibid.

[227] Ibid.

[228] Ibid.

necessary. Service contracts could last indefinitely with customers and they can choose to contract with the manufacturer after the warranty period is over, for however long they would like to (there is no time limit). This will mean that some products are in use with service contracts for more than 18 years of service. The warranty and service contract periods are not however, on average any different to other types of medical device.

The above life times were cross-checked with a hospital in Berlin. Non-confidential data on actual life times of MMDs could, however, not be obtained and in-depth investigations outside the information provided by the stakeholders are beyond the reviewers' mandate.

9.3.4 Field Failures

COCIR references several sources to show that lead-free soldered consumer products have a higher incidence of field failures (see section "Field Failure Rates in Consumer Products" on page 78). The "Squaretrade" 2009 insurer data propose that almost 32% of laptop PCs fail in the first three years, almost 11% of which due to accidental damage e.g. from being dropped. It is plausible to assume that in 2009, these laptops were using lead-free solders. The source does, however, neither explain whether the damages were due to broken lead-free solder bonds, nor does the source provide any data that would allow comparing lead-free with lead-soldered laptop PCs. Hence these data are inconclusive.

The same applies to the Gartner data COCIR submitted to justify the exemption request. Gartner shows that the failure rate for tin-lead soldered laptop PCs prior to 2006 was 22% over four years. This is less than the 31% over three years published by Squaretrade in 2009 for the lead-free-soldered laptops. COCIR states that this difference could be due to the change from SnPb to lead-free solders, but admits that other variables such as design (complexity will have increased) and the way the data in the two studies were collected were different. Additionally, the Gartner data is from mainly business users, which generally use more expensive laptops, whereas Squaretrade data reflects all users.

Taking into account this data background, COCIR's conclusion from this data that there appear to be more failures with lead-free soldered laptop PCs than with SnPb soldered laptop PCs, is not sound.

9.3.5 Scientific and Technical Practicability of Lead Substitution

9.3.5.1 EU-notified Body Approval for Lead-free Soldered MMDs

To justify the exemption request, COCIR suggests that lacking experience and knowledge with reliability testing of lead-free soldered printed circuit boards makes it impossible to demonstrate the reliability of lead-free soldered MMDs in order to obtain approval by a Notified Body under the Medical Devices Directive. The reviewers understood from COCIR's arguments that there is a lack of knowledge and experience on how exactly to test lead-free soldered equipment, and what conclusions to draw

from test results concerning the field reliability of such equipment. This situation was prevalent when, before 2006, manufacturers of electrical and electronic equipment (EEE) under the scope of the RoHS Directive started shifting to lead-free soldering.

The question arises, how the manufacturers would obtain the approval for other types of medical devices which use lead-free solders, but will not benefit from any exemption, if it is not possible to draw conclusions from reliability tests of lead-free soldered equipment as to their field reliability.

COCIR[229] explains that the majority of lead-free soldered medical devices that have been approved by EU Notified Bodies under the Medical Devices Directive are not MMDs and so will not suffer from the physical effects that can cause premature failure as COCIR had described in the exemption request. [230] For the approval of MMDs, COCIR[231] states that MMD manufacturers submit their technical files and design history files to notified bodies for assessment. The MMD manufacturers will describe in these files the uncertain reliability territories, e.g. due to being dropped, vibration, etc. The Notified Body might not accept the submission and will ask for more test data, which can be time-consuming. According to COCIR[232], manufacturers will not be certain of long term performance until the field data are available in the future after many years of service. Therefore, they will state in their files (both technical and history) that due to the change to lead-free solders, the products might not perform as with tin-lead solders due to reliability issues due to thermo-mechanical stress, vibration, drop and shock. Notified bodies will determine if the submission is acceptable and whether to grant approval.

In the course of the investigation, COCIR[233] stated that approvals have been granted for medical devices made with lead-free solders. COCIR[234] later confided that COCIR it has information about the approval of only one MMD, the Philips MX40 portable patient monitor[235], which is classified as class IIA medical equipment according to Annex IX of the Medical Device Directive (MMD) 93/42/EEC. COCIR[236] states that this MMD is a new design where it has been possible to eliminate the risk of premature failure by vibration, shock, etc.

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[229] Ibid.

[230] Op. cit. COCIR (2012a)

[231] Op. cit. COCIR (2012c)

[232] Ibid.

[233] Ibid.

[234] COCIR (2012d) Answers to 3rd Round of Clarification Questions, submitted by COCIR on 13 December 2012 to consultants via e-mail

[235] Philips Healthcare: *IntelliVue MX40 wearable patient monitor*, http://www.healthcare.philips.com/gb_en/products/patient_monitoring/products/intellivue_mx40/; source referenced in COCIR (2013a)

[236] Op. cit. COCIR (2012c)

COCIR[237] says that it only has information on the approved lead-free soldered Philips portable monitor because this exemption request is on behalf of COCIR's members, which includes only a few mobile medical device manufacturers. COCIR[238] states also that none of its members has applied for approval by notified bodies for lead-free soldered MMDs, and states that it has no information from other manufacturers which are not members of COCIR.

The case of the Philips portable monitor shows that manufacturing and approval for lead-free soldered MMDs is obviously technically and scientifically practicable at least for such class IIA MMD. COCIR[239] expects class IIA MMDs to be RoHS compliant sooner than class IIB MMDs, probably before the end of 2016. COCIR[240] reports that building reliable and RoHS compliant MMDs is possible only by completely redesigning products and by using the relatively new low silver-content SAC alloys. Currently, COCIR[241] states, alternative designs do not exist for most Class IIA MMD and this research cannot be completed by July 2014.

COCIR[242] continues that class IIB MMD need more time than class IIA ones. They need more extensive testing and clinical trials due to higher risk to life from unexpected failures. According to COCIR[243], at this time, it is not possible to determine how long this exemption will be needed, but this is likely to be until 2021 at least. COCIR states that currently, no RoHS compliant Class IIB MMDs exist and none are planned to be submitted for approval to EU-notified bodies in the foreseeable future.

9.3.5.2 Lacking Input from MMD Manufacturers outside COCIR

COCIR has 30 corporate and several national association members[244]. According to COCIR[245] only a few of its members manufacture MMDs, while the majority of such manufacturers are not members of COCIR. No information is available on the status of lead-free soldered MMDs from any other manufacturer outside COCIR. Even though COCIR's exemption request was published for commenting in the stakeholder consultation, neither MMD manufacturers nor any other stakeholders submitted any information or commented on COCIR's exemption request.

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[237] COCIR (2013a), COCIR Answers to 4th Round of Clarification Questions submitted by COCIR to Consultants via e-mail on 8 December 2013

[238] Ibid.

[239] Ibid.

[240] Ibid.

[241] Ibid.

[242] Ibid.

[243] Ibid.

[244] European Radiological, Electromedical and Healthcare IT Industry (COCIR), retrieved from http://www.cocir.org/content.php?level1=2&mode=1; last accessed 22 January 2013

[245] Op. cit. COCIR (2012b)

COCIR, in the reviewers' opinion, has fulfilled its obligations to prove the justification of the exemption request. The reviewers' mandate does not cover comprehensive bespoke investigations and studies going beyond the information provided by stakeholders. Though an effort was made to contact other stakeholders in order to verify that COCIR's arguments indeed apply to the scope of products for which the exemption was requested, additional information was not available. As the scientific and technical information provided by COCIR is plausible, it is concluded that, in the absence of contrary evidence, COCIR correctly describes the situation with the reliability, testing and approval of lead-free soldered MMDs.

9.3.6 Environmental Arguments

COCIR[246] submitted environmental arguments intended to support the request. As substitution or elimination of lead is currently scientifically and technically impracticable, and as the applicant did not base its exemption request on environmental, health and safety impacts of the substitute being likely to outweigh the benefits of substitution, these arguments were not reviewed. The consultants would like to point out, however, that this neither indicates agreement nor disagreement with the applicant's environmental arguments.

9.3.7 Conclusions

Generally, after more than six years of lead-free soldering and scientific research, there is much more knowledge and experience about reliability testing of lead-free soldered EEE compared to the situation as it was in 2006. The information submitted by the applicant plausibly explains that MMDs are exposed to harsher conditions compared to stationary equipment. In combination with high reliability requirements and the necessity to prove the reliability requirement is met in order to obtain approval from EU-notified bodies according to the Medical Device Directive, it is also plausible that MMDs require more experience, effort and time for a complete redesign of the relevant devices where the substitution of lead in solders is concerned.

Given the fact that at least one lead-free soldered class IIa product, a portable patient monitor, has achieved approval by a notified body according to the Medical Device Directive, the substitution of lead is scientifically and technically practicable at least for portable monitors. Based on the submitted information and in the absence of contrary information, the reviewers consider it plausible that there is need for further research at least for class IIb MMDs given the specific conditions MMDs are exposed to combined with long life times, high safety and reliability requirements and the necessity to prove the reliability of these products in order to obtain approval by a notified body according to the Medical Device Directive.

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[246] Op. cit. COCIR (2012a)

Besides scientific and technical practicability, COCIR argues that the complete redesign of MMDs to meet the reliability and safety requirements takes time beyond 2014, when this equipment will fall under the scope of the RoHS Directive. Goodman[247] recommended a transition time of six years until the inclusion of medical equipment into the scope of the RoHS Directive. In the reviewers' opinion, producers could only be obliged to start their transition efforts towards RoHS compliance once the inclusion into the scope of the RoHS Directive was officially announced, which happened in July 2011 for medical equipment with the publication of the new RoHS Directive in the Official Journal of the European Union. In this sense there is support for the view that the process of redesign for these products could require further time beyond 2014, when the products come into scope.

COCIR[248] concedes that manufacturers can achieve RoHS-compliance for class IIa MMDs probably before the end of 2016, while for class IIb equipment, this is likely to take until 2020 at least, according to COCIR.[249]

- For class IIa MMDs, where at least for monitors the principle practicability of lead substitution is proven, the 2016 deadline remains within the six year time limit which Goodman[250] recommended in the past.
- The class IIb equipment deadline of 2020 would be beyond the six year timeline that Goodman had foreseen (starting the coming into force of RoHS 2, i.e., July 2011 – July 2017).

That said, as the applicants argumentation can be followed, it stands to reason that the redesign and qualification of some products may take longer in some cases than in others. Progress with IIa products suggests that the medical sector is already engaged in efforts towards the future compliance of MMD products. In the consultant's view, in light of the information supplied, it can be followed that more time is needed for achieving RoHS compliance of IIb products, and longer than was foreseen by Goodman[251].Summing up, taking into account the above arguments, the information submitted, and the absence of contrary evidence, an exemption would be in line with the requirements of Art. 5 (1) (a).

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[247] Goodman, P. (2006) *Review of Directive 2002/95/EC (RoHS) categories 8 and 9 – Final Report*, ERA Report 2006-0383, July 2006, amended September 2006, retrieved from http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf; last accessed 9 November 2012

[248] Op. cit. COCIR (2013a)

[249] Op. cit. COCIR (2012a)

[250] Op. Cit. Goodman (2006)

[251] Ibid.

9.4 Recommendation

The information submitted during and after the consultation process plausibly explains that MMDs are exposed to harsher conditions compared to stationary equipment. In combination with high reliability requirements over a long life, and the necessity to prove the reliability to obtain approval from EU-notified bodies according to the Directive 93/42/EEC (Medical Device Directive), the available information also plausibly illustrates that MMDs require more experience, efforts and time for a complete redesign of the devices to substitute lead in solders.

This situation applies, however, to a different degree for class IIa and class IIb MMDs. According to the applicant, manufacturers can achieve RoHS-compliance for class IIa MMDs before the end of 2016, while for class IIb equipment, this is likely to take until 2020 at least.

Based on the submitted information, and in the absence of contrary evidence, an exemption would be in line with the stipulations of Article 5 (1) (a). It is therefore recommended to add an exemption to Annex IV of the RoHS Directive with the following wording, which was agreed with COCIR[252],[253]:

> *Lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices others than portable emergency defibrillators*
>
> *Mobile medical devices are medical devices which are designed and approved by a notified body according to Directive 93/42/EEC to be hand carried, or to be transported on own wheels, on a cart or trolley or in a vehicle, aircraft or vessel during and/or between operations.*
>
> *The exemption expires on 30 June 2016 for class IIa mobile medical devices, and on 31 December 2020 for class IIb medical devices.*

9.5 References Exemption Request 4

COCIR (2012a) Original exemption request no. 4, document "COCIR_-_Exemption_request4_-_Lead_in_mobile_MD_V2.pdf", COCIR 2012, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_4/COCIR_-_Exemption_request4_-_Lead_in_mobile_MD_V2.pdf, last accessed 20 November 2012

COCIR (2012b) Stakeholder document "Request_4_1st_Clarification.pdf" submitted by COCIR 2012 on exemption request no. 4 in 2012 within the consultation, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_4/Request_4_1st_Clarification.pdf; last accessed 20 November 2012

[252] COCIR (2013c) Answers to Clarification questions, submitted to Consultants per e-mail on 21 January 2013

[253] Op. cit. COCIR (2013d)

COCIR (2012c) Stakeholder document “Request_4_2nd-Questionnaire Answers 10-12-2012-revised.docx” submitted by COCIR to consultants via e-mail on 10 December 2012

COCIR (2012d) Stakeholder document “Request_4_3rd-Questionnaire 13_12_12 v1.docx” submitted by COCIR to consultants via e-mail on 13 December 2012

COCIR (2013a) Stakeholder document “Request_4_4th-Questionnaire MMD answers 07012012.docx” submitted by COCIR to Otmar Deubzer via e-mail on 8 January 2013

COCIR (2013b) Stakeholder document “Request_4_5th-Questionnaire MMD answers 07012012.docx” submitted by COCIR to Otmar Deubzer via e-mail on 11 January 2013

COCIR (2013c) Stakeholder document “COCIR 2013 c.pdf” submitted by COCIR to Otmar Deubzer via e-mail on 21 January 2013”

COCIR (2013d) Stakeholder document “COCIR 2013 d.pdf” submitted by COCIR to Otmar Deubzer via e-mail on 22 January 2013”

Goodman (2006) Goodman, Paul: *Review of Directive 2002/95/EC (RoHS) categories 8 and 9 – Final Report*. ERA Report 2006-0383, July 2006, amended September 2006, retrieved from http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf; last accessed 9 November 2012

10.0 Exemption Request No. 5:"Decorative Ceramic Lamp Bases or other Ceramic Components of Luminaires Containing Lead and/or Cadmium in the Glaze / Colouring"

Abbreviations

Pb	Lead
Cd	Cadmium
CELMA	Federation of National Manufacturers Associations for Luminaires and Electrotechnical Components for Luminaires in the European Union

According to CELMA, decorative ceramic lamp bases or other ceramic components of luminaires can be specifically designed as a lamp base, or can be a traditional glazed ceramic vase/pot etc. which is "converted" to be used as a lamp base. [254] These products are used in stately homes, palaces, hotels, theatres, restaurants etc. and in households more generally for decorative ambiance. In the case of converted products, the lead-glazed vases etc. are not covered by the RoHS 2 Directive, but the specifically designed lamp bases are. As lead and cadmium are present in some of the glazing and colouring materials used for these ceramic parts, these products do not comply with the RoHS regulations.

Therefore the Federation of National Manufacturers Associations for Luminaires and Electrotechnical Components for Luminaires in the European Union (CELMA) has applied for an exemption for:

> *"Decorative ceramic lamp bases or other ceramic components of luminaires containing lead and/or cadmium in the glaze/colouring"*

10.1 Description of Requested Exemption

CELMA[255] states that Lead and Cadmium are components of the glazes and colourings used to glaze ceramic lamp bases or other ceramic components of luminaires. Lead is used in glazes and colourings. Cadmium is predominantly used to provide a bright red/orange colour.

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[254] CELMA (2012a) Original request for exemption No 5, Submitted by CELMA, 30 January 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_5/CELMA__Exemption_request5_Glaze_30012012.pdf

[255] Ibid.

CELMA[256] elaborates that it is impossible to quote absolute numbers because of the variability of the articles in question (type of colour, glaze thickness etc). Treating just the glaze as a homogeneous material (as it forms a coating layer that could be ground away) the lead content is generally <30%. The levels of cadmium, where used, would be much lower, at around 1%.

10.2 Applicant's Justification for Exemption

The applicant's main argumentation focuses around the aesthetical properties that may be established by using lead and cadmium based colours and glazes. CELMA[257] explain that decorative lighting products are, as their name suggests, a decorative item where the aesthetics are equally, if not more important to the consumer than the functionality. For further details see Section 10.2.1 below.

Concerning the use of the specific substances in glazes and colours, the applicant suggests that

- Lead lowers the glaze melting point and, as a silicate glaze, gives a smooth, glossy, bright finish. It is also used to provide special effects (reactive glazes); and
- Cadmium provides bright red/orange colours.

The applicant[258] further argues that ceramic luminaires (lamp base/components) are produced in exactly the same way as Ceramic Tableware to which stringent standards apply, originally as Directive 84/500 EC revised as 2005/31 EC. The Directive sets limits for Lead and Cadmium release for articles in contact with food where any human exposure would otherwise be an issue.

10.2.1 Possible Substitute Alternatives

As for the possible substitution of lead and cadmium based colours and glazes, CELMA[259] explains that lead free glazes do exist, but these cannot replace lead glazes in many applications.

Further information provided by the applicant[260] provides that lead in glazes is used to facilitate the melting of glazing particles which creates a thin glass-like surface on

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[256] Ibid.

[257] Ibid.

[258] Ibid.

[259] Ibid.

[260] CELMA (2012b), Response to 1st clarification questions concerning exemption No 5, Submitted by CELMA, The Federation of National Manufacturers Associations for Luminaires and Electrotechnical Components for Luminaires in the European Union, 20 June 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_5/CELMA_DOM_SM_264_CELMA_replies_to_OEko_Institute_on_CELMA_RoHS_Exemption_request_for_Glaze_20062012.pdf

otherwise porous pottery. Lead is also associated with richness of colour in glazes. As for using cadmium in ceramic glazes and colours, the applicant explains that red colours have long been a challenge for the ceramic industry as most red pigments are unstable at high temperatures. The deep red colour produced by cadmium selenium sulphide is prized for its pure deep red colour. Cadmium is also used to increase the vividness of ceramic glaze colours.

According to CELMA[261], the reduction in available finishes will reduce consumer choice and disadvantage producers of lighting products. This is explained through it being impossible to reproduce the aesthetic effects currently possible without the use of lead and cadmium in the glaze. Many colours, decorative finishes etc. would no longer be possible for luminaires (lamp base/components) even though the same finishes would remain available and totally acceptable for other ceramic products. Without the aesthetic ability of the luminaire (lamp base/components) to match corresponding items of a decorative nature (e.g. vases, jugs, plates etc) the luminaire (lamp base/components) may not be purchased.[262]

Furthermore, according to the applicant[263], in most cases ceramic luminaires (lamp base/components) are produced on the same production line as table ware, vases, jugs, ashtrays etc. and cannot be processed differently[264]. The applicant states that many luminaires (lamp base/components) are manufactured in small quantities and by SMEs. SMEs do not have the purchasing power to demand changes to production techniques and processes where most products do not need to comply with RoHS. Other SMEs purchase a ceramic vase etc. and convert it into a lamp base.

CELMA[265] elaborates that in all cases these types of ceramic luminaire (lamp base/components) would have to be withdrawn from the market, leading not only to lost sales for the lamp bases, but possibly also, for the associated matching vases, tableware etc. CELMA estimates that the loss of business in the UK alone would be around £4m and is estimated across Europe to be in excess of €30 million.

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[261] Op. cit. CELMA (2012a)

[262] CELMA clarifies that some ceramics companies offer table lamp versions of their tableware or decorative ceramic products, which complement their product range and result in additional sales. The assumption that some sales of vases and tableware would be affected is based on the fact that often these products are sold as matching sets- e.g. a customer might purchase a set of decorative ceramic vases and matching table lamp. In the event that the lamp cannot comply with RoHS whereas the rest of the range of identical ceramics can legally be sold, the sales potential of the matching set is removed with a subsequent potential loss of sales for the entire range. CELMA, 2012, Information provided by the applicant on 13 November 2012, in answer to clarification questions.

[263] Op. cit. CELMA (2012b)

[264] The consultants would like to note that the applicant later clarifies that it is not that it is impossible to produce ceramic-ware for lamps differently, but rather that their share of total production is not significant enough for suppliers to use separate lines or implement different production specifications for their production. This statement has not been substantiated with exact numbers that could demonstrate the market share of these products.

[265] Op. cit. CELMA (2012a)

In response to clarification questions, the applicant[266] explained that it is important to understand that the EU market for glazed ceramic table lamps is relatively small and is almost always a business arising from the conversion of ceramic vases and other ceramic goods for which there are no requirements to limit the lead and cadmium content in the glazes internationally. As a result of the small proportion of ceramic products which are converted, the ceramic producers have no incentive to investigate the production of cadmium and lead-free alternatives. The lighting industry in this particular area consists of small SMEs that search for artisan suppliers the world over to find decorative objects that can be converted to table lamps. These artisan suppliers of ceramics are not asked by any of their other customers for such detailed technical information and as a result there is no research available to the lighting industry relating to work to find alternatives. The concern of the lighting industry is that compliance with requirements to produce lead and cadmium free ceramic products will outlaw the tradition of small SMEs sourcing decorative ceramics the world over and converting them to light fixtures. These same ceramics can legally be sold in Europe as vases and other decorative items and some are deemed safe for food consumption. However, once a lamp-holder is attached to the decorative ceramic item it falls within the scope of the RoHS Directive and would be considered illegal.

10.2.2 Possible Design Alternatives

The applicant states repeatedly that though lead free alternatives exist, products produced with these glazes are not equivalent to those compared with lead-based glazes and colours.

A representative of the Danish ceramic ware manufacturer Royal Copenhagen,[267] who was contacted seeking information as to possible alternatives, elaborated that as the Pb free alternatives result in different colours and light refraction effects, it is not possible to maintain production of designs in which lead based glazes were applied in the past. Instead the producer has closed down such production lines and designed new products using the available alternatives; however these products are different and are not to be regarded as an equivalent substitute: "*The lead free colours look nice in themselves - but you cannot replace existing decorations.*"

10.2.3 Environmental Arguments

Referring to risks of substance emission, CELMA[268] explains that in all cases the materials are fired with, or onto, the ceramic base. Essentially the glaze forms a glassy phase on the exterior surface(s) of the ceramic base. Similarly the firing pro-

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[266] Op. cit. CELMA (2012b)

[267] Royal Copenhagen (2012) Information provided by Royal Copenhagen in response to clarification questions of the consultants, submitted per e-mail, 24 October 2012

[268] Op. cit. CELMA (2012a)

cess incorporates the decoration, or colours, into the glassy phase. The result is an extremely stable, resistant, insoluble and permanent cover or finish to the ceramic article. Only severe abrasion or chemical attack can cause even marginal release of any of the components.

As for the use of lead in glazes and colours, CELMA[269] states that Pb lowers the glaze melting point. This is to say, where lead free substitutes are used to achieve similar affects (however not equivalent), either higher glazing temperatures must be applied, or the firing period must be prolonged.

