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

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Öko-Institut e.V. – Institute for Applied Ecology, Germany (main contractor)

Carl-Otto Gensch

Yifaat Baron

Markus Blepp

Andreas Manhart

Katja Moch

Fraunhofer Institute for Reliability and Microintegration – IZM (subcontractor)

Otmar Deubzer

Öko-Institut e.V.
Freiburg Head Office
P.O. Box 17 71
79017 Freiburg, Germany
Street Address
Merzhauser Str. 173
79100 Freiburg
Phone +49 (0) 761 – 4 52 95-0
Fax +49 (0) 761 – 4 52 95-288

Darmstadt Office
Rheinstr. 95
64295 Darmstadt, Germany
Phone +49 (0) 6151 – 81 91-0
Fax +49 (0) 6151 – 81 91-133

Berlin Office
Schicklerstr. 5-7
10179 Berlin, Germany
Phone +49 (0) 30 – 40 50 85-0
Fax +49 (0) 30 – 40 50 85-388

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1 Background and objectives

The RoHS Directive (2002/95/EC) (RoHS 1) has been recasted and has now become Directive 2011/65/EU that entered into force on 21 July 2011 and will lead to the repeal of Directive 2002/95/EC on 3 January 2013. With the launched contract 070307/2011/600236/ SER/C2 the Commission requests technical and scientific support for the evaluation of exemption requests under the new RoHS 2 regime. This includes a few new aspects compared to the former RoHS 1:

- The scope covered by the Directive is now larger as it covers all EEE (as referred to in Articles 2(1) and 3(a)).
- The former list of exemptions (now included in Annex III) has been enlarged to include medical devices and monitoring and control instruments (Annex IV).
- The procedure and criteria for the adaptation to scientific and technical progress has changed:
  - Links to the REACH Regulation (1907/2006/EC) now need to be taken into account (Article 5(1)(a) so as not to weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006").
  - In addition the formerly valid criteria concerning the practicability of substitution and its environmental, health and consumer safety impacts have to be fulfilled as well as the new criterion on reliability of substitutes.
  - Furthermore, 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.
  - A new aspect is also that all exemptions now need to have an expiry date and that they can only be renewed upon application.
- 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.

Against this background and taking into account that exemptions falling under the enlarged scope of RoHS 2 can already be applied for upon entry into force, the Commission has contracted Öko-Institut together with the Fraunhofer IZM (in the following "the consultants) in view of technical and scientific assistance for the evaluation of exemptions (new exemption requests, renewing existing exemptions, amending exemptions or revoking exemptions). Furthermore, in order to harmonise and facilitate the exemption process, the contractor is

requested to deliver a draft standard format for future applications and a draft guidance document.

2 Project set-up

Assignment of project tasks to Öko-Institut and Fraunhofer IZM started 20 September 2011. The overall project has been led by Carl-Otto Gensch, as successor of Stéphanie Zangl. At Fraunhofer IZM the contact person is Otmar Deubzer. The project team at Öko-Institut consists of the technical assistant Katja Moch and as additional technical experts Yifaat Baron, Markus Blepp and Andreas Manhart.

3 Scope

In the course of the project, one stakeholder consultation has been conducted; eighteen new RoHS exemption requests have been evaluated. Two additional exemptions (2 and 11) had been submitted to the commission but they were not included in the consultation. An overview on the covered exemptions and exemption requests is given in Table 1.

In addition to the review of exemption requests, a guidance document was formulated on the subject of “How to apply for an exemption” as well as a draft for a harmonized application form, to be approved by the commission.

The stakeholder consultation was launched on 24 January 2012 and ran until 20 March 2012. It covered all 18 exemption requests.

A specific project website was set up in order to keep stakeholders informed on the progress of work: http://rohs.exemptions.oeko.info. The four consultations held during the project were carried out according to the principles and requirements of the 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:
http://circa.europa.eu/Public/irc/env/rohs_2010_review/library.

The evaluation of the stakeholder contributions included inter alia getting back to stakeholders for further discussion, exchange in order to clarify remaining questions and cross-checking with regard to technical correctness and confidentiality issues. Where seen necessary, stakeholder meetings were held.

4 Overview on the evaluation results

In the course of the project, eighteen new RoHS exemption requests have been evaluated. Five exemption requests (1, 12, 15, 16 and 19) were withdrawn by the applicant towards the end of the evaluation. Concerning three other requests (17, 18, 20) changes to the wording and new information obtained after the stakeholder consultation, requires making new information available for public contributions. A stakeholder consultation is to be launched shortly to this avail.