This is further substantiated by information submitted by an external expert, Markus Thielen[270], as well as by Royal Copenhagen ceramic ware manufacturer, both of whom were contacted seeking information concerning the technical qualities of lead based and lead free colours and glazes. Royal Copenhagen also explains that as the lead free alternatives flow in a different way, a thicker layer is needed in comparison to lead based glazes[271].

It should be clarified that data was not submitted to allow a comprehensive understanding of the technical differences between lead / cadmium based colours and glazes and the various lead and cadmium free alternatives. The applicant stated that:

> *"the Lighting Industry has insufficient knowledge of the details of the firing process as most companies supplying decorative lighting are merely purchasing ceramic vases or tableware and converting them to table lamps."*

Subsequently CELMA suggested that organisations such as, for example, in the UK, Cerame-Unie or the British Ceramic Confederation, might be best placed to answer these questions. These companies have been contacted; however at present no further information has been provided that would allow making a quantifiable comparison.

10.3 Stakeholder Contributions

In support of the application, Markus Thielen[272], an independent expert, explains that:

> *"Ceramic glazes are glasses with a melting point lower than the glassy component in the base ceramic. The spectral absorption characteristic makes the glass color unique, always dependent on the light source spectrum. Chromium and especially Cadmium-Selenium colored glasses exhibit a special spectral*

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[269] Ibid.

[270] Thielen, M. (2012) Contribution submitted to RoHS Exemption Request Evaluation on September 3rd, 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_9/20120903_Thielen_RoHS_stakeholder_consultation_contributuion_Ex_No_9.pdf

[271] Op. cit. Royal Copenhagen (2012)

[272] Op. cit. Thielen, M. (2012)

absorption curve which cannot be achieved using other ingredients. Lead is often part of the glass batch-composition not only to reduce the melting point as the applicant states, but merely to provide a necessary electron band structure at the local atomic positions of the Cadmium and Chromium atoms within short-range order of the tetrahedral silica glass structure. These facts are well known since mid of the last century, and up to today, no replacement of these ingredients in colored glasses could be found. For this reason, especially where colored glasses act as filter for light… (for example: lamp shades, lamp bulbs, or neon/fluorescent tubes - HLDT), these ingredients cannot be replaced and thus the exemption has to be granted."

An objection has been brought forward in a contribution made by the Climate and Pollution Agency in Norway[273], it was stated that:

*"It is **not** impracticable to change the lamp bases into other materials without lead and cadmium. According to the application it is estimated that annual quantities of the hazardous substances used in these particular applications is up to 5,000 t/year for lead and 25 t/year for cadmium. In our perception this may have a significant impact on the waste stream and the environment. We therefore consider this may prevent the reuse of the ceramic. The main consideration in this question must be the environmental aspects, not the aesthetical aspects. We therefore can't support this request."*

The Danish Ministry of Environment[274] has also submitted a contribution objecting the requested exemption. In their objection they also state that:

"it is also not technically or scientifically impractical to change into other types of ceramics. In Denmark ceramic containing more than 100 ppm lead has been forbidden since 2007[275] and several both large and small enterprises have substituted the lead in their ceramics".

Furthermore, the Agency explains:

"concerning the Socio-economic factors it is our impression that the impact is highly overestimated. First, of all it is stated to be a very small market where ceramic vases are converted into lamps. Since the ceramic production includes many objects it is highly unlikely that the loss of one type of object would lead businesses to close down. Further, we do not agree in the percep-

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[273] The Climate and Pollution Agency in Norway (2012) Contribution submitted to RoHS Exemption Request Evaluation on September 3rd, 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_5/RoHS_Stakeholder_Contribution_Exemption_No_5_CPA_Norway.pdf

[274] The Danish Ministry of the environment (2012) Contribution submitted to RoHS Exemption Request Evaluation on September 4th, 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/General_contributions/20120904_Danish_EPA_RoHS_stakeholder_consultation_contributuion_Ex_No_5_6_7_8_9.pdf

[275] This prohibition applies only to decorative items, whereas dinnerware is regulated after other legislations, that is the EU directive 1935/2004/EG.

tion that a consumer will not purchase vases and tableware if they cannot also buy a lamp base that matches. Thus the estimated impact 30 million Euros is in our perspective speculative and highly overestimated."

Based on past experience a representative of Royal Copenhagen[276] stated that:

"It is not possible to get the same materiality without lead - and in praxis it is impossible to make the same product without lead."

The result was that lead containing production was ceased and new products were designed using lead-free colours and glazes, however the representative emphasizes that such products are not equivalent, and that lead free colours and glazes can therefore not be regarded as comparable substitutes.

10.4 Critical Review

10.4.1 REACH Compliance - Relation to the REACH Regulation

Chapter 5.0 of this report lists the authorizations and restrictions listed in the REACH Ordinance that apply to RoHS regulated substances dealt with in the context of this project.

According to the REACH Regulation, Entry 23 in Annex XVII restricts the use of cadmium and its compounds. Restrictions apply to cadmium in mixtures, and articles produced from synthetic organic polymers, as well as to metal plating of articles and parts containing cadmium. Various applications are mentioned to indicate application categories falling under, or excluded from, the scope of these provisions, though this scope does not appear to include the use of cadmium in ceramic glazes.

Various cadmium and lead compounds are listed in the respective substance annexes mentioned in Entry 28 and 30. These substances and compounds may not be placed on the market as substances, constituents of substances or in mixtures. As lead is part of a glaze in the applications referred to in this request for exemption, it does not appear to fall under the scope of these restrictions.

Some lead compounds are listed in the Annex XIV Authorization list. The applicant did not submit information concerning the exact compounds that are used in various colours and glazes, and it is assumed that this information would be difficult to obtain, as luminaire producers are not the producers of the ceramic components. In case an exemption was granted, this information would have to be obtained and reviewed to establish that the protection afforded by the REACH Ordinance was not being weakened by the exemption.

[276] Op. cit. Royal Copenhagen (2012)

10.4.2 Scientific and Technical Practicability of Lead and Cadmium Substitution

The main argumentation provided by the applicant focuses around the aesthetic properties that the use of cadmium and lead in glazes and colours achieves:

- The use of lead results in smooth, glossy, bright finishes. Its addition to other glazes enriches the colour and may also provide special effects (reactive glazes).
- Cadmium is used to obtain bright red/orange colours and may also be used to increase the vividness of ceramic glaze colours

As further supported by representatives of the ceramic industry, approached by the consultant in seek of technical information, the statement that lead-free alternatives cannot provide equivalent products to those manufactured with lead-based colours and glazes has some support. As for the cadmium colours, it has been sufficiently supported that certain hues may only be obtained with cadmium based colours.

This was also established in an evaluation of a similar request in the course of 2008:[277]

> *"Aesthetically, the result of the elimination and substitution is not equivalent, as not all glazes and colours are producible in the same quality as with lead and cadmium".*

However this aspect is not considered crucial to the actual function of ceramic ware as the use of different colours and glazes does not inhibit the article's functionality; in this case a lamp-base, ability to hold the light fixture, nor does it inhibit the lamps ability to produce light. Certain aesthetic qualities cannot be reproduced. As aesthetics are a question of taste and fashion, however, they cannot be considered from a technical standpoint.

It could be argued that by using other glazes, the light shall be reflected differently from the ceramic base, but as the light is reflected rather than being filtered through a glass that may significantly change the wavelength, it is again more of an aesthetical issue and less of a technical one.

10.4.3 Environmental Arguments

The applicant, as well as some of the stakeholders, has stated that lead lowers the glaze melting point. In this sense, corresponding to parameters such as glaze layer thickness and dimensions of the article, firing of ceramics would either entail lower glazing temperatures or shorter firing times. However, quantifiable information was

[277] Gensch, C.; Zangl, S.; Groß, R.; Weber, A. K.; Deubzer, O. (2009) *Adaptation to scientific and technical progress under Directive 2002/95/EC; Final Report*, Öko-Institut e.V. and Fraunhofer IZM, February 2009, http://ec.europa.eu/environment/waste/weee/pdf/report_2009.pdf

not submitted to allow a comprehensive comparison, indicating the impact of this on the total energy consumption of manufacturing the relevant ceramic ware.

As colours and glazes are often applied prior to a second firing process, it is not clear if the difference in using lead based and lead-free substances would correspond to a significant difference in energy consumption. Furthermore, even if this difference were quantifiable, it would still need to be weighed against the corresponding use of lead and possible impacts that may be attributed to it along the life cycle of the product, in order to show if negative impacts on health and the environment are outweighed by the positive change in energy consumption.

10.4.4 Conclusions

According to the RoHS 2 Directive, an exemption would only be possible under the fulfilment of one of the conditions listed in Article 5(1) a:

- "The elimination or substitution… is scientifically or technically impracticable": As the applicant states, the impracticability of substitution is consequential to the inability to reproduce certain aesthetic qualities. However the applicant was not able to provide information or data for quantifying these qualities on a technical or scientific basis. In any case, this condition could only be considered to be fulfilled if aesthetics are regarded as crucial for the functionality of the products. Additionally, as other lamp bases may be manufactured with cadmium and lead free ceramics as well as with other materials, it would appear to be the case that elimination cannot be considered impracticable.
- "The reliability of substitutes is not ensured": Article 3 of the Directive defines reliability of a substitute as the probability of EEE using the substitute to perform a required function without failure. As the elimination of lead based colours and glazes does not inhibit the lamp bases' or the luminaires' ability to perform their main functions, this condition is not fulfilled;
- "The total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the… benefits thereof". As has been summarized above, the possible benefits of lead based glazes in terms of energy consumption could not be quantified due to the lack of technical data. Nor has a comparison been carried out to estimate if this difference would provide sufficient benefits to outweigh other negative impacts attributed to the use of lead in ceramic articles. However, the positive impacts mentioned would usually apply only to the consumption of energy throughout the second firing of the item before which the glaze is usually applied. Though no detailed data has been made available in respect of this matter, it cannot be conclusively demonstrated that substitution would give rise to detrimental impacts as referred to in the Directive.

Lead- and cadmium-free materials are available, but, according to the applicant, they do not facilitate the full variety of colours to be achieved on ceramics, or not in the quality of the glazes and colours containing lead and cadmium. Not granting the exemption thus would impact the properties of future lamps. They would look different and might even disappear from the market. Customers might not appreciate the

lead- and cadmium-free colours, or the more limited variety or even lack of colours compared to the current status, as in particular bright red and yellow colours would no longer be available. The applicant has stated that this could cause loss of business to the decorative ceramic lamp sector as well as to the ceramic sector in general.

The applicant puts forward that "Many luminaires (lamp base/components) are manufactured in small quantities" and others are manufactured through the conversion of vases. As it was later stated by the applicant that "the EU market for glazed ceramic table lamps is relatively small and is almost always a business arising from the conversion of ceramic vases", it is difficult to see how prohibiting the use of lead and cadmium based colours and glazes could have such a grave impact on the general market for ceramic ware in Europe, and thus, upon the business of SME's who produce ceramic ware. From the correspondence that the consultant has had with a Danish ceramic producer, where the use of lead in decorative ceramics has been prohibited since 2007, it seems that although it cannot be denied that this measure has had an effect on the manufacturer's production, the ensuing innovations and redesign of products have allowed the company to maintain its activity.

The fact that there has been a market for these products shows an appreciation by customers who buy these products for the aesthetical aspects. However, it remains unclear how significantly the demand for ceramic luminaires, as well as for other matching ceramic products, has been affected by the elimination of lead- and cadmium-free glaze and colour.

In this sense loss of business would be of high concern primarily for SME's whose main and possibly only activity consists of sourcing decorative ceramics the world over and converting them into light fixtures. Besides the fact that it remains to be clarified what the total magnitude of such establishments is, this argument could only be considered on a socio-economic level. As socio economic aspects are not viewed as a main criteria for justifying an exemption but rather as a supporting argument (and then, principally with regard to consumers), this impact would not be sufficient on its own to justify an exemption according to article 5(1)(a) of the RoHS 2 Directive.

10.5 Recommendation

Lead and cadmium cannot be fully substituted in glazes and colours of these ceramic parts without some impact on the quality and variety of colours that can be achieved. However from a technical standpoint, the substitution or elimination of lead and cadmium in this application is technically practicable.

Aesthetically, the result of the elimination and substitution is not equivalent, as not all glazes and colours may be reproduced on an equivalent basis to that accomplished with lead and cadmium. However the consultant does not find this aspect to be crucial to the functionality and therefore does not believe this aspect could justify an exemption in line with Article 5(1)(a) of the Directive.

This line of thought is further supported by the end result of an evaluation that took place in 2008 of a similar request for exemption of "Lead and cadmium in glazes and colours used on ceramic lamp bases, lamp carriers and clocks"[278]. In this case a clear recommendation could not be made and room for interpretation was left to the commission to decide if aesthetic qualities could justify an exemption according to Article 5 (1)(a). In that case, an exemption was not granted, and based on this, it is understood that aesthetic aspects were not considered sufficient grounds to justify an exemption.

The consultant thus recommends not granting the exemption requested.

It is worth highlighting the inconsistency in the Regulation of vases and luminaires where the matter of lead and cadmium is concerned. The applicant notes that if a vase using the same materials is produced and not converted into a lamp, its use is perfectly legal. Such inconsistencies in the application of environmental regulations have the potential to undermine the credibility of the regulations concerned. To the extent that the case for an exemption does not appear to have been made in this case, questions will reasonably be asked as to whether it makes sense to allow use of the same materials in vases as are being banned for use in lamps.

10.6 References Exemption Request 5

CELMA (2012a) Original request for exemption No 5, Submitted by CELMA, 30 January 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_5/CELMA__Exemption_request5_Glaze_30012012.pdf

CELMA (2012b) Response to 1st clarification questions concerning exemption No 5, Submitted by CELMA, The Federation of National Manufacturers Associations for Luminaires and Electrotechnical Components for Luminaires in the European Union, 20.6.2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_5/CELMA_DOM_SM_264_CELMA_replies_to_OEko_Institute_on_CELMA_RoHS_Exemption_request_for_Glaze_20062012.pdf

The Climate and Pollution Agency in Norway (2012) Contribution submitted to RoHS Exemption Request Evaluation on September 3rd, 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_5/RoHS_Stakeholder_Contribution_Exemption_No_5_CPA_Norway.pdf

The Danish Ministry of the environment (2012) Contribution submitted to RoHS Exemption Request Evaluation on September 4th, 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/General_contributions/20120904_Danish_EPA_RoHS_stakeholder_consultation_contributuion_Ex_No_5_6_7_8_9.pdf

Gensch, C.; Zangl, S.; Groß, R.; Weber, A. K.; Deubzer, O. (2009) *Adaptation to scientific and technical progress under Directive 2002/95/EC*; Final Report, Öko-Institut e.V. and Fraunhofer IZM, February 2009, http://ec.europa.eu/environment/waste/weee/pdf/report_2009.pdf

Royal Copenhagen (2012) Information provided by Royal Copenhagen in response to clarification questions of the consultants, submitted per e-mail 24 October 2012

[278] Op. cit. Gensch et al. (2009)

Thielen, M. (2012), Contribution submitted to RoHS Exemption Request Evaluation on September 3rd, 2012;
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_9/20120903_Thielen_RoHS_stakeholder_consultation_contributuion_Ex_No_9.pdf

11.0 Exemption Request No. 6:"Lead in Solder of Decorative Lamps to Join/Coat Copper Foil Jointing Strips to Provide a Permanent Bond"

Abbreviations

Pb	Lead
CELMA	Federation of National Manufacturers Associations for Luminaires and Electrotechnical Components for Luminaires in the European Union

The "Federation of National Manufacturers Associations for Luminaires and Electrotechnical Components for Luminaires in the European Union" (CELMA) has applied for the following exemption:

> *"Decorative lamp shades and bases (luminaires) containing lead in the solder used to join/coat the copper foil mounting strips for the glass/shell/other materials used in Tiffany (like stained glass windows), Capiz shell and similar products"*

11.1 Description of Requested Exemption

According to CELMA, the exemption would be used in Tiffany (like stained glass windows), capiz shell and similar products.[279] These products are used in stately homes, palaces, hotels, theatres, restaurants etc. and in normal homes for decorative ambiance. These decorative lamp shades and bases (luminaires) contain lead in the tin/lead solder consisting of 40% (weight) lead. The lead solder is used to join/coat the copper foil jointing strips with the glass/shell/other materials to provide a permanent bond. It must be easily and quickly worked to avoid thermal stress to the glass/shell etc.

When asked as to the amount of lead that comes into Europe through this application, CELMA[280] explained that*, "owing to the small level of production and the fact that all suppliers are small SME's there is no data available for sales of Tiffany and traditional glass lanterns either worldwide or in the EU. Response from UK suppliers*

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[279] CELMA (2012a) Original exemption request no. 6, document retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_4/COCIR_-_Exemption_request4_-_Lead_in_mobile_MD_V2.pdf, last accessed 26 November 2012

[280] CELMA (2012b) CELMA replies to Öko-Institut on CELMA RoHS Exemption request for "Lead in solder to join/coat copper foil jointing strips to provide a permanent bond", 20 June 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_6/CELMA_DOM_SM_265A_CELMA_replies_to_OEko_Institute_on_CELMA_RoHS_Exemption_request_for_Tiffany_20062012_public_consultation.pdf last accessed 26 November 2012, submitted by CELMA 2012 on exemption request no. 6 in 2012 within the consultation

suggests the market is worth approximately 2.5m Euros in the UK and perhaps 13m Euros across the member states. Calculating the lead content from a number of typical fixtures (see appendix) provides an average figure of 24.5% lead by weight of the product. In order to estimate the quantity of lead placed on the market we can calculate that on average 0.0048kg of lead is used per UK pound (equates to approximately 0.0041kg per Euro of sales) which leads us to an estimate of 53.3 tonnes for the EU per annum. We do not have figures for total lead consumption within the EU but understand that collectively the member states production of lead is around 2 million tonnes and that the EU is also a net importer of lead. Our estimates are that production of specialist lighting accounts for approximately 0.0002% of all lead consumed in the EU".

The consultants would like to emphasize that CELMA start by explaining that there is no data available to allow a good estimation of the number of products sold per year in the EU. It is thus not completely clear if these figure are based in fact on the amount of products manufactured in the UK in general, in which case, according to the applicant many of these products are exported, or if this figure is indeed an estimation for the European market.

CELMA further elaborates that, collectively, the EU Member States' production of lead is around 2 million tonnes, and that the EU is also a net importer of lead. CELMA estimates that the production of specialist lighting accounts for approximately 0.0002% of all lead consumed in the EU.[281]

11.2 Applicant's Justification for Exemption

11.2.1 Substitution of Lead

CELMA accepts that the use of lead-free or high melting point lead solders (as exempt under RoHS) is technically practicable in these applications.[282]

The main pillar in the applicant's argumentation therefore is the socioeconomic impact of having to produce RoHS-compliant lamps.

[281] Ibid.

[282] Ibid.

11.2.2 Socioeconomic Impacts of Lead Substitution

11.2.2.1 Cost Increases for RoHS-compliant Products

CELMA argues that lead-free solders melt at a higher temperature, and the process is consequently slower and more expensive, and the use of high melting point lead solders would lead to higher scrap levels.[283] Lead-free solders are more brittle and less suited to the production of artisan produced shades, which leads to greater reject levels. In a separate document, CELMA explains that the production of Tiffany and other leaded glass lanterns is a traditional craft, which is almost entirely hand made. Lead free solders are more expensive to buy, but the largest cost increase is due to the higher melting point temperature and therefore a slowing of the process and increased labour cost.[284] The overall cost typically increases by around 70% according to CELMA, which, they argue, would make the product uneconomic to produce.[285]

11.2.2.2 Competitive Disadvantages and Excess Investment Requirements for Lamp Producers

According to CELMA, around 90% of the production of this type of product is destined for the USA market where there are no RoHS requirements. Therefore, EU distributors are faced with requiring manufacturers to prepare separate production runs, which contributes to the 70% cost increase.[286]

CELMA notes that in the main market, the US market, there is no requirement to use lead-free solder and therefore all production facilities are geared for lead solder. The relatively small sales of EU Tiffany and other leaded glass lanterns make it unviable for suppliers to set up separate production runs for lead-free products.[287]

According to CELMA, production runs also manufacture similar products for the giftware market, which are not electrical products and thus not subject to RoHS requirements, which further isolates any specialist production of electrical lighting items for the EU market using lead free solder.[288]

It is also argued that many lampshades and bases of this type are manufactured in relatively small quantities and by SMEs. SMEs do not have the purchasing power to

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[283] Op. cit. CELMA (2012a)

[284] CELMA (2012c), Answers to Third Round of Clarification Questions, submitted to consultants via e-mail on 7 December 2012

[285] Op. cit. CELMA (2012b)

[286] Ibid.

[287] Ibid.

[288] Op. cit. CELMA (2012c)

demand changes to production techniques and processes when most of the products, which are mainly destined for the USA market, do not need to comply with RoHS.[289]

11.2.2.3 Overall Consequences of Forced RoHS-compliance

CELMA concludes that the resulting increase in price for the end user, of approximately 70%, is unsustainable in a market where existing prices are subject to a downward pressure. The result would be a closure of some long established businesses in this market as consumers and business customers will be unable to pay the increased prices.[290]

The applicant reports that currently, in some European countries, these styles of lampshades are sold separately from the lamp base (as non-electrical equipment not covered by RoHS). It argues that this causes many difficulties, and cost increases for manufacturers and retailers, who cannot pack and sell a complete product, as well as possible assembly issues for the consumer.[291]

11.2.3 Environmental Arguments

CELMA argues that the use of high melting point lead solders or of lead-free solders would lead to higher scrap levels.[292] CELMA does not provide further details about the environmental impacts. It does make the claim, however, that the average life of a consumer luminaire is over 20 years, and even longer for high value products such as Tiffany shades and leaded glass lanterns. If consumers tire of these products they are usually sold on rather than disposed of as waste.[293]

11.2.4 Road Map for Substitution

CELMA suggests the exemption to expire 2018, but does not provide a roadmap detailing any activities towards the substitution or elimination of lead in this application.[294]

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[289] Op. cit. CELMA (2012b)

[290] Op. cit. CELMA (2012c)

[291] Op. cit. CELMA (2012b)

[292] Op. cit. CELMA (2012a) and CELMA (2012b)

[293] Op. cit. CELMA (2012b)

[294] Ibid.

11.3 Stakeholder Contributions

The Norwegian Climate and Pollution Agency (CliPA) and the Danish Environmental Protection Agency (DEPA) commented on CELMA's exemption request during the stakeholder consultation. Both organizations stated that they did not support this exemption request.

Both organisations focus on CELMA's statement that "*The use of lead-free solders is not technically impossible*". They conclude that there is no basis for granting an exemption, as Article 5(1)(b) only allows an exemption from the substance restrictions in Article 4(1) if the elimination or substitution of the restricted substance via design changes or material changes … is technically or scientifically impracticable. DEPA states that lamp shells can easily be produced without lead. Thus it is also possible to substitute via design and material change.[295]

CliPA suspects that the up to 53 t lead, which CELMA indicates to be used per year in this exemption, may have a significant impact on the waste stream and the environment. CliPA highlights that the main consideration in this question must be the environmental aspects, not the aesthetical aspects, so that CliPA does not support this exemption.[296]

11.4 Critical Review

11.4.1 REACH Compliance - Relation to the REACH Regulation

As this request concerns lead in solders and not a specific compound, Annexes XIV and XVII were reviewed for entries concerning lead. Chapter 5.0 of this report lists 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 mentioned in this request might weaken the environmental and health protection afforded by the REACH Regulation.

The restriction for substances under entry 30 of Annex XVII does not appear to apply to the use of lead in this application. The interpretation adopted here is that putting lead in a solder used in a lamp shade which is then placed on the market does not

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[295] DEPA (2012) "20120904_Danish_EPA_ _contributuion to RoHS_stakeholder_consultation concerning _Ex_No_5_6_7_8_9" retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/General_contributions/20120904_Danish_EPA_RoHS_stakeholder_consultation_contributuion_Ex_No_5_6_7_8_9.pdf; last accessed 26 November 2012

[296] CliPA (2012) "RoHS CPA Norway Contribution to RoHS Stakeholder consultation Concerning Exemption_No_6.pdf" retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_6/RoHS_Stakeholder_Contribution_Exemption_No_6_CPA_Norway.pdf; last accessed 26 November 2012

constitute a supply of lead or 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 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 12 December 2012).

The review of related restriction and authorization processes, revealed some processes underway concerning lead and lead compounds (see Chapter 5.0 above). This includes the use of lead and lead compounds in articles intended for consumer use, for which Sweden has submitted an intention to propose a restriction. Depending on its final scope, such a restriction may have implications for the exemption under discussion, if it is to be approved. As these processes have not yet led to the addition of further substances to the authorization list, Annex XIV, or to the listing of new restrictions in Annex XVII, such future changes as may arise could not be taken into account in the recommendation for this exemption request. 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.

11.4.2 Scientific and Technical Practicability of Lead Substitution

CELMA does not dispute the fact that the substitution of lead is technically practicable, but argues that this could increase the prices of the lamps by 70%. The socioeconomic impacts of lead substitution therefore are the main pillar in the applicant's justification.

11.4.3 Socioeconomic Impacts

11.4.3.1 Market Collapse Due to Increasing Prices for RoHS-compliant Products

As noted above, CELMA claims that the shift to lead-free solders would typically increase the cost of the lamps by about 70%, which would make the production of these lamps uneconomic. The applicant was asked to explain the cost increase in more detail, and what "uneconomic" means in this context.

Figure 11-1 displays three examples of lamps, which are available as lead and lead-free versions. Table 11-1 shows the prices of lead and the respective lead-free versions of the above lamps, with the figures being based around a list of 10 types of lamp reviewed by CELMA. The examples show that the price increase for the lead-free

versions ranges between 34% and 54%.[297] These types of increase are, according to CELMA:[298]

"[…] not an isolated case and other suppliers have confirmed the level of increase."

Figure 11-1: Examples of lamps in the focus of this exemption requests

Source: Op. cit. CELMA (2012d)

Table 11-1: Price Comparisons of Lead and Lead-free Versions of Lamps

	Lamp 1 (left)	Lamp 2 (middle)	Lamp 3 (right)
	DIMENSION: D16″×H. 22″	DIMENSION: H 22″× Φ 16 ″	DIMENSION: 16″DX22″H
PRICE(lead):	$52.80	$67.90	$62.40
PRICE(lead)shade only:	$31.90	$48.80	$42.80
PRICE(lead free):	$70.90	$104.80	$89.50
PRICE(lead free)shade only:	$52.20	$87.50	$71.90
PRICE base only:	$25.40	$25.40	$24.30
Price Increase (Total Lead-free/lead)	34%	54%	43%

Source: Op. cit. CELMA (2012 d)

[297] CELMA (2012d) "CELMA RoHS Exemption request for Tiffany_typical quotation_07122012.xls", submitted to consultants via e-mail on 7 December 2012

[298] Op. cit. CELMA (2012a)

For seven of the lamps, lead–free versions entail a total price increase between 41% and 44%. For two lamps, the increases are 34% and 37%, and the highest increase amounts to 54% (the middle lamp in Figure 11-1). The examples provided do not, therefore, support the originally estimated 70% total price increase, even though from a product point of view, the price increases, mainly based on increased labour costs (according to CELMA), are not inconsiderable.

As noted above, CELMA made clear that lamp producers sell the lamp shades separately from the lamp bases in some EU Member States as a means to circumvent the RoHS Directive. According to CELMA, this increases the cost of these products. Despite this cost increase, the lamps still seem to have a market. The higher cost for this proceeding would have to be subtracted from the higher cost of lead-free products, which reduces the cost differences shown in the above Table 11-1.

It is not clear how price sensitive the market is for Tiffany lamps and other lamps in the focus of this exemption request, but there is no evidence that the price increases of the lead-free manufactured products would actually result in a collapse of this market in Europe, because customers would no longer buy these lamps.

11.4.3.2 Collapse of SMEs and Competitive Disadvantages Due to Required Investments for RoHS-compliant Products

CELMA states that many lampshades and bases of this type are manufactured in relatively small quantities and by SMEs, which do not have the purchasing power to demand changes to production techniques and processes when most of the products are offered on the USA market.

CELMA was asked to explain in more detail which investments would be required, and the reasons why they felt these would overburden the producers', in particular the SMEs, purchasing power. CELMA indicated that there is not so much a problem of increased investment in plant and machinery, but that it is mostly a case of increased labour cost causing a dramatic rise in prices which are passed on to the consumer.

Thus, producing lead-free products has less to do with the investment costs of new machinery and the main reason for higher costs is increased labour costs, contributing to increase in the total price of products. This once again raises the question whether such increased prices would result in a collapse of the EU lamp market, which the applicant could not prove (see Section 11.4.3.1).

According to CELMA, the USA, which does not have in place a regulation like, or similar to, the European RoHS Directive, cover 90% of the market for these lamps and Europe the remaining 10%. CELMA puts forward that SMEs cannot produce lead-free as well as lead lamps. The applicant's arguments on cost increases however show that the main cost driver is labour, not investments in new equipment. There is thus no evidence that the producers would not be able to operate two separate production runs, or possibly to specifically design products for the European market. In the consultants' point of view, enterprises can be expected to adapt to changing market conditions, and the requirement to produce RoHS-compliant products is just one such condition among others to which producers are exposed to in a market economy.

Within Europe, the manufacturers of such lamps move on a competitive level playing field, as the required RoHS compliance forces all manufacturers to produce lead-free lamp shades for the European market. Price increases related to RoHS compliance would thus affect all manufacturers' products so that in Europe, however, as detailed information was not provided concerning this aspect, it cannot be verified that the market would develop according to a specific scenario. This is to say that it cannot be concluded that this would result in competitive distortions.

It cannot be excluded that some lamp producers might disappear from the market if this exemption is not granted. There is, however, neither proof that the whole branch of decorative lamp manufacturers in Europe would be doomed to extinction in this case, nor that such decorative lamps could no longer be offered on the European market.

11.4.4 Environmental Arguments

CELMA claims that using lead-free solders would increase the scrap levels, and that the products are longevity products, which consumers sell on rather than disposing of as waste. Further detail estimating these impacts was not provided.

11.4.5 Conclusions

Technically, lead-free solders can substitute lead solders used in the production of decorative lamps of the types which are in the scope of this exemption request. CELMA does not provide environmental arguments that would justify a recommendation to grant the exemption.

According to Article 5 (1) (a), socioeconomic impacts would only justify an exemption, if these impacts would be so severe that the whole market segment and the producers disappear so that indirectly, the manufacturing of a product becomes technically impracticable. The applicant could, however, not provide evidence that this would actually happen in case the exemption is not granted.

11.5 Recommendation

Based on the available information from the applicant and stakeholders, it is recommended not to grant this exemption. Technically, the use of lead-free instead of lead solders is practicable. There is no evidence as to how severe the socioeconomic impacts originating from the cost increase for RoHS-compliant products would be. Additionally, socio-economic impacts could only support an exemption if one of the main conditions outlined in article 5 (1) (a) were fulfilled, (impracticable substitution, reliable substitutes not ensured, negative environmental and health impacts outweigh benefits, Cf. above in Chapter 1.0).

11.6 References Exemption Request 6

CELMA (2012a) Original exemption request no. 6, document retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_4/COCIR_-_Exemption_request4_-_Lead_in_mobile_MD_V2.pdf, last accessed 26 November 2012

CELMA (2012b) CELMA replies to Öko-Institut on CELMA RoHS Exemption request for "Lead in solder to join/coat copper foil jointing strips to provide a permanent bond", 20 June 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_6/CELMA_DOM_SM_265A_CELMA_replies_to_OEko_Institute_on_CELMA_RoHS_Exemption_request_for_Tiffany_20062012_public_consultation.pdf last accessed 26 November 2012, submitted by CELMA 2012 on exemption request no. 6 in 2012 within the consultation

CELMA (2012c) Answers to Third Round of Clarification Questions, submitted to consultants via e-mail on 7 December 2012.

CELMA (2012d) "CELMA RoHS Exemption request for Tiffany_typical quotation_07122012.xls", submitted to consultants via e-mail on 7 December 2012

CliPA (2012) "RoHS CPA Norway Contribution to RoHS Stakeholder consultation Concerning Exemption_No_6.pdf" retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_6/RoHS_Stakeholder_Contribution_Exemption_No_6_CPA_Norway.pdf; last accessed 26 November 2012

DEPA (2012) "20120904_Danish_EPA_ _contributuion to RoHS_stakeholder_consultation concerning _Ex_No_5_6_7_8_9" retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/General_contributions/20120904_Danish_EPA_RoHS_stakeholder_consultation_contributuion_Ex_No_5_6_7_8_9.pdf; last accessed 26 November 2012

12.0 Exemption Request No. 7 "Mercury in single capped (compact) fluorescent lamps not exceeding (per burner)"

Abbreviations

Hg	mercury
ELCF	European Lamp Companies Federation
CENELEC	European Committee for Electrotechnical Standardization
CFL	compact fluorescent lamps

12.1 Description of Requested Exemption

The European Lamp Companies Federation (ELCF) has applied for an exemption for:

> *"Mercury in single capped (compact) fluorescent lamps not exceeding (per burner) – for long-life lamps <30W (specified with a lifetime of >15.000 hours)"*

The exemption request is extremely similar to one previously evaluated (exemption no. (1a) listed in Annex III of Directive 2011/65/EU (RoHS 2) – see Table 12-1). This exemption was evaluated and reviewed by Öko-Institut together with Fraunhofer IZM in the past[299].

Table 12-1: Excerpt from Annex III of Directive 2011/65/EU (RoHS 2)

Exemption		Scope and dates of applicability
1	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):	
1(a)	For general lighting purposes < 30 W: 5 mg	Expires on 31 December 2011; 3,5 mg may be used per burner after 31 December 2011 until 31 December 2012; 2,5 mg shall be used per burner after 31 December 2012

[299] Gensch, C.-O.; Zangl, S.; Groß, R.; Weber, A. K.; Deubzer, O. (2009) *Adaptation to Scientific and Technical Progress under Directive 2002/95/EC, Final Report*, Öko-Institut e.V. and Fraunhofer IZM, February 2009, http://ec.europa.eu/environment/waste/weee/pdf/report_2009.pdf

The applicant's case focuses around the following arguments:[300]

- The applicant states that the use of long life lamps is directed to areas where lamp replacement is difficult and expensive due to high ceilings, special luminaire design for critical application requirements, or too much disturbance of processes with long operating hours, as well as applications where the safety of people is at stake, e.g. heavy duty industry halls, the chemical industry and oil platforms requiring very reliable long life specifications;
- The current exemption limits the mercury content to 2.5 mg per burner after 31 December 2012. This is suitable for lamps <30W with life time's < 15,000 hours. However, according to the applicant, for long life lamps (>15,000 hours), 3.5 mg mercury is needed to avoid light output failures during the life of the product. The ROHS limit of 2.5 mg max, after 31 Dec 2012, is therefore scientifically impracticable;
- As no specific category for long-life lamps is available in RoHS for single-capped (compact) fluorescent lamps (CFL), the applicant requests a new exemption for these lamps: For long-life lamps <30W, (specified with a lifetime of >15,000 hours) 3.5 mg may be used after 31 December 2012; and
- According to the ELCF, suitable substitutes do not exist at this time.[301] They suggest the alternative is to install multiple normal standard lamps over the equivalent period, instead of using 1 long life lamp. Assuming 2 lamps would be used, the total amount of mercury dosed for 2 lamps during lifetime would then be 5 mg. The applicant therefore states that the total environmental impact is lower when one long life lamp is used with a total of 3.5 mg of mercury.

12.2 Applicant's Justification for Exemption

The applicant[302] makes a distinction between the required mercury content in relation to the lifetime of the lamp.

In general, mercury is a material that is essential for creating the right plasma, in the glass tubes of fluorescent lamps, needed to generate visible light and to create a highly efficient radiation of light inside the lamp.[303] Furthermore, the electrical characteristics of long life lamps are compatible to those of normal life lamps. This makes

[300] ELCF (2011) Original exemption request document no 7, European Lamp Companies Federation (ELCF), September 2011, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_7/ELCF_Exemption_Request7_Mercury_long_life_CFL.pdf

[301] Ibid.

[302] Ibid.

[303] Ibid.

it possible to use long life lamps in both new and existing installations, without further modifications.[304]

The mercury consumption/dose depends to a significant degree on the lamp lifetime. Mercury consumption also depends on many other factors such as application conditions during the lamp's lifetime, such as temperature, lamp current, operation frequency, switching cycle and physical dimensions.[305]

The lifetime performances of the various single capped lamps differ strongly when comparing lamp families. Applications of single-capped compact fluorescent lamps for consumer use (integrated CFL) and professional use (non-integrated CFL) and long life single-capped compact lamps, have average lifetimes of at least 15.000 hours in 3 hour-cycles (165 min. on – 15 min. off)[306].

In past evaluations, it can be seen that there is further support by representatives of the lamp industry, that standard lifetime (8,000–12,000 hours) lamps can properly reach their defined lifetime with a maximum mercury content of 2.5 mg.

The average mercury consumption must be increased, to ensure longer life times of approximately > 20,000 h, in order to prevent early failing of the lamp. Therefore the applicant requests the mercury content be limited to 3.5 mg (a 40% increase) to avoid impracticable early failures due to premature luminosity loss. In this case a content limit of 3.5 mg ensures a long life lamp functionality ranging from 20,000 up to 60,000 h, In order to ensure the life-time reliability of a broader range of long-life lamps (>20,000 hours), additional mercury is required per lamp.

Therefore a new exemption request is necessary to assure the specifications and reliability of long life CFL lamps.

The applicant has provided a reformulated wording in the first clarification round, adding reference to the lamp lifetime: [307]

- *For general lighting purposes < 30 W with longer lifetime (≥ 20.000 hours): 3.5 mg after 31 December 2012*

The applicant prepared a further paper to answer some of the open and implicit questions raised by contributions made by stakeholders (see Section 12.3) in the course of the public consultation.[308] In this paper, ELCF provided further support to the request that CFLs need a mercury content of more than 2.5 mg for lamps with a lifetime

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[304] ELCF (2012a) Answers to first clarification questions submitted by the applicant, European Lamp Companies Federation (ELCF), June 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_7/Request_No7_1st_Clarification_Questions_20120622_final.pdf

[305] Op. cit. Gensch (2009)

[306] Op. cit. ELCF (2012a)

[307] Ibid.

[308] ELCF (2012b), Answers to Clarification Questions, following the consultation, submitted by the applicant, European Lamp Companies Federation (ELCF), September 2012

of 20,000 hours and above. To cover the full range of long life lamps (e.g. 20-60.000 h), a content limit of 3.5 mg is needed.

Following the various contributions made during the stakeholder consultation concerning this RoHS exemption request, the applicant, ELCF, provided a final wording formulation for the requested exemption "Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):"

Table 12-2: Proposal for the Wording of the Requested Exemption

Exemption	Scope and dates of applicability
1(a)1 For general lighting purposes < 30 W with normal lifetime	5 mg expires on 31 December 2011 3,5 mg may be used per burner after 31 December 2011 until 31 December 2012; 2,5 mg shall be used per burner after 31 December 2012
1(a)2 For general lighting purposes < 30 W with longer lifetime (≥ 20.000)	3.5 mg after 31 December 2012

Source: ELCF (2012b)

12.2.1 Possible Substitute Alternatives

The applicant states that currently reliable alternatives for substituting mercury do not exist and that substitution is not feasible.[309]

12.2.2 Possible Design Alternatives

The applicant states that LED lamps for existing single-capped lamp applications are becoming available on the market; but for existing installations the efficacy levels are typically lower than for fluorescent (long life) lamps.[310] Moreover, many LED lamps create directional light. As the luminaire is designed for a specific light distribution of the fluorescent lamp, and as the lamp orientation in luminaires for single-capped lamps varies in the market, a full retrofit LED lamp solution is not yet sufficiently available, or affordable, for lamp replacement in many existing luminaires.

[309] Op. cit. ELCF (2012a)

[310] Ibid.

The applicant states that currently there are no suitable non CFL-lamps (e.g. LED Retrofit) available which could meet the compatibility criteria of long life uses. These criteria are specified by luminaire manufacturers, which are responsible for assuring specific performance and safety standards.[311]

If the maximum mercury content of long-life CFL lamps is to be reduced from 3.5mg mercury to 2.5 mg mercury, then numerous lamps will not reach the specified lifetime (>=20,000 hours).

Furthermore the applicant has submitted answers, to questions posed during a tele-conference that took place on the 4th of December. ELCF states that CFL lamps with ≤2.5 mg cannot always meet the requirements for using them in existing luminaires used in long life application circumstances. They will fail early resulting in early lamp replacement. Therefore, for industrial applications, customers do not accept this inferior option as it would mean much higher costs of lamp replacement due to more frequent maintenance requirements in comparison to proven long life CFL lamps.[312]

12.2.3 Environmental Arguments

ELCF explains that long life lamps are the best option from an environmental-, resource- and economical point of view compared to normal life CFL lamps.[313] In this case a content limit increase, from 2.5 to 3.5 mg, ensures the long life lamp functionality above 20,000 h, realizing more than double or triple the lifetime which is also, from a total environmental impact point view, a positive proposition.

It should be noted that the mercury content of fluorescent lamps has been reduced substantially in the past 30 years (by more than 90%) (see Figure 12-1).The applicant submitted information concerning life cycle assessment aspects for long-life lamps and its possible alternatives (LED, normal life lamps), to further enhance the argumentation. Information includes reference to energy consumption, carbon dioxide emissions and further key performance indicators.[314]

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[311] ELCF (2012d), Answers to the phone call on 4th December submitted by the applicant, European Lamp Companies Federation (ELCF), 13 December 2012

[312] Ibid.

[313] Op. cit. ELCF (2012a)

[314] Information provided by the applicant via e-mail, received 10 December 2012, including:
ELCF (2012c) Summary of LCA Information, Included in e-mail received from European Lamp Companies Federation (ELCF), on 10 December 2012;
OSRAM (2009) *Life Cycle Assessment of Illuminants: A Comparison of Light Bulbs, Compact Fluorescent Lamps and LED Lamps*, Prepared by OSRAM Opto Semiconductors GmbH and Siemens Corporate Technology;
Navigant (2009) *Life Cycle Assessment of Ultra-Efficient Lamps*, Prepared by Navigant Consulting Europe Ltd. for DEFRA

[314] It is important in this context to state that the reports, provided were based on analysis carried out according to various ISO standards: According to the Navigant report it is consistent with compliance

In general, the information submitted concerning these aspects is put forward to support that long-life lamps are the most suitable alternative. In short, the following aspects are mentioned:

- Less than 2% of the total energy demand is needed for production of the incandescent, CFL or LED lamp;
- The main environmental impact is created during the use phase and is due to the energy consumption (> 95%);
- The main mercury release is caused by emissions of power generation plants [emissions originating in coal combustion processes are one of the biggest contributions to total mercury emissions – evaluators comment] during the use phase of a lamp.
- Human toxicity potential therefore is mainly related to the energy consumption; and
- LED lamps have nearly identical impacts on the environment compared to CFL

The applicant delivered a reliable environmental impact comparison between CFLs with normal lifetime and CFLs with long-lifetime that demonstrates that such lamps have similar environmental impacts. ELCF estimated that it is not possible to reduce mercury below a maximum value of 2.5mg for all CFLs without creating early failures and decreasing the lifetime reliability.[315] The risk of lamp breakage during lamp exchange or disposal is for long-lifetime lamps up to three times less in comparison with normal lifetime lamps, [a result of less frequent maintenance requirements - evaluators comment]].

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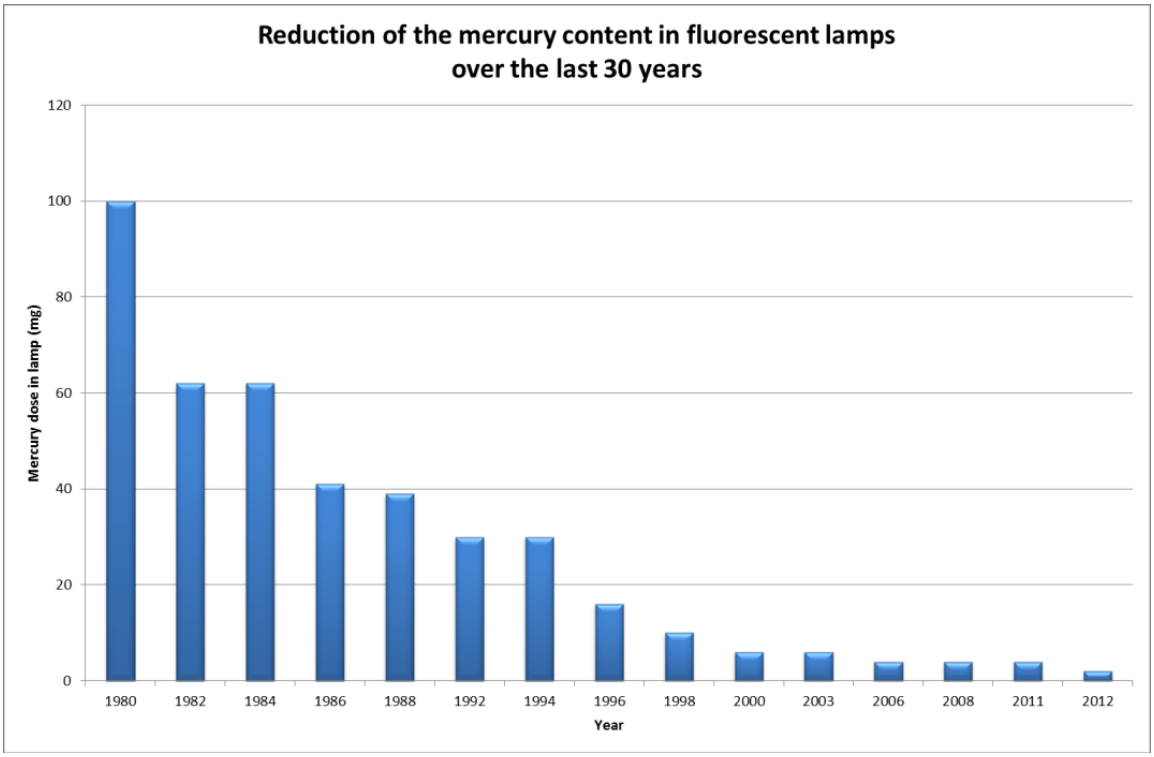
with the life cycle stages outlined by ISO 14062-2002. According to the OSRAM report, it was reviewed by an independent critical review panel to to ensure compliance with ISO 14040 and ISO 14044.