The exemption requests covered in this project together applicant name and the final recommendations and expiry dates granted are summarized in Table 1. Please refer to the corresponding chapters of this report for more details on the evaluation results. The final – not legally binding – recommendations for exemption request no. 1 through 20 (excluding requests 1, 2, 11, 12, 15, 16 and 19) were submitted to the EU Commission by Öko-Institut and Fraunhofer IZM and have already been published at the EU CIRCA website on 17 December 2012. So far, the Commission has not adopted any revision of the Annex to Directive 2011/65/EU based on these recommendations.

During the project duration, the applicant Test and Measurement Coalition was demanded to outline the efforts they plan to undertake in order to test substitutes and alternative materials or designs. This question is related to all requests that the Test and Measurement Coalition has submitted. Subsequently to receiving answers from the applicant concerning “Specificity of research, redesign and substitution in category 9 Sector Exemption applications” a face-to-face meeting with the Test and measurement Coalition took place in Brussels on the 6 June 2012.

Following the meeting, Agilent Technologies sent some additional information concerning cryo-cooler suppliers, relevant to exemption request 14.

Table 1: Overview on the recommendations and expiry dates

Exemption requests				
No.	**Wording**	**Applicant**	**Recommendation**	**Expiry / review date**
1	Cadmium and its compounds in electrical contacts or one shot pellet type thermal cut-offs with current ratings of 5 Amperes or more, for use in monitoring and control instruments (category 9.)	TMC[1]	Withdrawn	

[1] Test and Measurement Coalition

Exemption requests				
3	Cadmium in phosphor coatings in image intensifiers for X-ray images	COCIR[2]	Cadmium in phosphor coatings a) in image intensifiers for X-ray images b) in spare parts for x-ray systems placed on the EU market before 1 Jan 2020	31 Dec 2019 1 Jan 2020
4	Lead acetate marker for use in stereotactic headframes for use with CT and MRI and in positioning systems for gamma beam and particle therapy equipment	COCIR	Lead acetate marker for use in stereotactic head frames for use with CT and MRI and in positioning systems for gamma beam and particle therapy equipment	July 2021
5	Lead as an alloying element as a lubricant for bearings and wear surfaces in radiotherapy equipment and radiosurgery equipment and for patient and equipment support systems	COCIR	Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation	July 2021
6	Lead to enable thermal compression process to make a vacuum tight connection between aluminium and steel for X-ray image intensifiers	COCIR	Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers; expires 31 December 2019	31 December 2019
7	Lead in non-magnetic pin connector systems used at temperatures below minus 20°C	COCIR	Lead in the surface coatings of pin connector systems requiring non-magnetic connectors which are used durably at a temperature below -20°C under normal operating and storage conditions	July 2021
8	Lead in solder for electrical circuitry that is used at temperatures below -20°C	COCIR	Lead in ▪ solders on printed circuit boards, ▪ termination coatings of electrical and electronic components and coatings of printed circuit boards ▪ solders for connecting wires and cables, ▪ solders connecting transducers and sensors, that are used durably at a temperature below -20°C under normal operating and storage conditions.	July 2021

[2] European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Exemption requests				
9	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	COCIR	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	30 June 2020
10	Lead in solders to PCBs for mounting cadmium telluride and cadmium zinc telluride digital array detectors	COCIR	Lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards	30 June 2020
12	Lead and cadmium in optical and filter glass in monitoring and control instruments (category 9.)	TMC	Withdrawn	
13	Lead and cadmium in metallic bonds creating superconducting magnetic circuits	TMC	Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR, FTMS detectors	July 2021
14	Lead in alloys as a superconductor and thermal conductor in devices that depend on superconductivity for their operation	TMC	Lead in alloys, as a superconductor or as a thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and /or in industrial monitoring and control instruments.	July 2021
15	Lead not exceeding 20% in bronze bearings and bushes in monitoring and control instruments (category 9.)	TMC	Withdrawn	

Exemption requests				
16	Lead in solders consisting of more than two elements for the connection between the pins and the package of microprocessors with a lead content of more than 80% and less than 85% by weight used in monitoring and control instruments (category 9)	TMC	Withdrawn	
17	Lead in glass of electronic components and fluorescent tubes, or in electronic ceramic parts (including dielectric ceramic capacitors) used in monitoring and control instruments (category 9.)	TMC	Evaluation temporarily suspended due to reformulation	
18	Lead used in compliant pin connector systems for use in monitoring and control instruments (category 9)	TMC	Evaluation temporarily suspended due to reformulation	
19	Handicraft luminous discharge tubes (HLDT) used for signs, decorative lighting and light-artwork, in fixed or portable installations as per definition in EN50107-1(2002) “1 Scope” and in prHD60364-7-719 number 719-1	ESF[3]	Withdrawn	
20	Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes not exceeding 5 mg per lamp in lighting applications for monitoring and control instruments (category 9)	TMC	Evaluation temporarily suspended due to reformulation	

4.1 Guidance document

A draft for the guidance document for RoHS exemption requests on the basis of Article 5(8) Directive 2011/65/EU has been prepared and was sent to the commission for review along with the July progress report. A first draft of the harmonized application format was also submitted.