[315] Op. cit. ELCF (2012d)

Figure 12-1 Evaluation of Mercury Dosed per Lamp Over the Last 30 Years



Source: ELCF 2012a

12.2.4 Road Map for Substitution

According to the applicant there is continuous improvement concerning innovations for reducing the mercury consumption in lamps.

Applicant did not further detail the efforts that are intended for achieving additional improvement and/or future substitution or elimination.

12.3 Stakeholders' Justification for Exemption

Two environmental NGOs, The European Environmental Bureau (EEB) and the Green Purchasing Institute (GPI), have provided further useful information.[316] Inter alia they support the concept of allowing for more mercury in CFLs, where it is needed to facilitate a longer lamp life time. The discussion should, therefore, it is argued, concern the definition of a threshold limit value corresponding to the rated life time.

[316] EEB (2012) Stakeholder document submitted by Stakeholder within the consultation, European Environmental Bureau and the Green Purchasing Institute, September 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/General_contributions/20120904_EEEB_ZMWG_RoHS_Stakeholder_consultation_Ex_No_7_8_9.pdf

Based on the comparison of various parameters for a variety of lamps from the US and EU market, environmental NGOs have proposed the following limits corresponding to rated life times for <30 W CFLs

- For general lighting purposes a limit value of ≤20.000 hours: 2.5 mg
- For general lighting purposes a, limit value of >20.000 hours: 3.0 mg

This proposal is based on an own-initiative research resulting in a list of examples of CFLs. However, they suggest this threshold should only be qualified if a minimum rated life requirement is met when lamps are tested using the standard 3-hour test method and not the 12-hour standard method.

According to EEB & GPI, cold cathode compact fluorescent lamps (CCFLs) are an innovation that offers enormous benefits over existing CFL bulb technology. The average lifespan of CCFL bulbs is around 25,000 hours - much longer than the average CFL bulb. This has been achieved by reducing the thickness of the glass tube. However, cold cathode lamps for special purposes, used mainly for backlighting, are covered by Exemption 3. Single capped cold cathode CFLs would not be covered under this category.

The Danish EPA agrees with the applicant that it is reasonable to have, in principle, differentiated maximum mercury content levels related to the lifetime of the lamp.[317] However, it points out that there are no technical standards on how to measure the life time of lamps. At present the lifetime tests are part of confidential internal company knowledge. Thus, it claims that there are no reliable bases for providing such an exemption. It suggests that the Commission asks CENELEC to develop such a standard.

The Danish EPA also argues that it does not seem environmentally appealing to agree to 40% more mercury, while only gaining 33% in additional lifetime (from 15,000 hours (the level of 2.5 mg Hg) to 20,000 hours (the level of 3.5 mg Hg)). If a technical standard could be established the long life limit should be at least 30,000 hours in order to justify the increased amount of mercury.[318]

[317] Danish_EPA (2012) Stakeholder document submitted by Stakeholder within the consultation, Danish Ministry of the Environmental Protection Agency, September 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/General_contributions/20120904_Danish_EPA_RoHS_stakeholder_consultation_contributuion_Ex_No_5_6_7_8_9.pdf

[318] Ibid.

12.4 Critical Review

12.4.1 REACH Compliance - Relation to the REACH Regulation

Chapter 5.0 in this report lists conditions for mercury content; inter alia items 18 and 18a of the REACH regulation Annex XVII state that mercury shall not be placed on the market when used as an anti-fouling agent or when used in measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, and thermometers other than fever thermometers).

As Category 5 products for which this exemption renewal has been requested are not considered to fall under the scope of applications mentioned in items 18 and 18a, the consultants believe that in case an exemption is granted, the use of mercury in this application would not weaken the environmental protection afforded by the REACH Regulation.

12.4.2 Environmental Arguments

The applicant presents sufficient environmental data and statements comparing the environmental impacts of life cycles of CFLs with LEDs. The information includes LCA reports from which it can be followed that LEDs are at present not superior to CFLs when comparing environmental aspects throughout the product life cycle.

It can also be followed that environmental impacts are higher when using two lamps with 2.5mg mercury rather than allowing an additional one milligram of mercury content in long-life lamps. In general, the total negative environmental impacts of increasing the mercury amount would not outweigh the total benefits. Besides the comparison of resources, transportation and disposal needed for one lamp instead of two, being in favour of this exemption, it was shown in the past that the main source of reducing mercury emissions in respect with lamps (CFL'S and CCFL'S) is tied to the fact that the lamp itself consumes less electricity for the generation of light, thus resulting in less of the mercury emissions tied to the production of energy from certain sources.

The consultants conclude that it is reasonably supported that not granting an exemption for long lifetime lamps for professional customers would result in negative impacts to the environment in terms of consumption of resources and in terms of greater quantities of mercury and waste. This would outweigh the positive impacts of limiting the amount of mercury according to current exemption 1(a) which at present covers long life lamps in its scope and which will impose a 2.5 mg restriction starting 1.1.2013.

12.4.3 Scientific and Technical Practicability of Alternatives

In the consultants view, it has not been sufficiently clarified if LED-technology could allow for elimination in certain cases or not. The consultant asked the applicant to provide further details on lighting with LEDs. ELCF claims that LEDs are not a suffi-

cient substitute in this case, though without providing a detailed comparison of products. The applicant explains that:

> *"LED lamps for existing single-capped lamp applications are becoming available in the market; but for existing installations the efficacy levels typically are lower than for fluorescent (long life) lamps. Moreover, many LED lamps create directional light. As the luminaire is designed for a specific light distribution of the fluorescent lamp and as the lamp orientation in luminaires for single-capped lamps varies in the market, a full retrofit LED lamp solution is not yet widely available or affordable for lamp replacement in many existing luminaires."*[319].

LEDs are known to be highly efficient and to have very long lifetimes as well as already being well-established within the market. From the consultant's experience, the light distribution factor also provides a distinction between otherwise comparable CFL and LED products, though solutions for this aspect are becoming more available for standard consumer products (for use in households). Thus the main argument the applicant provides concerns the issue of light direction, in so far as that LEDs cannot provide a "drop-in" substitute in cases where the long life lamps are applied. LEDs, would have to be further developed to provide an equivalent application in terms of ensuring that the required efficacy levels are distributed over the relevant illuminated area. That is to say, that for existing installations, LEDs would not be able to provide similar luminous efficacy levels along with the same light distribution that the CFLs provide. Elimination would at present require a refurbishment of existing installations.

The applicant further explained that

> *"At the moment there are no suitable non CFL-lamps (e.g. LED Retrofit) available which could meet the compatibility criteria. These criteria are specified by luminaire manufacturers, which are responsible for assuring specific performance and safety standards. The first practicability criterion for a substitute of a CFL long life lamp is that it complies with the specifications against spare parts. Spare parts should meet the specifications for spare parts when they are used in existing luminaires.*
>
> *Luminaires for long life applications have a very long lifetime of approximately 15-30 years. These luminaires have specific electronic drivers inside regulating the ignition and the current of the lamp and have to meet specific performance and safety standards. A spare part lamp and the applied luminaire both have to meet these specific standards to assure a proper light performance and electrical compatibility and safety. Therefore, in this case of most CFL lamps a variety of specific lamp connectors (pin-based) are used to avoid a mix up in application (e.g. connecting lamps to the wrong electronics and luminaire). These lamps are pin-based and differ from the screw-based lamps used for many consumer applications (E27)…*
>
> *…At this time there are not yet LED-retrofit substitutes for all CFL lamp types, including long life. In case of retrofit LED lamps we have practical reasons, why*

[319] Op cit. ELCF (2012a)

they cannot substitute long-life CFL lamps. At first, most CFL long life lamps do not have integrated electronics, but the electronics is integrated in the luminaire. For non-ballasted LED lamps (electronics is inside luminaire), there are no standards for electrical compatibility (for performance, and safety; see specifications for spare-parts above) available so far.These lamps are not released and approved by luminaire manufacturers for existing luminaires. Therefore, this is not a solid option for professional customers. At second, however some retrofit LED lamps are offered by some suppliers, their foreseen lifetime in many cases is only 25.000h. This is in the lower end of the CFL long life lamp lifetime range, which is 20-60.000 hours or above."[320]

Though the provided information cannot fully reject that in some cases LED lamps may exist that could be used with existing luminaires as a comparable product, it can be followed that the electrical compatibility is not ensured and so if long-life CFLs were eliminated industrial users would be forced to scrap luminaires as present alternatives usually lack the correct connector or are not proven as reliable alternatives in terms of electronic compatibility.

Thus, the consultants lack sufficient information to establish if elimination through LED-technology could be possible in some cases, however it may be followed that this would not allow for a full retrofit.

12.4.4 Scientific and Technical Practicability

The consultants can follow that there is a correlation between the average mercury consumption and long life time. However, various operating conditions (e.g. temperature, operation frequency etc.) can affect the lifetime of lamps, whereas the proposed correlation between lamp life and mercury content disregards the influence of other factors.

Standard or normal lifetime lamps can properly reach their defined lifetime with a dose of max 2.5 mg. Long life lamps require higher mercury dosing to realize the lifetime extension while preventing early failing during operation.

Information provided by stakeholders also supports a differentiation of maximum mercury content limits according to lamp lifetime, though stakeholders refer to different values in terms of possible content limits proposed for various lamp lifetime values. Information provided by EEB & GPI, demonstrates that in some cases, more than 2.5 mg of mercury is needed for ensuring a lifetime above 25,000 hours. Thus, a 3 mg limit was proposed by stakeholders for long life lamps that have been registered as being used for certain applications.

The applicant requests a 3.5 mg limit for long life lamps and delivers a qualitative description of what is to be considered under the special applications for which they are used (see Section 12.1).

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[320] Ibid.

EEB & GPI provided an extensive compilation of data on CFLs above 30 watts, comparing the rated life in relation to the mercury content. Data available from manufacturers, demonstrates that CFL lamp lifetimes of at least 20,000 hours can be maintained with mercury content of 2mg or less.[321] Therefore, these lamps fall under the 2.5 mg limit and even a 2 mg limit would be sufficient.

This information appears to demonstrate that the mercury content in some cases is indeed lower than RoHS limit values. However the applicant puts forward that the aforementioned values are average values. Average values have to be lower than maximum values, because there is always a certain range in the measurements, which also stems from the uncertainty of usage conditions. The applicant explains that publications do not always state clearly if their values refer to average values, maximum values etc. The consultant concludes that this is comprehensive, in the sense that it cannot always be clarified in these cases how values relate to the maximum values regulated in RoHS.

The current RoHS limits represent legal obligations such that all lamps are below the RoHS limit values while continuing to meet customer requirements, in general applications as well as in professional applications. On the basis of the available information and evidence, it appears that the concept of more mercury for longer life lamps in professional applications is reasonably supported (e.g. industrial lighting). However information has not been provided to clarify that such an exemption would also be needed for consumer applications. As it has been shown that there are long-life lamps that have a mercury content lower than 2.5 mg, the consultants conclude that extending the validity of a general exemption (available for all single capped CFLs *< 30 W*) allowing 3.5 mg would place those manufacturers, who have invested in their production systems so as to comply with this limit value, at a disadvantage.

This suggests a need to define clearly the distinction between long and short life lamps. A key problem mentioned in this context by the stakeholders was that there are no agreed technical standards regarding how to measure the life time of lamps. However in response, the applicant provided additional information that there are two IEC standards (IEC 60969 and IEC 60901) that regulate the lifetime test conditions of lamps.

The applied measurement technique for mercury content in lamps is standardized in IEC62554 with a cycle of 3hours-cycle (165' on/15' off) and measuring the mercury content of lamps. Results of the 3 hours cycle test method, mentioned by the applicant, are regarded as confidential internal company knowledge. In parallel, EEB & GPI who have contributed information during the consultation, support the standard 3-hour test method.

Moreover, the applicant states that market surveillance and measurement criteria for the lifetime of lamps are specified in the ErP legislation (EC245/2009 and amendments in EC347/2010).

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[321] http://download.p4c.philips.com/l4bt/3/322873/master_pl-electronic_322873_ffs_aen.pdf or http://www.osram.com/osram_com/products/lamps/compact-fluorescent-lamps/index.jsp

Since the standards for measurement and test conditions are specified through the ErP legislation, therefore, the lifetime compliance and market surveillance aspects are covered.

12.4.5 Conclusions

The consultants' previous experience tends to support the view that for certain applications that require very reliable long life specifications, the longer lifetime required will necessitate an increase of mercury content. As full substitution is not possible, nor does it seem to be superior in relation to environmental impacts, the applicant's scientific and technical arguments can be followed according to the criteria stipulated in article 5 (1) (a) of the directive.

With respect to the wording formulation brought forward by the applicant in the correspondence following the stakeholder consultation and additional information, the requested exemption addresses applications similar to those in the existing exemption (1a)[322] scope, let alone the reference to the "lifetime" of the lamp and the definition of a threshold above which more mercury is essential. (see also Table 12-1). In this sense the consultants conclude that an exemption referring to the mercury content of 3,5 mg required for long life lamps would be adequate.

12.5 Recommendation

Based on the documents submitted by the applicant and the stakeholders and in the absence of contrary proposals, the requested exemption would be in line with the requirements of Art. 5(1)(a) The consultants recommend granting the following exemption for a period of 5 years, by which time it is assumed that either innovation will allow for a reduction in the mercury content, or substitution with LED lamps will have become possible.

In order to ensure a simplified but unambiguous wording the consultants recommend that the wording will be reformulated similarly to the wording of the existing Annex III exemption, but relating to higher mercury content for long life lamps ≥20.000 hours.

[322] For general lighting purposes < 30 W, 2.5 mg mercury shall be used per burner after 31 December 2012

Table 12-3: Proposed Exemption formulation

	Exemption	*Scope and date of applicability*
1	*Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):*	
1(g)	*For general lighting purposes < 30 W, with a lifetime equal or above 20,000h: 3.5 mg*	*31 December 2017*

The measurement technique for mercury content in lamps is standardized. There remains a concern; however, that a standard test method for lifetimes is not sufficiently widespread, therefore making it unclear how straightforward it would be to differentiate long life lamps from normal lamps for the purpose of market surveillance. It is important for the Commission to detail the conditions under which a CFL would be considered a longer-life model so that there is a fair comparison among all models.

12.6 References Exemption Request 7

Danish_EPA (2012) Stakeholder document, submitted by Stakeholder within the consultation, Danish Ministry of the Environmental Protection Agency, September 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/General_contributions/20120904_Danish_EPA_RoHS_stakeholder_consultation_contributuion_Ex_No_5_6_7_8_9.pdf

EEB (2012) Stakeholder document submitted by Stakeholder within the consultation, European Environmental Bureau and the Green Purchasing Institute, September 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/General_contributions/20120904_EEEB_ZMWG_RoHS_Stakeholder_consultation_Ex_No_7_8_9.pdf

ELCF (2011) Original exemption request document no 7, European Lamp Companies Federation (ELCF), September 2011, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_7/ELCF_Exemption_Request7_Mercury_long_life_CFL.pdf

ELCF (2012a) Answers to first clarification questions submitted by the applicant, European Lamp Companies Federation (ELCF), June 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_7/Request_No7_1st_Clarification_Questions_20120622_final.pdf

ELCF (2012b) Answers to Clarification Questions, following the consultation, submitted by the applicant, European Lamp Companies Federation (ELCF), September 2012

ELCF (2012c) Summary of LCA Information, Included in e-mail received from European Lamp Companies Federation (ELCF), on 10 December 2012

ELCF (2012d) Answers to the phone call on 4th December, submitted by the applicant, European Lamp Companies Federation (ELCF), 13 December 2012

Gensch, C.-O.; Zangl, S.; Groß, R.; Weber, A. K.; Deubzer, O. (2009) *Adaptation to Scientific and Technical Progress under Directive 2002/95/EC*, Final Report, Öko-Institut e.V. and Fraunhofer IZM, February 2009, http://ec.europa.eu/environment/waste/weee/pdf/report_2009.pdf

Navigant (2009) *Life Cycle Assessment of Ultra-Efficient Lamps*, Prepared by Navigant Consulting Europe Ltd.for DEFRA

OSRAM (2009) Life Cycle Assessment of Illuminants: A Comparison of Light Bulbs, Compact Fluorescent Lamps and LED Lamps, Prepared by OSRAM Opto Semiconductors GmbH and Siemens Corporate Technology

13.0 Exemption Request No. 10 “Lead in micro-channel plates”

Abbreviations

ALD	Atomic Layer Deposition
EBCCD	Electron-Bombarded Charge-Coupled Device
I.I.	Image Intensifier
MEMS	Micro-electromechanical system
MCP	Micro-Channel Plate
PD	Photodiode
PMD	Photomultiplier
PMT	Photomultiplier Tubes

13.1 Description of Requested Exemption

The “Japanese Business Council in Europe” (JBCE) has applied for an exemption for *“Lead in micro-channel plates”.*

JBCE requests the exemption until 2029.

13.1.1.1 Similarities to Exemptions Listed in Annex III or IV

The exemption request is related to exemption 3 currently listed in Annex IV of the RoHS Directive under the section “*Equipment utilising or detecting ionising radiation*” as:

> *“Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate”*

JBCE[323] states that the application scope of exemption 3 is restricted to electro-magnetic radiation amplification devices, and some important applications of the micro-channel plate are hence missing. In this sense, JBCE[324] clarifies that the re-

[323] JBCE (2012a) Original exemption request no. 10, submitted by JBCE, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_10/JBCE_exemption_request10_Lead_in_Micro_Channel_Plate_06Mar2012.pdf; last accessed 26 November 2012

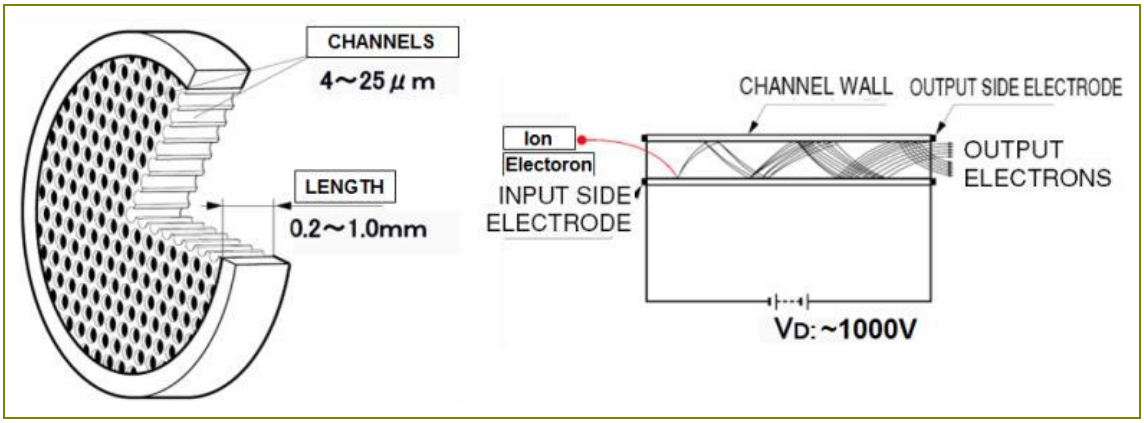
[324] Ibid.

quest is not really a new application but adds missing, though important uses. JBCE[325] explains that the requested exemption would be required until 2029.

13.1.1.2 Functional Principle

JBCE[326]describes a MCP as millions of glass capillaries lined up in two dimensions. The capillaries (channels) have diameters ranging from a few to few tens of micrometres. The capillaries work as an electron multiplier. Figure 13-1 shows the operating principle of an MCP.

Figure 13-1: Operating principle of an MCP



Source: Op. cit JBCE (2012a)

The voltage V_D between the input and output sides of the MCP generates a potential gradient along the channel. Multiple secondary electrons are emitted when an electron enters a channel from the input side and strikes its inner wall. The potential gradient accelerates these secondary electrons to draw parabolic trajectories that are determined by their initial velocities. They then strike the opposite wall in the channel causing further secondary electrons to be emitted. The electrons in this way travel towards the output end while striking the inner wall of the channel repeatedly. As a result, a large number of exponentially increased electrons are extracted from the output side.[327]

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[325] JBCE (2012e) Answers to 1st round of Clarificaton Questions, submitted by JBCE concerning exemption request no. 10 in 2012 within the consultation, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_10/Request_10_1st_Clarification_Questions_Answers.pdf; last accessed 25 November 2012

[326] Op. Cit. JBCE (2012a)

[327] JBCE (2012b) Reference II of the original exemption request no. 10, document, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_10/JBCE_Reference_No_2.pdf ; last accessed 18 December 2012

13.1.1.3 Application Fields of Micro-channel Plates

JBCE[328] says that the current exemption is limited to the equipment utilising or detecting ionizing radiation and that some important applications of the micro-channel plate are missing in this description, e.g. amplification of ions and electrons, as listed in Table 13-1.

Table 13-1: Applications of MCP based on other inputs than electromagnetic radiation

Illustrative Field,etc	Mass spectroscopy								Semiconductor inspection						Surface analysis										
Illustrative Application	Time-of-flight mass spectroscopy (TOF-MS) (MALDI)	Time-of-flight mass spectroscopy (TOF-MS) (LC-MS)	Time-of-flight mass spectroscopy (TOF-MS) (GC-MS)	Quadrupole mass spectroscopy (Q-MS)	Double focusing mass spectroscopy (Sector-MS)	Gas or liquidchromatographic mass spectroscopy (GC/LC-MS)	Inductive-coupled plasma mass spectroscopy (ICP-MS)	Secondary ion mass spectroscopy (SIMS)	Scanning electron microscope (SEM)	Scanning ion microscope (SIM)	Electron beam measuring system (EBMS)	Electron or ion beam lithography	Mask aligner	FIB system	Auger electron spectroscopy (AES)	Ion scattering spectroscopy (ISS)	Electron spectroscopy for chemical analysis (ESCA)	Rutherford backscattering spectroscopy (RBS)	Vacuum UV spectroscopy (VUVS)	Soft X-ray spectroscopy (SXS)	Reflection medium energy electron diffraction (RMEED)	Low energy electron diffraction (LEED)	Field ion microscope (FIM)	Tranmission electron microscope (TEM)	Soft X-ray microscope (SXM)	Positron detector
Input	Ion	Ion	Ion	Ion	Ion	Ion	Ion	Ion	Electron	Electron, Ion	Electron	Electron, Ion	Electron	Electron, Ion	Electron	Ion	Electron	Ion	UV	X-ray*	Electron	Electron	Ion	Electron	X-ray*	Positron

**Note: The applications of x-ray input are covered by the exemption "1. Lead, cadmium and mercury in detectors for ionising radiation." in Annex IV of the RoHS Directive 2011/65/EU*

Source: Op. cit. JBCE (2012b)

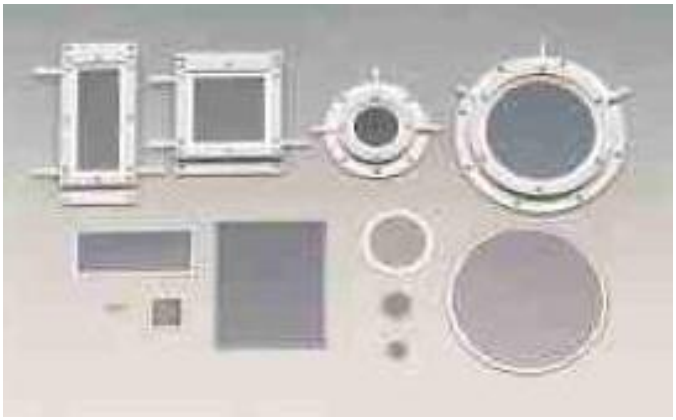
Table 13-1 shows that this kind of amplification is essential for, among others, mass spectrometers, semiconductor inspection equipment, and surface analysis equipment. In this sense, JBCE[329] states that its request is not really a new application, but adds important uses to exemption 3 of Annex IV.

Figure 13-2 shows examples of micro-channel plates.

[328] Ob cit. JBCE (2012a)

[329] Ibid.

Figure 13-2: Examples of micro-channel plates



Source: Op. cit. (JBCE 2012a)

JBCE[330] explains that the MCP technology itself has over 40 years of technological history, during which it has changed considerably.. MCPs are applied in a wide variety of devices, and they are one of the key components to advance the science world as a detector for various analytical instruments. JBCE[331] indicates several examples. MCPs are installed into MCP-PMT (photomultiplier tubes) and image intensifiers, which are used in equipment such as:

- for night-vision equipment,
- measurement apparatus' and analyzers,
- research instruments for medical and biological studies,
- high-speed cameras,
- highly sensitive broadcasting cameras,
- UV flame alarms,
- fluorescence lifetime spectrometers,
- time resolved imaging emission microscopes for semiconductor inspection,
- equipments for academic research,
- LIDAR (Light Detection and Ranging)

JBCE[332] refers to the internet for information on geometries and features of MCPs[333] and for examples of products using MCPs[334].

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[330] Ibid.

[331] Ibid.

[332] JBCE (2012f) Answers to 2nd Round of Clarification Questions, submitted per e-mail by JBCE on 5 December 2012

13.1.1.4 Glass Composition

According to JBCE[335] , the micro-channel plate (MCP) is formed with millions of two-dimensional glass capillaries. The glass contains lead and other constituents:

- mainly SiO_2 and PbO, which works as a conductor, as well as
- Na_2O, K_2O, Cs_2O, Rb_2O alkaline metal oxides and
- BaO, CaO alkali earth metals which create viscosity,
- Bi_2O_3 for electrical resistivity adjustment and
- Zr_2O for anti-acid characteristics.

JBCE[336] claims that MCPs at the current state of technology can only be produced with lead-containing glass.

13.1.1.5 Amounts of Lead Used in the Requested Exemption

According to JBCE[337], the Pb content of a MCP is 45% to 50% weight. The absolute weight contained in a MCP is at most 3.78 g, based on the largest sized MCP, which Hamamatsu Photonics K.K. produces. This is a device of 114 mm in diameter with 1 mm thickness. Most popular types sold are 25 mm in diameter and 0.33 mm thickness or 33 mm in diameter and 0.6 mm thickness. The former contains 0.19 g of lead, while the latter contains 0.52 g of lead

JBCE[338] presents the various main uses of lead in image intensifiers (I.I.) and analytical devices and their geographical distribution as illustrated in Figure 13-3.

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[333] Hamamatsu, http://jp.hamamatsu.com/resources/products/etd/pdf/MCPassy_TMCP0001E09.pdf; referenced in (JBCE 2012f)

[334] For TOF-MS, http://www.shimadzu.eu/lcms-it-tof%E2%84%A2; for surface analysis: http://www.jeol.com/PRODUCTS/ElectronOptics/SurfaceAnalysisSA/JPS9010Series/tabid/495/Default.aspx; for semiconductor inspection: http://www.hamamatsu.com/jp/en/product/category/5002/5012/TriPHEMOS/index.html and http://www.hamamatsu.com/resources/pdf/sys/e_triphe.pdf

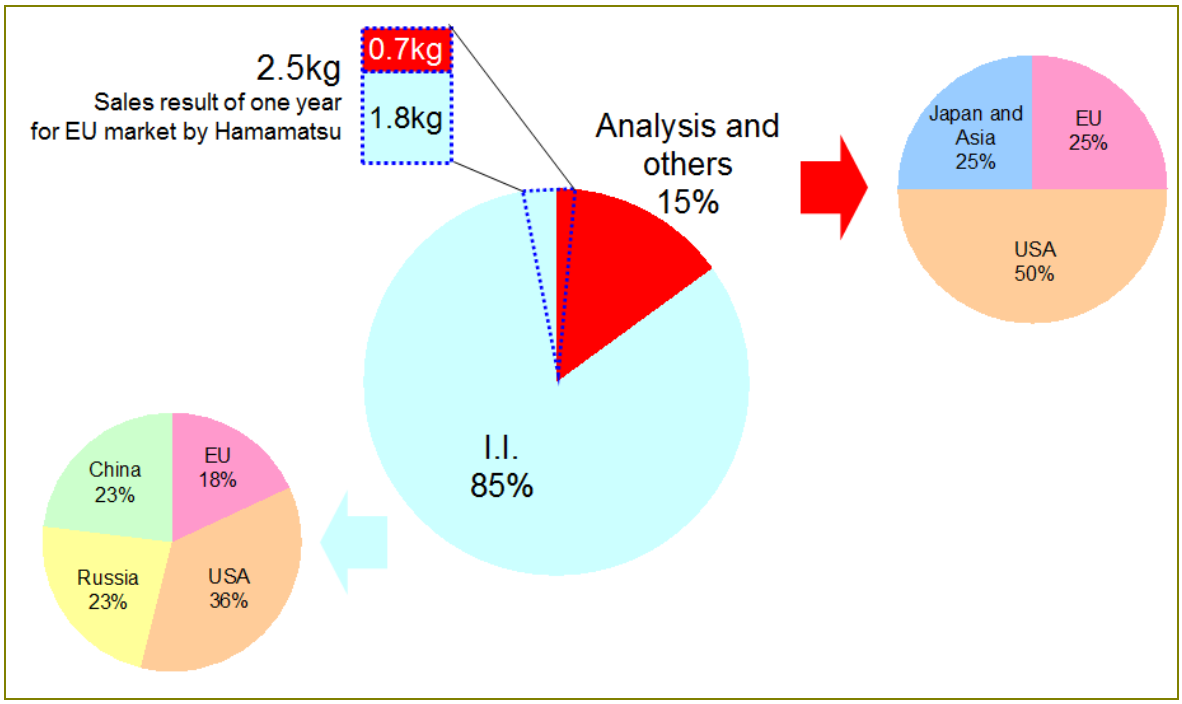
[335] Op. cit. JBCE (2012a)

[336] Ibid.

[337] Ibid.

[338] JBCE (2012h) *Lead Estimation*, submitted per e-mail by JBCE on 13 December 2012

Figure 13-3: Distribution of lead use over various applications and regions



Source: Op. cit. JBCE (2012h)

Table 13-2 shows the total amounts of lead that would be used under this exemption.

Table 13-2: Lead used annually in the requested exemption

	For Image Intensifiers	For Analysis and Others	Total
Hamamatsu for EU	1.8 kg	0.7 kg	2.5 kg
Hamamatsu and others for EU	15.3 kg	3.75 kg	19 kg
Wordwide including China and Russia	85 kg	15 kg	100 kg

Op cit. JBCE (2012h)

The total amount of lead used in micro-channel plates, put on the EU market, is around 19 kg, while worldwide around 100 kg of lead would be used for the applications described under this exemption.

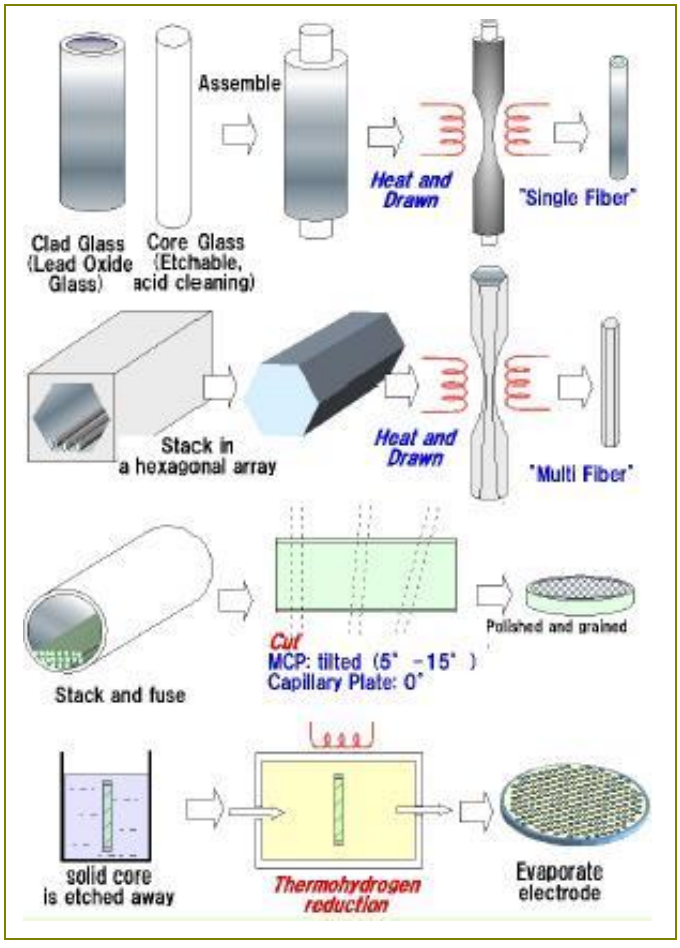
13.2 Applicant's Justification for Exemption

13.2.1 Lead Substitution

13.2.1.1 Constraints in MCP Manufacturing and Functionality without Lead-containing Glass

According to JBCE[339], MCPs at the current state of technology can only be produced with glass. The glass capillaries are produced by softening a glass tube with heat and stretching it several times until a diameter of a few to few tens of micrometres is obtained, as illustrated in Figure 13-4.

Figure 13-4: Production of MCP



Source: JBCE (2012k), Reference Attached to Answers to 4th Round of Clarification Questions, submitted per e-mail by JBCE on 19 December 2012

[339] Op. cit. JBCE (2012a)

JBCE[340] says that the production process is dependent on the softness and extensibility of glass and therefore, materials other than glass cannot be used for production at present. Furthermore, giving the conductivity quality to the glass is essential to obtain the electron multiplication for each channel. The glass itself is not conductive. According to the applicant, this quality is granted by adding PbO to the glass and its reduction treatment. The PbO is a chemically stable material once encapsulated in the glass and it cannot be replaced at present with other substances.

According to (JBCE[341], the structure and dimension of the channels are crucial for MCP's used in analytical instruments and for image intensifiers. The length of the channel is 40 to 80 times larger than its diameter (5 to 6 micrometres). Using a different material than the conductive lead glass would require coating the inside of the small channels homogenously with a conductive material along the length of the several million channels in a MCP. If the channels are not coated homogeneously, it causes a functional deficiency.

JBCE[342] claims that at the current stage of the development it is not yet possible to coat the inside of small channels homogeneously to achieve the conductivity of the glass. Therefore, the method to use the electrically-conductive property and electron emission of the lead glass material itself is still inevitable for MCPs.

13.2.1.2 Semiconductor-processed Ceramics as Potential Alternative

JBCE[343] notes that an alternative technology, the ceramic material with semiconductor processing approach, has been studied, but this material has limitations in its capillary (channel) size, of only a few hundred micrometres. JBCE[344] explains that it is possible to make many holes by etching silicon under masks with many holes. It is also possible to add functional gas materials inside the wall of these channels by chemical vapour deposition. The MEMS (micro-electromechanical system) technology enables drilling holes into silicon, but, according to JBCE[345], it is still impossible to make long tubes of around 10 micro meters diameter in order to achieve the high aspect ratio (length/diameter). It is also impossible for the MEMS technology to make bias holes, which is one of the most important points for electron multiplying: in order to obtain efficient striking between input energy and inner wall, the bias angle to the channel axis in the direction of input is essential. Moreover, technologies for adjusting resistance and for adding the function of electron multiplying are not established yet.

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[340] Op. cit.JBCE (2012a)

[341] JBCE (2012i) Answers to 4th Round of Clarification Questions, submitted per e-mail by JBCE on 19 December 2012

[342] Ibid.

[343] Op. cit.JBCE (2012a)

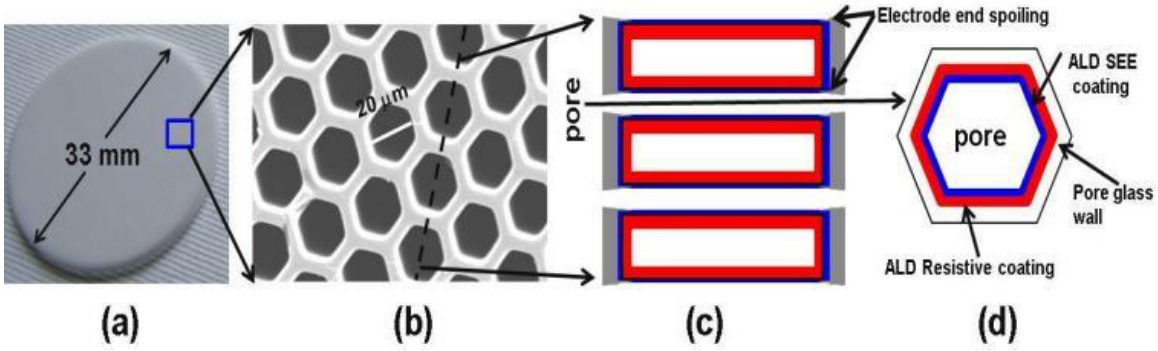
[344] Op. cit. JBCE (2012f)

[345] Ibid.

13.2.1.3 Atomic Layer Deposition as Potential Alternative Coating Technology for MCP

According to JBCE[346], research on Atomic Layer Deposition (ALD) for coating channels with conductive, RoHS-compliant materials is going on in the USA. ALD is a possible alternative to manufacture lead-free MCPs. The secondary emission electron (SEE) layer applied in the glass micro-channels (pores) by atomic layer deposition takes over the function of generating electrons form ionizing inputs. Neither leaded glass nor any other RoHS-restricted substance is required. Figure 13-5 gives an overview on the production and the construction of an ALD-MCP.

Figure 13-5: Fabrication sequence of MCP



(a) As received capillary glass array substrate, (b) Plan-view of capillary array front surface in a scanning electron microscope, (c) Schematic cross section of fully-functionalized MCP, (d) Schematic cross section of individual MCP pore after ALD functionalization. SEE: secondary electron emission

Source: Mane, Anil U., et al. (2011), A Novel Atomic Layer Deposition Method to Fabricate Economical and Robust Large Area Micro-channel Plates, retrievable from file:///C:/Users/deubzer/AppData/Local/Temp/Manuscript_for_SPIE_-02-14-2011-final-1.pdf; last accessed 6 March 2013; document submitted by JBCE, per e-mail on 06 March 2013

JBCE[347] states that the development is still at a very early stage and claims that it is impossible to coat homogeneously millions of holes with diameters of only a few micrometres, as they are common in MCPs. Moreover, an American company has a patent on this technique till 2029, according to JBCE[348].

JBCE[349] later stated that whether the ALD method can be applied for heavy ions is a big question, because the input energy should be large enough for the detection of heavy ions. The current ALD studies such as Mane et al.[350] only focus on electrons as

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[346] Ibid.

[347] Op. cit. JBCE (2012g)

[348] Op. cit. JBCE (2012f)

[349] Op. cit. JBCE (2012i)

[350] Op. cit. Mane et al. (2011)

input so that it is not yet established if other ionizing particle streams and radiation types (see Table 13-1 above) can be detected or not.

Therefore, JBCE[351] concludes, this alternative technology cannot be used to achieve RoHS compliance.

13.2.2 Elimination of Lead by Alternative Detectors

13.2.2.1 Alternative Detectors

JBCE[352] admits that detectors that are specific for certain types of ionizing radiation or particles can replace MCPs under specific conditions.

Table 13-3: Alternative Detectors for Ionizing Radiation and Particles

Type of Ionizing Radiation (Input)	Detector
Electrons	• MCP • EMT: Electron Multiplier Tube, also called Secondary Electron Multiplier (SEM) • CEM: Channel Electron Multiplier, Channeltron • PD: Photodiode, requires more than 5 keV input energy, therefore not suitable for detection of low energy inputs • PD-EBCCD: PD-electron bombarded charge-coupled device (for details see JBCE[353])
Ions	• MCP • EMT: Detects and multiplies secondary electrons emitted from the surface of a metallic plate where ions hit; detection efficiency based on acceleration voltage of ions
Ultraviolet (UV) Rays	• MCP • PMT: Photomultiplier Tube • PD • PD-EBCCD

[351] Op. cit. JBCE (2012a)

[352] Op. cit. JBCE (2012g)

[353] Op. cit. JBCE (2013f)

Type of lionizing Radiation (Input)	Detector
X-ray	• MCP • Image Intensifiers*

**JBCE (2012i) clarifies that the above-mentioned image intensifiers are those used in x-ray equipment[354]. They do not apply MCPs, while image intensifiers using MCPs are used for example in night vision equipment.*

Source: Op. cit. JBCE (2012i)

The applicant states that even though alternative detectors are available for specific tasks, MCPs have unique properties, which make their use indispensable.

13.2.2.2 Unique Properties of MCPs

According to JBCE[355], MCPs have the following unique properties:

- Detection of various ionizing radiations and particles with one device only;
- Two dimensional positioning information detection with a high resolution by small channel diameters;
- High speed response of less than 1 nanosecond of output wave form with full width at half maximum;
- High multiplication factors of 10,000 to 10,000,000 times;
- Wide detection area of up to 100 mm^2; and
- Compact size

JBCE[356] concludes that MCPs are essential and irreplaceable in analytical instruments requiring the unique properties which only MCPs can provide.

13.2.3 Environmental Arguments

According to JBCE[357], the micro-channel plate is only used in B2B equipment. Producers take back this equipment for refurbishing, recycling, other treatment or safe final disposal.

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[354] See exemption request for the use of lead in image intensifiers in medical x-ray equipment, http://rohs.exemptions.oeko.info/index.php?id=113; last accessed 28 December 2012

[355] Op. cit. JBCE (2012i)

[356] Op. cit. JBCE (2012g; 2012i)

[357] Op.cit. JBCE (2012a)

13.2.4 Roadmap to Substitution or Elimination

JBCE[358] states that Hamamatsu has started to study other methods besides atomic layer deposition (ALD). Achieving a homogeneous coating of all holes has been the most difficult technical challenge over the 40 years history of MCP and has not yet been achieved with lead-free materials.

JBCE[359] claims that a lead-free MCP having the same characteristics as the current MCPs (millions of holes with diameter of several micrometers only) may need 5 years for initial research such as material selection and establishment of process/condition, and 3 years for establishment of quantity production. Overall, JBCE[360] believes that it may take 8 to 10 years from the time of writing (end of 2012) to replace lead-containing MCPs with a RoHS-compliant alternative.

According to JBCE[361], MCPs have the following unique properties:

- Detection of various ionizing radiations and particles with one device only;
- Two dimensional positioning information detection with a high resolution by small channel diameters;
- High speed response of less than 1 nanosecond of output wave form with full width at half maximum;
- High multiplication factors of 10,000 to 10,000,000 times;
- Wide detection area of up to 100 mm^2; and
- Compact size.

JBCE[362] concludes that MCPs are essential and irreplaceable in analytical instruments requiring the unique properties which only MCPs can provide.

13.3 Critical Review

13.3.1 REACH Compliance – Relation to the REACH Regulation

Chapter 5.0 of this report lists entries 28 and 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 mentioned in this request might weaken the environmental and health protection afforded by the REACH Regulation.

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[358] Op. cit. JBCE (2012g)

[359] Ibid.

[360] Ibid.

[361] Op. cit. JBCE (2012i)

[362] Op. cit. JBCE (2012g; 2012i)

In the consultants' understanding, the restriction for substances under entry 30 of Annex XVII does not apply to the use of lead in this application. Putting lead in a glass of an MCP on the market, 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 articles, which, moreover, in most cases are not conceived to be used in private households. As such, entry 30 of Annex XVII 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 16 December 2012).

The review of related restriction and authorization processes, revealed some processes underway concerning lead and lead compounds (see Section 5.0 above). This includes the use of lead and lead compounds in articles intended for consumer use, for which Sweden has submitted an intention to propose a restriction. As far as MCPs are only used in other than consumer products, this restriction of lead use would probably not apply to the use of lead in this exemption request. Depending on its final scope, implications can, however, not be excluded in case the restriction proposal is to be approved. As these processes have not yet lead to the addition of further substances to the authorization list, Annex XIV, or to the listing of new restrictions in Annex XVII to this avail, such additions could not yet be taken into account in the recommendation for this exemption request.

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.

13.3.2 Stakeholders Supporting the Exemption Request

Originally, it seemed that only Hamamatsu, a manufacturer of MCPs, supports this exemption request. The question thus arose why only one MCP manufacturer applied for this exemption request, while the restriction of lead in the RoHS Directive will affect all MCP manufacturers and manufacturers applying MCPs in their products within the scope of the RoHS Directive.

On request, JBCE[363] named Photonis (USA, France), Litton (USA), Baspik (Russia), and Great Wall (China) as other main MCP manufacturers, from which only Photonis may produce MCPs not exclusively for military uses. Photonis was therefore contacted via phone and e-mail and asked whether it would support JBCE's justification for this exemption request. Photonis[364] confirmed that it manufactures MCPs and that lead is a necessary component for the manufacturing of MCPs. Photonis[365] supports the

[363] Op. cit. JBCE (2012g)

[364] Photonis (2013), Stakeholder Statement-Photonis Concerning Exemption Request 10, submitted per e-mail by Kees Brouwer, Photonis Group, on 07 January 2013

[365] Ibid.

justification for this exemption that JBCE[366] had provided in its original exemption request.

According to JBCE[367], the following manufacturers of analytical devices, which apply MCPs, support the exemption request as well:

- Canon Anelva
- Hitachi High-Technology
- JEOL
- Shimadzu

As at least two MCP manufacturers and several users of MCPs support JBCE's exemption request, it can be followed that the claim that lead is required for MCPs does not just reflect the situation and technological standard of one specific MCP manufacturer but is rather a mutual issue of concern.

13.3.3 Substitution of Lead

13.3.3.1 Technologies for Lead Substitution

JBCE explains that glass is used for MCPs, because it can provide a high diameter/length aspect ratio, which cannot be achieved with any other material. Lead must be added to make the glass conductive in order to achieve the electron multiplying effect.

JBCE mentions two technology alternatives: the atomic layer deposition (ALD) to achieve the conductivity of the channel surfaces, and the MEMS technology to produce holes in ceramic or silicon.

No further information could be obtained on the MEMS technology. For ALD-MCPs, a publication by Mane et al.[368] explains about ALD-MCP that the

> *"[..] newly developed ALD resistive layer shows conformal and uniform coating along the MCP pores and excellent reproducibility across multiple substrates and multiple batches. [...] Fully functionalized MCPs (33 mm) fabricated by this method, show good resistance stability, repeatable performance, uniform response, and gain comparable to commercial MCPs. We have demonstrated for the first time larger area MCPs (8"x8") functionalization by our newly developed process. Further work to characterize and test the large area MCPs is in progress."*

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[366] JBCE (2013a) Answers to 5th Round of Clarification Questions Concerning Exemption Request 10, submitted per e-mail by JBCE on 11 January 2013

[367] JBCE (2013m), Information Specifying Supportive Stakeholders fo Exemption Request No. 10, submitted by JBCE per e-mail on 08 March 2013

[368] Op. cit. Mane et al. (2011)

The publication of Mane et al.[369] was submitted by JBCE to show the status of the ALD technology in support of JBCE's arguments concerning the substitution of lead in MCPs. According to JBCE[370], it is impossible to coat homogeneously millions of holes with diameters of several micrometres only, as they are common in MCPs. Mane et al.[371] have produced an ALD-MCP of of 8 x 8", corresponding to 203.2 mm x 203.2 mm, with channel diameters of 20 µm. This is larger than the standard size of current commercially available MCPs (see table 1 on page 4 and table 2 on page 5 in JBCE[372]). The MCP channel diameters of the commercial products are in the range of 10 µm to 25 µm like the ALD-MCP.

JBCE[373] explains that smaller area MCPs with reasonable characteristics similar to the currently available MCPs should have smaller channel diameters and smaller pitches. JBCE[374] describes MCPs with channel diameters as small as 4 µm. JBCE[375] does, however, not have information about the smaller area ALD-MCP with the smaller diameter for each channel and smaller pitch than those described by Mane et al.

Additionally, according to JBCE[376], ALD-MCPs may not be appropriate for detecting heavy ions. The current ALD studies such as Mane et al.[377] only focus on electrons as input so that it is not yet established if other ionizing particle streams and radiation (see Table 13-1 above) can be detected or not. According to JBCE[378], it shall still impossible to substitute lead and achieve the same characteristics as lead-containing MCPs in the coming several years.

Mane et al.[379] present promising results from experiments with ALD-MCPs, but additionally states that *"Further work to characterize and test the large area MCPs is in progress."* Overall, based on the available information, JBCE's argument can therefore be followed that the ALD-MCP technology is currently not yet sufficiently developed to provide an alternative that would allow for lead substitution in MCPs. Furthermore, if a lead-free ALD-MCP or any other lead-free MCP technology would be available, the manufacturers and users of such devices had the chance to submit information dur-

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[369] Ibid.

[370] JBCE (2012g) Answers to 3rd Round of Clarification Questions Concerning Request 10, submitted per e-mail by JBCE on 13 December 2012

[371] Op. cit. Mane et al. (2011)

[372] JBCE (2013g), MCP Assembly, submitted by JBCE per e-mail on 6 March 2013.

[373] JBCE (2013k), Answers to Further Questions, submitted by JBCE per e-mail on 8 March 2013.

[374] JBCE (2013o), MCP & MCP ASSEMBLY, submitted by JBCE from Hamamatsu, retrieved from http://www.hamamatsu.com/resources/pdf/etd/MCPassy_TMCP0001E09.pdf: last accessed 9 March 2013

[375] Op. cit. JBCE (2013k)

[376] Op. cit. JBCE (2012i)

[377] Op. cit. Mane et al. (2011)

[378] Op. cit. JBCE (2012g)

[379] Op. cit. Mane et al. (2011)

ing the stakeholder consultation to object to the approval of this exemption. As such information was not submitted, it can be followed that possible alternatives require additional development to allow for the elimination of lead used in MCPs.

Nevertheless, ALD-MCPs may be further developed in the coming years to allow for the elimination of lead in MCPs, in particular for MCPs with larger channel diameters for the detection of electrons. The patent, which an American company has for this technique until 2029 according to JBCE[380], is not a principle obstacle against the deployment of this technology as long as the availability of MCPs produced with this technology can be ensured. The patent can therefore not serve as a justification for this exemption.

Based on the submitted information, the consultants conclude that currently and in the coming years, lead cannot be substituted in MCPs, while in the medium and long term, ALD technology may enable the manufacturing of lead-free MCPs at least for larger channel diameters and for a limited number of inputs.

13.3.4 Elimination of Lead by Alternative Technologies

In its original exemption request, JBCE had not addressed any alternative technologies that may replace MCPs allowing the elimination of lead. However, in the course of the review, it became evident, that such alternative technologies do indeed exist. In response to further requests, JBCE specified the alternative detectors listed in Table 13-3. The exemption must therefore be restricted to those cases, where the unique properties of MCPs are required, i.e., where alternative detectors cannot sufficiently replace the need for MCP detectors.

JBCE had provided information about the unique properties of MCPs which cannot be achieved with other detectors (see Section 13.2.2.2). It was, however, not clear whether, and to what degree, other detectors can cover at least in part, the performance spectrum of MCPs, and whether clear threshold values can be derived, demarcating the unique performance features of MCPs from those of alternative detectors. JBCE[381] therefore submitted Table 13-4 illustrating the performance characteristics and the differences between the detectors in more details.

[380] Op. cit. JBCE (2012f)

[381] JBCE (2013h), Table 1: Comparison of detectors, submitted by JBCE per e-mail on 6 March 2013

Table 13-4: Properties of Detectors

Detector	Detectable input	Dimensions of spatial input signal resolu-tion	Thickness (mm)	Response time (ns) (*1)	Detection area (mm2)	Multiplica-tion factor per detector (*2)	Possi-bility of stacking
MCP	• Ionising radiation • UV light • Electrons • Ions	1 and 2	0.2–1.0 2.0 on special order	≥ 0.2	50–10,000	10^3–10^8	Up to 3 MCPs
EMT	• Electrons • Ions	1	60–150	≥ 5	48–314	5.0 x 10^5 to 4.0 x 10^7	no
PD	• UV light • Visible light • Near infrared light	1	≥ 1.5	≥ 0.2	0.01 - 1,000	≤ 50	no
PD	• Specified for UV light	1	1.65–4.9	≥ 0.4	0.03–100	≤ 50	no
PD-EBCCD [382]	• Electrons • UV light	1 and 2	16.8	≥ 25	63–149	7.0 x 10^2 to 1.3 x 10^3	no
PMT	• UV light	1	18.2–127	≥ 3.27	50–2,123	1.6 x 10^5 to 1.9 x 10^7	no

Source: Op. cit. JBCE (2013h), modified

[382] JBCE (2013f), EBCCD Technology, submitted by JBCE per e-mail on 6 March 2013

Based on the above table, JBCE[383] proposed the following wording with threshold values and features in which MCPs surpass all other potential alternative detectors:

Lead in micro-channel plates used in equipment where at least one of the following properties is required:

1. Two-dimensional spatial resolution for detecting electrons or ions, when the response time faster than 25 ns is required, or when the detection area larger than 149 mm^2 is required, or when the multiplication factor larger than 1.3 x 10^3 is required.
2. Compact size of the detector detecting electrons or ions due to spatial limitations in the device, when the thickness of the space for detector is less than 3 mm/MCP, including the MCP-related installation.
3. Response time faster than 5 ns for detecting electrons or ions
4. Detection area larger than 314 mm^2 for detecting electrons or ions
5. Multiplication factor larger than 4.0 x 10^7

JBCE[384] explains the background of the above wording in detail.

Article 1: Two-dimensional spatial resolution for detecting electrons or ions, when the response time faster than 25 ns is required, or when the detection area larger than 149 mm2 is required, or when the multiplication factor larger than 1.3 x 103 is required.

Besides MCPs, only the PD-EBCCD can detect two-dimensional information. However, the PD-EBCCD cannot achieve a response time of less than 25 ns, and it cannot detect sample areas larger than 149 mm^2. Furthermore, the maximum multiplication factor of the PD-EBCCD is 1.3 x 10^3. Performances higher than these threshold values for the two-dimensional spatial resolution of the input signal require the use of MCPs.

Article 2: Compact size of the detector detecting electrons or ions due to spatial limitations in the device, when the thickness of the space for detector is less than 3 mm/MCP, including the MCP-related installation.

MCPs, contrary to other detectors, can be installed even when only little space is available. Additionally to the maximum MCP thickness of 1 mm, or 2 mm on special demand, 1 mm of additional space is required for the installation of the MCP, resulting in a maximum space (- dimension width) of 3 mm/MCP. PDs are thin as well (down to 1.5 mm), but they cannot detect ions or electrons. The only alternative detector for electrons and ions is the PMT, which has a minimum thickness of 60 mm. PD-EBCCDs can detect electrons, but are at least 16.8 mm thick. Assum-

[383] JBCE (2013i), Final Exemption Wording Proposal, submitted by JBCE per e-mail on 6 March 2013

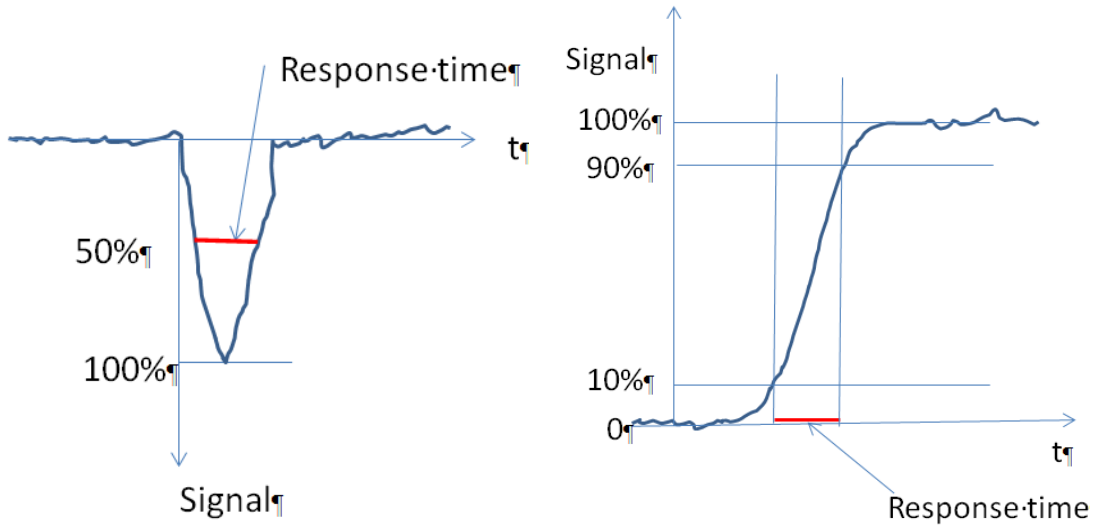
[384] Ibid.

ing that 3 of the 2 mm MCPs would be stacked – resulting in a total of 3 x 3 mm = 9 mm - the minimum thickness requirement of 3 mm per MCP in the exemption wording still restricts the use of MCPs to those cases where alternative detectors are too big to be used.

Article 3: *Response time faster than 5 ns for detecting electrons or ions*

JBCE[385] explains that the response time for MCPs and PDs is defined as the time when the waveform reaches 50% of the full range signal as illustrated in Figure 13-6.

Figure 13-6: Response time definition for MCPs and EMTs (left) and for PDs (right)



Source: Op. cit. JBCE (2013i)

For ions and electrons, only MCPs can detect signals faster than 5 ns. EMTs can detect ions and electrons with a minimum response time of 5 ns, but not faster. The response time of PDs (0.2 ns) and of PMTs (3.27 ns) is shorter than 5 ns, but they cannot detect ions or electrons. The detection of ions and electrons with a response time of less than 5 ns, therefore, is only viable with MCPs.

Article 4: *Detection area larger than 314 mm² for detecting electrons or ions*

Besides MCPs, only EMTs can detect ions and electrons. EMTs are limited to a maximum detection area of 314 mm². PD (EB-CCD) can detect electrons only, but not over a sample area of more than 149 mm². For the detection of ions and electrons, only MCPs hence can cope with sample areas of more than 314 mm².

Article 5: *Multiplication factor larger than 4.0 x 10⁷*

Besides MCPs, EMTs achieve a multiplication factor as high as 4.0 x 10⁷. Only MCPs can perform even better, because up to 3 MCP's can be stacked. The indi-

[385] Ibid.

vidual multiplication factors of each MCP in the stack are then multiplied. For example, if two MCP's with a multiplication factor of 10^3 each are stacked, the resulting multiplication factor is $10^3 \times 10^3 = 10^6$. With three MCP's stacked, the resulting multiplication factor is about 10^8 only, not 10^9, because of a saturation that comes into effect in this case. JBCE[386] provides more information on stacking of MCPs.

In the reviewers' opinion, the above explanations plausibly and sufficiently clearly demarcate the cases where the use of lead-containing MCPs cannot be eliminated through the use of alternative detectors.

13.3.5 Conclusions

13.3.5.1 Justification of the Exemption

Based on the available information, the consultants conclude that the substitution of lead in MCPs is impracticable at the current state of science and technology. The elimination of lead is practicable, as alternative detectors can replace MCPs where their unique properties are not required. JBCE provided a wording adequately demarcating properties which require the use of MCPs, as they cannot be achieved with alternative detectors. An exemption could thus be justified in line with Article 5 (1) (a) of the RoHS Directive.

The consultants proposed a slightly different wording for the exemption based on the proposal of JBCE[387].

Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is required:

a) *A compact size of the detector for electrons or ions where the space for the detector is limited to*
   - *to a maximum of 3 mm/MCP (detector thickness + space for the installation of the MCP); and*
   - *to a maximum of 6 mm in total;*

   and an alternative design yielding more space for the detector is scientifically and technically impracticable.
b) *A two-dimensional spatial resolution for detecting electrons or ions*
   - *Where a response time shorter than 25 ns is required; or*
   - *Where a sample detection area larger than 149 mm^2 is required; or*
   - *Where a multiplication factor larger than 1.3 x 10^3 is required.*
c) *A response time shorter than 5 ns for detecting electrons or ions*
d) *A sample detection area larger than 314 mm^2 for detecting electrons or ions*

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[386] Op. cit. JBCE (2013g)

[387] Op. cit. JBCE (2013i)

e) A multiplication factor larger than 4.0 x 10^7

This exemption does not cover the uses of micro-channel plates in exemption 3 of Annex IV.

The last paragraph was added to avoid overlaps with exemption 3 of Annex IV for MCPs.

The space limitations were further specified compared to the wording proposed by JBCE[388]. The maximum thickness of MCPs is 2 mm. For the installation of the MCP into the device, another 1 mm is necessary resulting in a maximum space requirement of 3 mm per MCP. Unlike other detectors, MCPs can be stacked. According to JBCE[389], a maximum of two of the 2 mm MCPs, or a maximum of 3 of the 1 mm MCPs can be stacked. The resulting maximum space requirements are

(2 mm + 1 mm) * 2 = (1 mm + 1 mm) * 3= 6 mm

To restrict the exemption scope to those applications where the use of MCPs is indispensable, the maximum total space criterion of 6 mm was included in the recommended exemption wording formulation. JBCE[390] show that the thickness of the MCPs is always by far the smallest dimension of their outer geometries, and all other detectors are much larger than MCPs. A further specification of the spatial orientation of the minimum space available for the detector therefore is unnecessary and was therefore avoided, to keep the exemption wording as simple as possible.

JBCE[391] agreed to this exemption wording.

13.3.5.2 Assessment of the Expiry Date

The ALD-MCP technology seems to be a promising technology allowing the substitution of lead in MCPs. The technology is currently still in the research phase and has not yet achieved a status where it could be industrialized and used as a substitute for MCPs in which lead glass is present. Alternative detectors sufficient to fully replace the full MCP application range, thus eliminating the use of lead, are not yet foreseeable, even though the scientific and technological progress shall bring about new detector technologies, e.g the PD-EBCCD detectors.

JBCE claims a 3–7 year development period shall be needed once a lead-free MCP or an alternative RoHS-compliant technology becomes available. Taking into account the available workforce with sufficient qualifications, and the customary redesign cycles,

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[388] Op. cit. JBCE (2013i)

[389] JBCE (2013n) Information Concerning Stacking MCPs, submitted by JBCE per e-mail on 8 March 2013

[390] Op. cit. JBCE (2013g; 2013o)

[391] JBCE (2013p) Approval of final wording, submitted by JBCE per e-mail on 11 March 2013

a full model change for the analytical instruments of high quality may be accomplished in a 10-year cycle. JBCE states that it will overstress in particular small and medium sized enterprises' product innovation and business if they are limited to significantly shorter redesign cycles.

JBCE's arguments are confirmed by Goodman[392]:

> *"Test and measurement products have on average product lives of 10 years before being replaced […]".* Such developments require *"[…] experienced engineers with highly specialised skills to develop new products or to modify existing products to comply with RoHS. The number of suitably qualified engineers available is finite and currently, within the medical and monitoring and control sectors, most are working on new product development."*

A 10 years development time from now on for analytical instruments with lead-free MCPs or alternative detectors would result in an expiry date around 2023, provided that a new technology to substitute or to eliminate lead would be available. Research, e.g for lead-free ALD-MCPs, is, however, still on-going, and at present there is no hint that alternative detectors, with properties making the use of lead-containing MCPs dispensable, shall become available in the next few years. It can therefore be concluded that from the technological point of view that the exemption is likely to be needed beyond 2023, before the complete phase out of lead in MCPs is possible.

From the applicant's information it was understood that the exemption is needed in particular for equipment that falls in category 9 (both industrial and non-industrial products). The applicant cannot exclude that it may also be required in category 8 including the subcategory in-vitro diagnostics, because they are defined, among others, as *"[…] instrument, apparatus, equipment, or system […] to be used in vitro for the examination of specimens"*[393].

Lead-MCP detectors may therefore be needed for EEE within cat. 8 and 9, where the unique properties defined in the proposed exemption wording, are needed. It is therefore not recommended to further restrict the use of MCPs within categories 8 and 9 to avoid the abuse of the exemption.

As the exemption will be required beyond 2023, it is recommended to grant the maximum validity period so that the exemption expires on

- 21 July 2021 for medical equipment (cat. 8) and for monitoring and control instruments (cat. 9)
- 21 July 2023 for in-vitro diagnostics (sub-cat. 8 in-vitro)

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[392] Goodman, P. (2006) *Review of Directive 2002/95/EC (RoHS) categories 8 and 9 – Final Report,* ERA Report 2006-0383, July 2006, amended September 2006, retrieved from http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf; last accessed 9 November 2012

[393] *Definition of in vitro diagnostic medical devices in Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices*, Article 1(2)(b)

- 21 July 2024 for industrial monitoring and control instruments (sub-cat. 9 industrial)

13.4 Recommendation

The information submitted by stakeholders – JBCE and Photonis - shows that currently and in the foreseeable future, the substitution of lead in MCPs is scientifically and technically impracticable. The elimination of lead with alternative detectors, however, is viable, unless certain specific conditions require the use of MCPs. Thus granting an exemption for these cases where the performance and specific features of MCPs surpass alternative detectors would be in line with Art. 5(1)(a). The replacement of MCPs by alternative detectors and thus the elimination of lead is scientifically and technically impracticable and, like the substitution of MCPs, not foreseeable in the coming years. Granting the exemption for the maximum validity period would therefore be justified according to the criteria specified in the RoHS Directive (Article 5(a)(1).

The consultants recommend adding an exemption to Annex IV of the RoHS Directive with the following wording:

Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is required:

a) A compact size of the detector for electrons or ions where the space for the detector is limited to
   1. *to a maximum of 3 mm/MCP (detector thickness + space for the installation of the MCP); and*
   2. *to a maximum of 6 mm in total;*
   3. *and an alternative design yielding more space for the detector is scientifically and technically impracticable.*

b) A two-dimensional spatial resolution for detecting electrons or ions
   1. *Where a response time shorter than 25 ns is required; or*
   2. *Where a sample detection area larger than 149 mm^2 is required; or*
   3. *Where a multiplication factor larger than 1.3 x 10^3 is required.*

c) A response time shorter than 5 ns for detecting electrons or ions

d) A sample detection area larger than 314 mm^2 for detecting electrons or ions

e) A multiplication factor larger than 4.0 x 10^7

f) This exemption does not cover the uses of micro-channel plates in exemption 3 of Annex IV.

The exemption expires on

- 21 July 2021 for medical equipment (cat. 8) and for monitoring and control instruments (cat. 9)

- 21 July 2023 for in-vitro diagnostics (cat. 8)

- 21 July 2024 for industrial monitoring and control instruments (cat. 9)

13.5 References Exemption Request 10

Goodman,P. (2006) *Review of Directive 2002/95/EC (RoHS) categories 8 and 9 – Final Report*. ERA Report 2006-0383, July 2006, amended September 2006, retrieved from http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf; last accessed 9 November 2012

Hamamatsu, http://jp.hamamatsu.com/resources/products/etd/pdf/MCPassy_TMCP0001E09.pdf; referenced in (JBCE 2012 f)

JBCE (2012a) Original exemption request no. 10, submitted by JBCE, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_10/JBCE_exemption_request10_Lead_in_Micro_Channel_Plate_06Mar2012.pdf; last accessed 26 November 2012

JBCE (2012b) Reference II of the original exemption request no. 10, document, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_10/JBCE_Reference_No_2.pdf ; last accessed 18 December 2012

JBCE (2012e) Answers to 1st round of Clarificaton Questions, submitted by JBCE concerning exemption request no. 10 in 2012 within the consultation, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_10/Request_10_1st_Clarification_Questions_Answers.pdf; last accessed 25 November 2012

JBCE (2012f) Answers to 2nd Round of Clarification Questions, submitted per e-mail by JBCE on 5 December 2012

JBCE (2012g) Answers to 3rd Round of Clarification Questions Concerning Request 10, submitted per e-mail by JBCE on 13 December 2012

JBCE (2012h) Lead Estimation, submitted per e-mail by JBCE on 13 December 2012

JBCE (2012i) Answers to 4th Round of Clarification Questions, submitted per e-mail by JBCE on 19 December 2012

JBCE (2012k) Reference attached to Answers to 4th Round of Clarification Questions, submitted per e-mail by JBCE on 19 December 2012

JBCE (2013a) Answers to 5th Round of Clarification Questions Concerning Exemption Request 10, submitted per e-mail by JBCE on 11 January 2013

JBCE (2013f) EBCCD Technology, submitted by JBCE per e-mail on 6 March 2013

JBCE (2013g) MCP Assembly, submitted by JBCE per e-mail on 6 March 2013

JBCE (2013h) Table 1: Comparison of detectors, submitted by JBCE per e-mail on 6 March 2013

JBCE (2013i) Final Exemption Wording Proposal, submitted by JBCE per e-mail on 6 March 2013

JBCE (2013k) Answers to Further Questions, submitted by JBCE per e-mail on 8 March 2013.

JBCE (2013m) Information Specifying Supportive Stakeholders of Exemption Request No. 10, submitted by JBCE per e-mail on 8 March 2013

JBCE (2013n) Information Concerning Stacking MCPs, submitted by JBCE per e-mail on 8 March 2013

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Mane, Anil U., et al. (2011) *A Novel Atomic Layer Deposition Method to Fabricate Economical and Robust Large Area Micro-channel Plates*, retrievable from file:///C:/Users/deubzer/AppData/Local/Temp/Manuscript_for_SPIE_-02-14-2011-final-1.pdf; last accessed 6 March 2013; document submitted by JBCE, per e-mail on 6 March 2013

Photonis (2013), Stakeholder Statement-Photonis Concerning Exemption Request 10, submitted per e-mail by Kees Brouwer, Photonis Group, on 7 January 2013

14.0 Exemption Request No. 11: "Lead as an Activator in the Fluorescent Powder of Discharge Lamps when used as Photopheresis Lamps Containing Phosphors such as BSP (BaSi2O5:Pb)"

Abbreviations

BSP	Barium Silicate Phosphor
ECP	ExtraCorporeal Photopheresis
UVA	Ultraviolet A (light)

According to the applicant, Therakos Photopheresis [394], Certain medical conditions (see below) are characterized by states of immunologically induced inflammation. Patients with these conditions are, for the most part, extremely acutely ill. Extracorporeal photopheresis (ECP) is frequently the last therapeutic option offered to patients. ECP is used to treat several medical conditions including:

- Cutaneous T-cell Lymphoma (CTCL), which is a type of Non-Hodgkin's lymphoma cancer that manifests itself primarily in the skin;
- Graft versus Host disease which is a serious complication of bone marrow transplants;
- Cardiac transplant rejection; and
- Lung transplant rejection.

The applicant further elaborates that the treatment involves exposure of leukocytes, temporarily removed from the patient's blood, to light from lamps with lead doped barium silicate phosphor (BSP). The light activates a drug which has been introduced into the leukocyte fraction of the blood. This type of phosphor emits a unique spectrum that is optimal for this medical treatment. All other UVA phosphors contain less light of the effective wavelengths, or have shorter wavelengths that cause further damage to cells. There is currently no substitute lamp type that may be used for treatment of this disease with extracorporeal photopheresis.

[394] Therakos Photopheresis (2012a) Original request for exemption no 11, submitted 20 April 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_11/Therakos_ROHS_Exemption_Request_20_Apr_2012.pdf

Therakos Photopheresis has therefore applied for an exemption for

"*Lead as an activator in the fluorescent powder of discharge lamps when used as photepheresis lamps containing phosphors such as BSP (BaSi2O5:Pb)*"

14.1 Description of Requested Exemption

The applicant[395] explains that an ECP treatment is comprised of the *ex vivo* exposure of autologous leukocytes (a type of white blood cell transferred from the patient's own body) to a liquid formulation of 8-methoxypsoralen and ultraviolet A (UVA) light, followed by the subsequent reinfusion of the white blood cells to the patient. During an ECP treatment, blood is drawn from the patient into the Therakos Photopheresis system instrument and is centrifuged in order to separate it into its components. The red blood cells and plasma components are returned back to the patient. The white blood cells are collected, concentrated and prepared for treatment with 8-methoxypsoralen and UVA light. The treated white blood cells are then returned back to the patient. The 8-methoxypsoralen is inert until exposed to UVA light and its activation is dependent on exposure to UVA light frequencies. The activation of the 8-methoxypsoralen is critical to the entire process. This drug (brand name UVADEX™ 20 mcg/mL Solution) is exposed to a computer controlled, specific dose of intense ultraviolet light from a BSP lamp of 1–2 joules per cell. The UV light causes a photochemical reaction to occur between the drug and DNA of the white blood cells which forms cross links between the drug molecules and the DNA. The exposure to psoralen, and subsequent photo-activation of the white blood cells, induces apoptosis (normal programmed cell death) of the treated white cells. Administration of cells which have been induced to undergo apoptosis has the effect of creating a state of immunologic tolerance. The overall effect of this therapy can be thought of in terms of having an anti-inflammatory effect.

The exact mechanism by which this treatment works is not understood, but it is clear that the induced process alleviates the patients' devastating symptoms. These symptoms include extensive itching, fissuring, scaling and oedema. The skin of many patients resembles burn victims. In these cases, and without photopheresis treatment, 50% of these patients die from infection. ECP is administered only in medical centres which have undergone specific training for the administration of this unique therapy. The above conditions are also considered as "orphan conditions"[396] since the numbers of patients who have these conditions is very small. The cumulative number of patients (< 20,000), with the above 4 conditions, who would be candidates for this therapy, meets the criteria for orphan status (less than 200,000 cases in EU annually).

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[395] Ibid.

[396] "Orphan" diseases are defined in the EU as ones which affect less than 5 per 10,000 of the population (<1 in 200,000 in the USA) http://www.nice.org.uk/niceMedia/pdf/smt/120705item4.pdf

14.2 Applicant's Justification for Exemption

Therakos Photopheresis[397] states that research has shown that the wavelength of the UV light used is critical to photo activate the drug and that the BSP lamps are ideally suited, having a relatively narrow UVA emission spectrum. The wavelength peaks at 350nm. The spectral range and most appropriate light dose (1-2 joules per cell) of this lamp are specified in the US FDA PMA and NDA approval and the EU Medical Device Directive (CE Mark) approvals for this equipment. Although the 350nm peak is important, the entire curve of the UVA spectrum generated by the custom BSP lamp has been proven to be safe and effective in delivering the 1-2 joules of energy to each collected cell. The aim is for complete binding of DNA so that cancerous cells cannot reproduce. If cancerous cells die, then the body will clear them out. If this step is not carried out correctly, incomplete damage to the DNA may occur which can cause further mutations to the leukocytes and consequently more cancer. The shape of the emission spectrum is required to elicit the desired response and to avoid negative consequences as discussed below:

- The energy attributed to light of longer wavelengths is too low[398], thus it will not promote the photochemical reaction
- The energy attributed to light of shorter wavelengths is higher and may thus result in damage to DNA, possibly promoting undesirable side-reactions between the drug and DNA, such as incomplete cross linking of the DNA and sister chromatid exchanges of the DNA
- Broader spectra have less energy at the critical 350nm wavelength so that longer treatment times are needed for the same effect which increases the risk of infection. The risk of infection is proportional to the time that the patient is connected to the treatment system.

Any changes to the UV light wavelength will alter the proportions of desired light spectrum to adequately photo-activate the drug combined with the DNA of the collected cells and disturb the desirable balance that is created to benefit the patient. In addition, shorter wavelengths could cause patient safety issues, undesirable damage to DNA, side-effects and certain lack of efficacy.

To treat a patient, the UV exposure unit contains 18 special BSP lamps that are designed solely for this treatment. In this treatment the current passed to the BSP lamps is much greater than is normally used for other applications for BSP lamps. This is to produce as much UV light as possible from the lamp, to achieve the shortest possible treatment time. This type of use greatly shortens the lamp's life to 150 hours. As the lamps decay the photoactivation time set by the computer increases. Once the lamps have been used for 150 hours the computer controlled photopheresis instrument instructs the operator to change the lamps.

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[397] Op. cit. Therakos Photopheresis (2012a)

[398] UV radiation energy is inversely proportion to its wavelength so that long wavelengths (e.g. visible light) have less energy than short wavelengths (e.g. UV): $E = hv = hc/\lambda$
Where E = energy, h = planks constant, v = frequency, c = speed of light and λ = wavelength.

Each lamp contains ~1 gram of phosphor material and this material contains ~0.7% lead as the dopant. Therefore each lamp will contain 7µg of lead. The estimated number of BSP lamps placed on the EU market in 2012 for photopheresis treatment is 4600.Therefore it is estimated that EU consumption of lead for this application is ~ 32g. Market usage is expected to grow to an equivalent of 74 grams of lead by 2020.

14.2.1 UV Lamps

The applicant explains[399] that ultraviolet light is generated by the interaction between the emission spectrum from excited mercury vapour with specially designed phosphors which adsorb the mercury emission wavelengths and emit their own characteristic spectrum. UV lamps therefore consist of a glass tube with electrodes at each end, containing a partial vacuum with a small amount of mercury. When a voltage is passed between the two electrodes, a plasma is created in the low pressure gas inside the tube which vaporises the mercury, subsequently emitting a light of high energy and relatively short wavelengths, with most falling between 200 – 360nm. The short wavelengths are very harmful so these must be completely converted into longer wavelength light, which is achieved by the coating of phosphor material on the inside of the glass tube. The chemical composition of the phosphor controls the emission spectrum.

Phosphors are available for a very wide variety of spectral emissions. Phosphors used in fluorescent lamps, used for ambient lighting, convert all of the mercury emission into visible light with no dangerous UV. Several phosphors have been developed that emit UV light with wavelengths that are longer than the mercury emission. One composition, barium silicate doped with lead, gives the optimum narrow spectrum with a maximum emission at 350nm. This is the BSP lamp.

14.2.2 Risk of Substance Emissions from the Application

Concerning possible emissions of lead from the application, the applicant[400] elaborates that the phosphor is located inside the sealed lamps and so no exposure to patients or hospital staff occurs during proper use.

Additionally, the lamps are housed within the ECP device so breakage during proper usage is not likely. If a lamp should break during maintenance, the BSP phosphor is bonded to the inside of the lamp glass, so very little dust (if any) should be emitted in such a case due to the phosphor. In general the amount of lead in this glass will

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[399] Op. cit. Therakos Photopheresis (2012a)

[400] Therakos Photopheresis (2012b) Answers to clarification questions for exemption no 11, submitted 21 June 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_11/Request_11_1st_Clarification_Questions_final_Therakos_response__21_June.pdf

greatly exceed the lead in the phosphor. RoHS exemption 5(b) allows up to 0.2% lead in the glass of fluorescent tubes so the presence of an additional 7µg lead per BSP lamp will have a negligible impact. 1 BSP lamp weighs 64 grams (90% glass) so 0.2% of this is 115 mg (115,000 µg) of lead, far more than in the lamp phosphor.

The 18 lamps are removed and replaced by new lamps. These lamps are relatively short tubes (14 inches in length) and so are not easily broken, so damage to more than one or two is unlikely to occur.

The applicant mentions having performed extensive simulated transportation testing of the packaged lamps based on ASTM method D4169 as required by the medical device licenses. There were no failures. This demonstrates that the likelihood of exposure to lead during unpacking for routine lamp changes is extremely slight.

The applicant further elaborates on the risk of emission and health effects in cases where a lamp is broken. To summarize, in these cases, the emitted amount of lead would not be substantial enough to result in significant health effects.

As for the recycling and reuse at end of use, relatively small numbers of BSP lamps will normally be recycled with large numbers of other fluorescent lamps. The glass used to make fluorescent lamps will contain a small amount of lead as an impurity, partly from recycled lamp glass. As detailed above, the additional amount of lead attributed to the phosphor is negligible, in comparison with the lead present within the lamp glass itself.

14.2.3 Possible Substitute Alternatives

According to Therakos Photopheresis[401] the light emission spectrum is governed by the crystal structure dimensions of the phosphor. Each crystalline chemical compound has different crystal lattice dimensions and so, is capable of emitting different ranges of light output wavelength. To emit light, the crystal lattice needs to be distorted by a dopant atom and the size and valence of the dopant affect the amount of distortion and as a result the output wavelengths. Several compounds are used for UV phosphors apart from barium silicate including several borates, phosphates and silicates, although these emit UV light only with the correct dopant atoms.

BSP lamp phosphors use lead as the dopant in barium silicate. Both lead and barium are divalent so lead can easily bond inside the barium silicate lattice but as lead is larger than barium, the lattice is distorted. There are no other large divalent ions that can be used in the barium silicate lattice. In the periodic table, the other large atoms are stable only in different valence states and so will not be able to bond in the same way to the barium silicate. The largest divalent ion apart from lead is Europium but this is significantly smaller and so gives a completely different spectrum. If even smaller ions such as manganese are used as the dopant, only visible light emission occurs.

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[401] Op. cit. Therakos Photopheresis (2012a)

Therakos Photopheresis[402] put forward that there are about 17 phosphors that emit in the ultraviolet spectrum and provide a comparison of these phosphors that may be seen in Table 14-1 below.

Table 14-1: UV Lamp Phosphors

Reference	Chemical composition	Peak wavelength (nm)	Band width (nm)
2011	BaSi2O5:Pb	**350**	41
2030	YMgB5O10:Gd,Ce,Pr	312	2
2040	YPO4:Ce	335 & 357	35
2052	SrB4O7:Eu	371	18
2080	LaPO4:Ce	318 & 335	41
2090	(Sr,Mg)Al11O19:Ce	338	53
2091	(Ba,Mg)Al11O19:Ce	**347**	53
2093	(Ba,Mg)Al11O19:Ce	**347**	54
2094	CaAl11O19:Ce	333	39
2095	(Y,Mg)Al11O19:Ce	344	51
2096	(Sr,Mg)Al11O19:Ce	309	38
	(Ca,Na)P2O7:Ce	330	40
	(Mg,Sr)P2O7:Eu	395	40
	CaSO4:Eu	388	16
U738	(La,Gd)B3O6:Bi	312	2
NP-804	Ca3(PO4)2:Ti	326	57
NP-803	(Ca,Zn)3(PO4)2:Ti	306	39

Source: Op. cit. Therakos Photopheresis (2012a)

The applicant explains that the currently used BSP phosphor is 2011 which has a symmetrical spectrum with a peak wavelength of 350nm and a bandwidth of 41 nm. This has a symmetrical spectrum which is the basis for the entire safety and effectiveness profile of this lamp. The entire procedure is based on this requirement given the unique photo-activation properties of Methoxsalen. There is very little radiation emitted below 310nm and also very little above 390 nm. Of the phosphors in the above table, only types 2091 and 2093 have similar peak wavelengths but they have broader spectra and 2093 also has a secondary peak at ~380nm. So with both 2091 and 2093, there is less energy available at the important 350nm wavelength. 2095 will also be less suitable as its peak wavelength is at a higher energy of 344nm and

[402] Ibid.

has a broader spectrum than 2011. In the original request for exemption, further details are given to complete the comparison, including, comparison of the emission spectra for similar phosphors.

14.2.4 Possible Design Alternatives

Therakos Photopheresis[403] states that suitable alternative fluorescent lamps that have a lead-free phosphor emitting ultraviolet light with a spectrum that is identical to the spectrum from the BSP lamp are not available. There would be a risk to human health from using alternative UV lamps that emit shorter, more energetic wavelengths as these could cause harmful side-effects, whereas UVA lamps that emit longer wavelengths will have no medical effect. Additionally, alternative lamps lack authorisation and thus could not be used as an immediate substitute as these are not approved by the medical devices Directive and approval will require many years of clinical trials as described in Section 14.2.6 below.

Therakos Photopheresis[404] also contends that alternatives to the ECP treatment are, at present, unavailable. The same holds true concerning alternatives to the drug in use with this treatment, which could, in theory, be substituted with a photo-activated drug, sensitive to a different spectrum.

14.2.5 Environmental Arguments

Even though no technically viable substitute has been identified at present, Therakos Photopheresis[405] has submitted further information concerning life cycle assessment aspects, to further enhance their argumentation. Information includes reference to extraction and production of materials, resources required in lamp production, and information concerning the re-use and recycling of waste.

Concerning the use phase, the applicant emphasises that if the substitute lamps emit less UV light in the useful wavelength range, treatment times would need to be longer, and so energy consumption would increase in proportion to the treatment time. This is also likely to increase the risk of infection for patients.

14.2.6 Road Map for Substitution

According to the applicant[406] there are several medical treatments for cutaneous T-cell lymphoma (and the other disease states mentioned above) but the procedure

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[403] Ibid.

[404] Op. cit. Therakos Photopheresis (2012b)

[405] Op. cit. Therakos Photopheresis (2012a)

[406] Ibid.

using BSP lamps is the only option, once other approaches have been exhausted. As explained above, the only option for a substitute would be an alternative UV lamp phosphor that does not contain lead. Use of one of the currently available UV emitting phosphors such as one from Table 14-1 could be evaluated for the medical treatment but as the spectra of all of the lamps are different, they cannot replace BSP without first carrying out extensive clinical trials and gaining approval under the medical devices and drug Directives. For these trials, only the lamps with similar wavelengths to BSP could be used as lamps with much shorter wavelengths are likely to be harmful. It is noteworthy that this procedure requires both a device and drug approval to be able to market it. As all lamps are different, therefore posing a risk to patients who are already ill, trials will need to be carried out in several stages:

- Before clinical trials could begin there would need to be extensive in-vitro (adduct formation, cell viability and PHA mitogen stimulation studies) and animal non-clinical toxicology work to demonstrate the new lamp photo-activates the cells according to company specifications;
- The instrument would require new software to control the photo-activation time if a lamp with the correct spectral output could be found;
- The instrument would need to be reengineered and electrically safety tested;
- The redesigned instrument would then need to pass EMC emissions and susceptibility requirements to comply with EU legislation and to ensure that it does not interfere with other medical equipment;
- Given the orphan rare nature of the disease, finding suitable patients with this rare disease for trials will take much longer than would be needed for common illness. The first trial would be with a small group of patients over at least 4 years (time needed for finding suitable patients, treatment and follow up) to ensure that the alternative lamps are effective and do not cause undesirable side-effects;
- If these trials show that the alternative lamp is equally effective, that there are no serious side-effects and that treatment times do not need to be extended, then a larger trial will be carried out. This would be to confirm that the small-scale results are correct and to look for less common undesirable side-effects. This trial would establish whether any alternative lamps afford the patient with the same medical benefits attributed to the BSP lamps. Inferior treatments would not be acceptable. These trials would last at least 5 years given the specific patient population that would be required to be enrolled; and
- Assuming an alternative lamp is found to give the same benefits to patients with no increase rate of harmful side-effects, then approval under the medical device and drug Directives can be sought. This procedure will take a minimum of 1 year and the treatment cannot be used until approval is granted from both the device and drug regulatory authorities in the EU and other global markets.

Development of new phosphors – The development of lamp phosphors is very mature and it is very unlikely that a new phosphor with an emission spectrum identical to BSP will be found. The chances of success are extremely low as so many combinations of materials have already been prepared and evaluated. Research could be carried out

but it is likely to be at least three years, the length of a PhD research project, before any alternatives are available for clinical trials.

Possible timetable

Basic science and non-clinical studies	2 years
Preliminary clinical trial	4 years
Evaluation of results	6 months
Larger clinical trial	5 years
Evaluation of results	6 months
Medical Device Directive approval	1 year
Drug approval /can be concurrent with device approval	(1 year)
Total without development of a new type of phosphor	**13 years**

Once approval is granted, patients are monitored for a further 5 years (post treatment follow up) to ensure that the change to the treatment is safe and effective. If any evidence is found that it is not safe, the approval can be withdrawn.

14.3 Critical Review

14.3.1 REACH Compliance – Relation to the REACH Regulation

Chapter 5.0 of this report lists entry 30 restricting the use of lead and its compounds in Annex XVII and the related authorization and restriction processes in the REACH Regulation.

In the consultants' understanding, entry 30 of Annex XVII does not apply to the use of lead in extracorporeal photopheresis lamps since lead is not made available to the public as a substance, as a constituent of another substance or in a mixture, but rather within an application. In other words, the use of Lead in question is not subject to any restrictions by REACH.

The consultants conclude that the use of lead in extracorporeal photopheresis lamps does 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.

14.3.2 Scientific and Technical Practicability of Lead Substitution

The applicant[407] provides sufficient evidence to demonstrate that at present, neither substitution of lead in the phosphor used for ECP treatment lamps, nor the elimination of the use of these lamps or the ECP application, is possible. The applicant further enhances its case by providing evidence concerning the possible health risks associated to using the available phosphors that possess a similar output spectrum. This is also enhanced through the likelihood of the additional energy consumption that would result from the longer wavelengths comprising alternative phosphor spectrums. The technical information provided, as well as the timeframe outlined in the provided substitution roadmap, plausibly justify that the current use of lead in this application cannot be eliminated, and nor does a feasible substitute appear to be available.

14.3.3 Environmental Arguments

Therakos Photopheresis[408] present environmental data and statements concerning the life cycle aspects of lead. As none of the substitutes can actually be used at present, these arguments were not reviewed.

The consultants would like to point out, however, that this neither indicates agreement nor disagreement with the applicant's environmental arguments

14.3.4 Conclusion

The applicant's scientific and technical arguments are plausible. Based on the information submitted, it appears that a scientifically and technically practicable possibility for substitution or elimination of lead in this application is currently not available.

In this regard, and in the absence of substitution and elimination possibilities, as well as knowledge concerning the development of such possibilities, there seems to be no clear reason to recommend an expiry date prior to the seven years maximum validity of exemptions adopted to Annex IV.

An exemption for a similar application exists and is still valid. Exemption 18(b)[409] regards "Lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP ($BaSi_2O_5$:Pb)".

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[407] Ibid.

[408] Ibid.

[409] RoHS Directive (2011) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT

As no information was provided during the stakeholder consultation, it is assumed that the validity of the current exemption granted for lead in BSP lamps used for sun tanning applications is sufficient for this application, and that BSP lamps are not in use for any other application in which lead substitutes are not sufficiently available.

It appears, therefore, that the requested exemption is required only for a specific application falling under category 8 (medical devices) and as a result, it seems the exemption should be granted only for this application.

14.4 Recommendation

After consulting the applicant, the wording has been altered to address the specific application and it is recommend that an exemption is granted for:

> *"Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi2O5:Pb) phosphors"*

The exemption is to be added to Annex IV, as it shall be applicable only for category 8 applications.

As for the validity period, under the foreseeable circumstances concerning possible substitutes, there appears to be no reason not to grant the exemption for the maximum period of 7 years. The consultants therefore recommend setting the expiration date at 22 July 2021.

14.5 References Exemption Request 11

Therakos Photopheresis (2012a) Original request for exemption no 11, submitted 20 April 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_11/Therakos_ROHS_Exemption_Request_20_Apr_2012.pdf

Therakos Photopheresis (2012b) Answers to clarification questions for exemption no 11, submitted 21 June 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_11/Request_11_1st_Clarification_Questions_final_Therakos_response__21_June.pdf

RoHS Directive (2011) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT

APPENDICES

A.1.0 Appendix 1: Answers from COCIR to 2nd Round of Clarification Questions

Questionnaire for Further Clarification

Exemption Request 3 "Lead in solders for Positron Emission Tomography detectors and data acquisition units installed in Magnetic Resonance Imaging equipment"

Background

The review and evaluation of the previously provided information on the above exemption request raised some further questions, which we ask you to answer until 19 November 2012.

Questions

1. As an answer to question 8 of the clarification questionnaire you submitted confidential data. Please provide the clarification questionnaire again without the confidential data. We can otherwise not publish the non-confidential part of the questionnaire, which is, however, an indispensable condition for our recommendation to the Commission. Please provide these data again in a separate sheet. We ask you to take into account, however, that the recommendation for your exemption request cannot be based on confidential data. If you believe these data to be crucial for your request, please consider whether you can submit them as non-confidential data.

Non-confidential version of previous answers are supplied as a separate document.

2. Please provide a substantiated calculation of the 15 kg of lead that would be used for this exemption worldwide and within the EU. 26 DAU/detector tri-flex pairs per system * 50 systems per year => 10.12 * 26 * 50 = 13.2 kg => 15 kg exemption request.

Model no. PCB	PCB name	PCB in comp.	Sum Pb-mass [g] PCB	Process step	Pb mass [g]	Printing area %	PCB area mm^2
10413384	DAU-M	1	3.50	SMD-Top	1.25	12.3%	54568
				SMD-Bot	0.63	6.2%	54568
				THT	1.61		
10413518	DAU-I	1	0.96	SMD-Top	0.25	5.0%	26767
				SMD-Bot	0.00		
				THT	0.72		
10413472	DAU-C	1	1.42	SMD-Top	0.00		
				SMD-Bot	0.00		
				THT	1.42		
10413504	DAU-AIF	6	0.15	SMD-Top	0.04	5.0%	4517
				SMD-Bot	0.00		
				THT	0.11		
10413506	DAU-POF	2	0.26	SMD-Top	0.09	10.0%	4744
				SMD-Bot	0.00		
				THT	0.17		
10413509	DAU-I2CF	1	0.16	SMD-Top	0.08	10.0%	4517
				SMD-Bot	0.00		
				THT	0.08		
10504163	Triflex	2	1.34	SMD-Top	0.89	10.0%	47775
				SMD-Bot	0.45	5.0%	47775
				THT	0.00		
10414179	Component DAU-M Assembly "+2" Triflex		7.45				
			10.12				

3. To make sure we correctly understand, we would like to ask your feedback on our conclusion we draw from your statements on the pad coatings used:

   You write in your request dossier:
   "Tin whiskers have however been found to form on thicker electroless tin coatings that are used as protective coatings on PCB pads. Thin electroless tin may not form whiskers but as tin combines rapidly with copper to form an intermetallic phase, which does not wet to solder, thin coatings have too short a shelf-life. As a result, electroless tin pad coatings are rarely used but due to the specific characteristics of PET/MRI PCBs, this is the only option."
   "Electroless tin is non-magnetic, thicker coatings have a longer shelf-life than silver and it is perfectly flat and so is suitable except for the risk of tin whiskers."

   In the 1st clarification questionnaire, you state:
   "Electroless tin deposition is a self-limiting process so the thickest possible electroless tin coatings are ~ 1µm."
   "The request dossier explains that thin electroless tin has too short a shelf life whereas thicker tin has a risk of whisker formation but is the only option available."

   The conclusion we draw from this is that MRI/PET uses thick (close to the technically possible maximum of 1 µm) electroless tin surfaces, compared to other electroless tin coatings that are thinner. Is this conclusion correct?

   a) If so, please indicate the thickness of the tin layers.

b) If not, please provide the correct conclusion to be drawn from your above statements. Immersion Silver is used as the DAU PAD metal layer. Tin plating is not used due to the risk of whisker formation quoted above.

4. In the clarification questionnaire, you state that "Whiskers can grow to lengths of several millimeters and there are examples at http://nepp.nasa.gov/WHISKER/photos/index.html . One example shown here is of a tin whisker that short-circuits an 8mm gap. Whiskers that form as a result of stresses caused by tin corrosion induced by high humidity have no limit on the maximum length and the longest whiskers are believed to form as a result of this mechanism. Therefore whiskers are often longer than the 0.4mm gap between pads."

   a) The NASA source illustrates only photos of whiskers without specifying any details such as thicknesses of coatings, test specifications, soldering conditions etc. Can you please provide evidence that whiskers grow under the conditions that are realistic for the environmental and use conditions of MRI/PET?

MRI/PET will be used in all parts of the EU and at some hospitals, these will not be air-conditioned rooms and so high humidity will occur from time to time at some locations due to the local weather conditions. Tin whiskers are known to grow on electroplated tin coatings. These are used as solderable terminations on components and are usually in the range of 2 – 3 microns, for MRI/PET and any other type of electrical equipment. Soldering conditions are not relevant because it is only the coatings that do not melt that are susceptible to whisker formation. There are many publications including the NASA website that states that whiskers may grow in high humidity conditions and there is evidence that under these conditions, whisker length can be longer than the 0.4mm gap between pads. Research is still being carried out on this phenomenon as it is not yet fully understood. One problem is that most research is with tets for <2 years whereas whisker initiation can be more than 2 years and once formed will continue to grow unless there is a mechanism to stop growth and there is evidence that with humidity, there is no "stop-mechanism" (see accompanying paper by Craig Hillman, Gregg Kittlesen and Randy Schueller). INEMI published test results in 2010[1] from extensive testing of components under accelerated conditions, high temperature and humidity and whiskers were found after <1 year under the most extreme conditions but the longest test was 10,100 hours, only <1.2 years. It is not possible to find published research with data on whisker

[1] Heidi L. Reynolds, John W. Osenbach, Gregory Henshall, Richard D. Parker and Peng Su, Tin Whisker Test Development—Temperature and Humidity Effects Part I: Experimental Design, Observations, and Data Collection, IEEE TRANSACTIONS ON ELECTRONICS PACKAGING MANUFACTURING, VOL. 33, NO. 1, JANUARY 2010

growth in high humidity conditions for the much longer periods that will be experienced by MRI/PET, i.e. >15 – 20 years and so the NASA images of very long whiskers are the only evidence available that very long whiskers may form in suitable conditions after many years.

b) You explain that in particular whiskers induced by humidity have no growth limit. How realistic is the assumption that MRI/PET would work under such conditions of high humidity?

We believe that it is realistic that some MRI/PET will experience high humidity. This may not be common in the EU, although does occur in some parts of the EU, but all medical devices are designed for use globally and must be able to withstand all environmental conditions that could occur.

5. You state in the clarification questionnaire that it is not always practical to design PCBs to avoid high g-forces.

a) Please describe the measures you apply in the design of the PCBs to avoid high g-forces.

- Mechanical support by chassis/housing
- Compliant thermal/mechanical gasket between PCB and chassis/housing
- Compression of PCB by clam-shell chassis/housing interface
- Location of PCB assembly relative to gradient field/static magnetic field
- Minimizing distance between PCB support to reduce/control resonant frequencies
- Air bladder between gradient coil and detector housing to apply continuous normal force along the detector length to keep the detector within the gantry pocket
- Rigid gantry structure to hold the DAU and detector assemblies

b) Please explain where it is not possible to apply these measures and why.

- DAU location is governed by maximum system length and patient tunnel length requirements and has been optimized to the design boundary conditions. Detector location must be within the MR bore centered within the MR Field of View.
- PCB Free lengths are also governed by the area required for the respective circuit components within the volume formed by the housing/chassis interface.

6. In the clarification questionnaire you state that you do not know whether lead-free solder bonds will survive the high vibrations occurring in the MRI/PET combination for 25 years with no failures. The acceleration factors for vibration simulations of lead-free solder

bonds are not yet known because lead-free solders have not been used in this type of environment for a sufficiently long period.

a) Please explain your research since July 2014 and for the coming years to arrive at reliability tests for lead-free solders. We are pursuing section 12 item 1 of the clarification questions "Manufacture lead-free PCBs". Coming years plans as per section 12 of the clarification questions shown below:

1. Manufacture lead-free PCBs	From 0.75 up to 1 year
2. Accelerated testing and redesign to optimise vibration performance	From 0.75 up to 1 year
3. Long term PCB testing	From 2.5 up to 3 years
4. PET/MRI testing	From 1.5 up to 2 years
5. Reliability testing to collect data for Medical Device Directive approval	From 0.75 up to 1 year
6. Apply for approval under the Medical Device Directive	From 0.75 up to 1 year

Total timescale would be up to 9 years.

b) Are there any results of such research available already? No – We are manufacturing lead-free PCBs which will then be tested as described above.

7. You state in the clarification questionnaire that the pads of the PCBs in the DAUs may not contain magnetic nickel, even though the pads are, like the nickel-components on these PCBs, arranged symmetrically around the patient. As reason you mention (1) the magnetic field uniformity, which needs to be shimmed mechanically and electrically to a uniformity of 1ppm and (2) the ability to service the respective assemblies safely with the high-strength (3T) magnetic field present.

a) Please explain the meaning of your argument (1) above. As we understood from the original exemption request dossier, the symmetrical installation of the DAUs around the patient compensates the potential distortions from the nickel in the components. Why is the same not true for the nickel on the PCB pads? It does hold for nickel on PCBs as well, however it is essential to minimize nickel content wherever possible. The DAU PCB is fabricated using immersion Silver deposited directly onto the copper pads with no intervening nickel layer.

b) What does "*servicing* the assemblies with the high-strength magnetic field mean?" Is it that higher amounts of the magnetic nickel in the magnetic field would exert higher magnetic forces on the nickel-containing components? Yes. It is a requirement that Service technician can safely remove system components when the 3T magnetic field is on. Any magnetic material within the component creates a hazard that the component could be taken from the service technician and accelerated into the magnet. The higher the field strength the greater the hazard. Objects flying at high speed through the air are a serious hazard to people and to the equipment

c) If the above statement under b) is correct, why can the exemption not be limited to MRIs with strong magnetic fields, e.g. more than 1.5 Tesla? Force on magnetic materials is proportional to field strength and one could be traded for the other. Therefore, there could be circumstances where smaller magnetic fields are used but the field strength is large enough to distort the MRI image.

8. In your request dossier, you provide the below figure that shall prove that the DAUs and detectors are arranged symmetrically around the bore of the MRI. Can you please indicate the DAUs and detectors in the below figure for clarification?

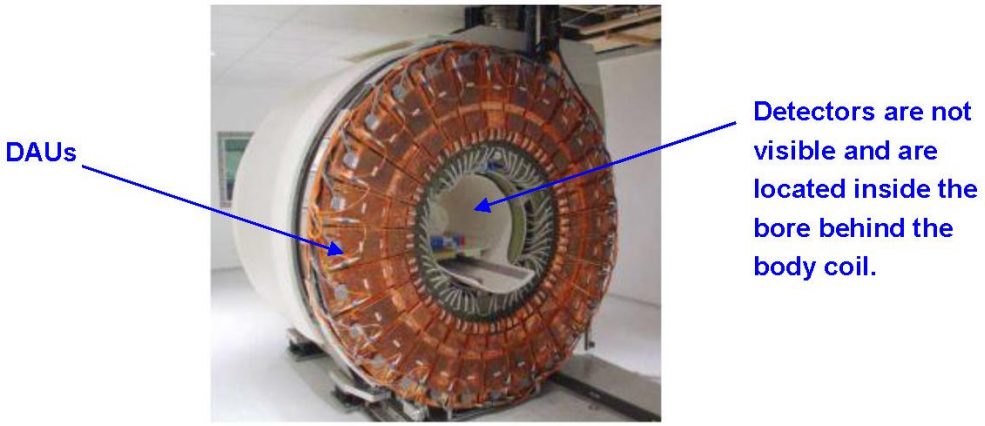

Figure 1: PET detectors and data acquisition units arranged symmetrically around the bore of an MRI

9. You propose two slightly different wordings for the requested exemption:

Lead in solders for Positron Emission Tomography detectors and data acquisition units installed in Magnetic Resonance Imaging equipment

Lead in solders used on detector and data acquisition unit printed circuit boards of PET/MRI scanners

We would like to combine the two proposals and propose the following wording:

Lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs, which are integrated into Magnetic Resonance Imaging equipment.

Would you agree with this wording? Yes

A.2.0 Appendix 2: Answers from COCIR to 3rd Round of Clarification Questions

Questionnaire for Further Clarification

Exemption Request 3 "Lead in solders for Positron Emission Tomography detectors and data acquisition units installed in Magnetic Resonance Imaging equipment"

Background

The review and evaluation of the previously provided information on the above exemption request raised some further questions, which we ask you to answer until 7 December 2012 latest.

Questions

1. In this exemption request, the strong vibrations are a main pillar of your justification to continue the use of lead-solders. The root cause of the vibrations are the strong magnetic fields applied. In your exemption request 9 of the previous consultation ("Lead in solders and solderable coatings used on non-magnetic components and circuits that are used in magnetic fields or are associated with circuits used inside strong magnetic fields", vibrations are mentioned, but the justification is based mainly on effects related to the obligatory use of non-magnetic components in the strong magnetic fields.

   Strong magnetic fields and hence nickel-free components are applied in MRI as well as in MRI/PET combination devices. Please explain the differences in your justification of the two exemption requests.

   In the MR application, lead solders together with non-magnetic components are used within the body coil and patient local coil assemblies. The MR assemblies are exposed to vibrations generated by the gradient coil that are mainly acoustically and mechanically coupled.

   In the MR-PET application, the detectors and DAUs are high-density large assemblies with integrated RF shielding. In addition to acoustically and mechanically coupled vibration, Lorenz force induced vibrations are coupled to the detectors and DAUs due to gradient field Eddy currents induced within the integrated shielding and acting against the static high field strength MR magnetic field. The DAUs are located on the back of the magnet where the static field lines return to the magnet, so the field strength in the DAU location can be up to 2.5 times larger than the field strength in the MR bore. The nature of the DAU electronics requires very heavy shielding to combat the gradient fields and ensure reliable operation of the digital signal processing taking place within.

2. What is the distance of the detectors and DAUs from the isocenter of the magnetic field?

Fifty six detectors are 70cm long and are located in a cylindrical insert within the MR bore at a radius of 37cm. The detectors have 20cm axially positioned on one side of the isocenter and 50 cm positioned on the other side of the isocenter.

Twenty eight DAUs are located on a disc in a star pattern on the back of the magnet, offset 1100cm axially from the isocenter and within a 1m radius from an axial line parallel to the patient bore passing through the isocenter.

3. Based on our phone conference last week, I would like to propose combining exemption request 3 with exemption request 9 of the previous evaluation round. In case we can recommend the Commission to grant this exemption, we would propose the following wording adding the MRI/PET combination as c) to the wording we proposed for the previous exemption request 9:

   "Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors which are used

   a) in magnetic fields within the sphere of 1 m radius around the isocenter of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere.

   b) in magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy

   c) on printed circuit boards of detectors and data acquisition units of Positron Emission Tomographs that are integrated into Magnetic Resonance Imaging equipment.

The integrated MR-PET solution has printed circuit boards (1) within the patient bore - detectors, (2) mounted on the back of the magnet outside the patient bore – DAUs, (3) on the filter plate of the RF cabin and (4) in equipment rooms outside the RF cabin. 'c' as written could be interpreted to cover all four of the above deployment circuit board locations. I understand this is the wording of our original exemption request – do we want to keep such an expanded exemption request? What I had in the original spreadsheet was "Lead in solders and component termination coatings used in MR PET hybrid imaging acquisition electronics located on or within the magnet" and "Lead in solders and component termination coatings used in MR PET hybrid imaging PET detectors within the magnet bore" - which is more narrow and specific to the magnet.

The exemption expires on 30 June 2020

In my understanding, the paragraph before section a) expands the scope for the use of lead from solders to other applications of lead, but I believe that the restriction to printed circuit boards of detectors and DAUs in c) indirectly restricts the exemption to solders and finishes (which may be considered as solders as well, even if this is not always clear). In case the scope nevertheless is still wider than originally intended, I believe that section a) would allow the use of lead in these applications anyway, at least within the 1 m radius, even though interpretations might be possible as well excluding this.

Vice-versa, in my opinion the above proposal would not narrow the scope of the exemption below the scope you proposed in your request for the use of lead in MRI/PET devices.

a. Do you agree with this argumentation? There is one concern with lead in solders within components contained on the circuit board – for example APDs soldered to ceramic carriers that are mounted on the circuit board – This is lead in solder so should be covered by the above wording. Lead in glass or ceramics of electronic components will be covered by existing exemption 7c.

b. Please let us know whether you agree with the above wording proposal. In general I agree, please see comments above and update as appropriate.

A.3.0 Appendix 3: Clarification of Class IIA & Class IIB Mobile Medical Devices

Source: COCIR (2012 a), Original exemption request no. 4, submitted 22.2.2012 by COCIR[410]

EU Class IIB Mobile Medical Devices

- **Automated Cardio Pulmonary Resuscitation (CPR)**

  CPRs are battery powered mobile devices that are carried in ambulances and medical helicopters. They are used in combination with defibrillators. As such they are exposed to the same tough use environment as defibrillators outside of the hospital. Medical guidelines call for the application of CPR before attempting to restart the heart if there is any question as to how long it has been since the victim's heart stopped beating[411]. Providing 1.5 to 2 minutes of CPR is a physically demanding effort. In the event that the heart does not resume a normal rhythm after defibrillation, the CPR must be restarted for several more minutes before another shock can be administered. It is these situations, where CPR is required for extended periods of time that demand the need for automation. These devices can satisfy the medical guidelines that require that any adult chest be compressed by 5cm at a rate of more than 100 compressions per minute. A human being can only sustain this level of effort for several minutes before someone else needs to take over the work. Outside of the hospital with a team of only two individuals to draw upon, the need for reliable automated CPR is an absolute must. This is crucial as without the continuous flow of oxygenated blood, the heart cannot be restarted, and both the heart muscle and the brain experience irreversible damage. Timing is critical as the likelihood of revival and a return to a normal life is reduced by 10% for every minute that therapy is delayed. Therefore, there is no time to troubleshoot or retrieve a spare device.

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[410] Retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_4/COCIR_-_Exemption_request4_-_Lead_in_mobile_MD_V2.pdf

[411] M. F. Hazinski (Ed.) (2010) *Highlights of the 2010 American Heart Association Guidelines for CPR and ECC*, American Heart Association;
M. L. Weisfeldt and L. B. Becker (2002) Resuscitation after cardiac arrest, *Journal of the American Medical Association*, Vol. 288 (23), December 2002, p 3035;
both sources referenced in (COCIR 2012a)

- **Ventilators**

  These MMD provide total ventilatory support and augment patient breathing in treatment of respiratory insufficiency. Failure of these devices can result in patient respiratory failure followed by death. Ventilators can be classified by where they are used. Some are only used within hospitals; others are used additionally in homes, outdoors, and in transit. Each of these environments has unique shock and vibration requirements for ventilators.

  Hospital ventilators are specified to withstand 100-g shocks due to impacts with doorway and elevator thresholds; walls, doorways, elevator doors, and other equipment; and during loading on and off of delivery vehicles and are subjected to vibration during transport in delivery vehicles between medical facilities.

  Home, outdoor, and transit ventilators can be exposed to 300-g shocks due to drops as high as 50 cm and higher; vibration during use and transport in ambulances and helicopters; and temperature extremes.

- **Infant Apnea Monitors**

  Infant apnea monitors are used for the continuous monitoring of patients of normally less than three years of age. The monitors provide audible and visual alarms to alert caregivers, typically parents, when the infant experiences a cessation of breathing due to central apnea, bradycardic or tachycardiac events, or a decrease in oxygen saturation. In such life threatening situations, the monitor alarms are necessary for caregivers to respond to these events and provide proper care. Infant Apnea Monitors are used primarily in the non-clinical environments like home, outdoor, and transit. They are designed for use by non-healthcare professionals and are subject to high levels of vibration, frequent drops, and temperature extremes as described above.

- **Carbon Dioxide-(CO2) Sensors**

  These are used to monitor breathing of patients having endotracheal (ET) tubes. ET tubes keep patients' airways open. It is necessary to ensure that the tube is in the correct position when patients are transported, for example in an ambulance, and CO_2 sensors monitor breathing[412] and ensure that the tube has been placed in the trachea (connects to lungs) and not in the esophagus (passes food to stomach). The American Heart Association[413] has found that

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[412] http://journals.lww.com/em-news/Fulltext/2005/04000/Monitoring_CO2_Improves_ID_of_Misplaced_ET_Tube.21.aspx, and http://erexpert.com/RevisedArticles07/Confirmation%20of%20Endotracheal%20Tube%20Placement.pdf; both sources referenced in (COCIR 2012a)

[413] Guidelines 2000 for Cardiovascular Resuscitation and Emergency Cardiovascular Care, *Circulation* 102 (suppl I) 8, August 22, 2000; referenced in (COCIR 2012a)

observation of patients for clinical signs due to misplaced tubes is unreliable and that other signs that indicate serious harm may take several minutes to be observed.

Portable CO_2 monitors are delicate instruments and susceptible to damage if dropped or subject to intense vibration, as may occur in ambulances and emergency helicopters as well as on hospital trolleys.

EU Class IIA Mobile Medical Devices

Patient worn devices (PWD), portable ultrasound and portable monitors are less safety critical than portable defibrillators and so are classified as class IIA "non-life sustaining and diagnostic tool devices" according to the Medical Device Directive 93/42/EEC. In some circumstances another device will be available if one fails and failure will not always be life threatening unlike portable defibrillators. However there will be circumstances where defects or complete failure would be life threatening. For example, if a patient with a PWD suffers heart failure while out of sight, no alarm would be sent. If the monitor being used for a patient in an ambulance fails, any changes to the patient's condition would be missed. At best, equipment failure will delay diagnosis or treatment and this can have serious implications.

- **Patient-Worn Devices (PWD)**

  PWD are RF devices carried by patients who may have very recently completed surgery, are anesthetized, or have been recently discharged from the hospital and need home monitoring. In the past, these devices were large and not portable so patients could not move around. Modern portable devices, however, allow remobilizing patients so that they can move around in the hospital/home and be continuously monitored while they are walking or being moved and in locations where wired connections are not possible.

  The vital signs data such as heart condition, blood pressure and temperature are wirelessly transmitted in a short range radio frequency from the PWD to the nearby network router, which will then download the data to the nurse stations via an Ethernet network. PWD units are also used to detect if a patient falls on the ground. The PWD is expected to make a call to a Personal Response Centre. If a PWD is dropped onto the floor by a patient, which is likely in view of their condition, the PWD could be damaged and fail to transmit a warning alarm. PWD must also be unaffected if they are worn by a patient taking a shower or if dropped into water (bath, toilet, etc.).

- **Mobile Ultrasound Equipment**

  Ultrasound equipment was in the past relatively large and not mobile, but smaller MMD equipment has been developed that it can be carried in ambulances and by general practitioners. Small hospitals and doctor's practices may have only one ultrasound monitor and increasingly these will be portable types. These are susceptible to damage from vibration during transportation

and if dropped in the same way as portable defibrillators. If they fail to function, as there will be no alternative equipment nearby, patients would be at risk in an emergency. Small ultrasound equipment mounted on trolleys is also used with CT for visualising soft tissue and then with radiotherapy to find the correct location for treatment. This ultrasound therefore is moved around the hospital and so can suffer impacts with walls, doors and lifts. Any malfunction can cause a delay to treatment for cancer which may prevent the timely and successful eradication of tumours.

➢ Patient monitors

Patient monitoring equipment is safety critical because if it were to malfunction, any life-critical changes to a patient could be missed. Equipment for monitoring body functions of patients are widely used in hospitals, ambulances, emergency helicopters and elsewhere. These monitor a variety of functions such as pulse, blood pressure, temperature, etc. Most are designed to be used in a variety of locations and many are fitted with batteries to allow transportation. Some are mounted on a stand by a patient's bed and so do not need to be readily portable, but others are hand carried or attached to other portable equipment such as patient transportation trolleys or stretchers. More examples of how these products are used include:

- monitors mounted on tiltable / swivel arms, where users tend to pull on the device rather than on the handle provided
- patient monitors permanently mounted on wheeled anaesthesia machines or ventilator carts, and these carts being wheeled to the ventilator maintenance department (may happen twice a week for critical care ventilators!)
- patient monitors mounted permanently to patient stretchers in emergency departments or patient receiving areas, where they travel everywhere the stretcher goes
- small patient monitors that are used inside a baby incubator in neonatal intensive care units, where the caregiver constantly has to make sure the device is out of reach of the patient
- flexible/ replacement/ spare monitors that are wheeled or hand-carried to the location inside a hospital where they are immediately needed
- patient monitors mounted permanently to patient stretchers in CT or NMR set-ups or radiology C-bows, where they constantly travel with the stretcher or C-bow.