These were reviewed by the commission and remarks were received on 25 July, 2012 and integrated into the documents. The final documents are included in this report in the Annex (section A.1).

[3] European Sign Federation

The previous draft was reviewed by Mr. Markus Hornberger of the Fraunhofer Institut IPA, who has submitted a few initial remarks, which have been of assistance. We would like to consult the commission as for having the documents reviewed by additional practitioners.

5 REACH-related aspects

The specific REACH related aspects are discussed within each of the exemption recommendations in the next sections. A short summary of specific provisions under REACH found for possible substitute substances mentioned in reference with the applications, for which exemptions have been requested, can be found in Table 3 below.

Article 5 of the RoHS 2 Directive 2011/65/EU on “Adaptation of the Annexes to scientific and technical progress” states that “inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV, provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006.” RoHS 2 does not further specify the meaning of this clause.

REACH, for its part, addresses chemicals of concern through authorization and restriction:

- Substances that may have serious and often irreversible effects on human health and the environment can be identified as Substances of Very High Concern (SVHCs). Following the identification as SVHC, a substance may be included in the Authorisation list, Annex XIV “List of Substances Subject to Authorisation” of the REACH Regulation. If an SVHC is placed on the Authorisation, list companies have to apply for authorisation for specified uses.
- If a chemical poses an unacceptable risk to human health and the environment that needs to be addressed on an EU-wide basis, there may be restrictions on the manufacturing, placing on the market or the use of that chemical of concern. These restrictions are laid down in Annex XVII “Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Mixtures and Articles”.

In the consultants’ opinion, only the inclusion of substances into the procedures related to authorization or restriction of substances and articles under REACH may weaken the environmental and health protection afforded by REACH if at the same time RoHS grants an exemption for these uses. This approach has already been performed for the re-evaluation of the existing RoHS exemptions 7(c)-IV, 30, 31 and 40 (see report “Adaptation to Scientific and Technical Progress under Directive 2011/65/EU – Transferability of previously reviewed exemptions to Annex III of Directive 2011/65/EU”). The recommendation to each exemption request will only shortly refer to the relation to the REACH regulation indicating the results of the REACH check described below.

When evaluating the below exemption requests with regard to the 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 or **Registry of Intentions**,
- on the list of substances of very high concern (SVHCs) or **Candidate List**,
- in the recommendations of substances for Annex XIV or **Authorisation List**,
- listed in REACH Annex XIV itself (authorization),
- listed in REACH Annex XVII (restrictions).

As the European Chemicals Agency ECHA is the driving force among regulatory authorities in implementing the EU's chemicals legislation, we consider the ECHA website as the reference for the above metnioned lists as well as for the exhaustive register of the Amendments to the REACH Legal Text. The following bullet points explain in detail the above mentioned lists and where they can be accessed:

- The list of substances proposed for the adoption to the Candidate List or **Registry of Intentions**: Member States Competent Authorities (MSCAs) and/or 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. There are different registries of intentions: First, a list of the current, active intentions of Member States and/or the Commission; secondly the registrys on the Annex XV dossiers submitted that are still under one of the three decision-making processes (identification as SVHC, Harmonised C&L, restrictions). The list of the intentions that have been withdrawn after evaluation by a Member State or ECHA was not considered here. 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 list of substances of very high concern (SVHCs) or **Candidate List**: The identification of a substance as Substance of Very High Concern and its inclusion in the Candidate List is the first step of the authorisation procedure; the Candidate List is available at the ECHA website at http://echa.europa.eu/web/guest/candidate-list-table.
- Recommendations of substances for Annex XIV or **Authorisation List**: 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.
- Substances etc. listed in Annex XIV itself (authorization) and listed in Annex XVII (restrictions): As the last amendment of the REACH Legal Text dated from 20 May

2011 (Commission Regulation (EU) No 494/2011); the consolidated version of the REACH legal text, dated 10 December 2011 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:2006R1907:20111210:EN:PDF.

For lead, cadmium and their compounds as well as for mercury covered in the exemption requests that were evaluated in this project, we have found that relevant entries can be found in Annex XVII. Neither lead nor cadmium (at least in the form described here) or mercury is subject to activities related to authorization. The conditions of restriction of mercury, cadmium and its compounds and cadmium oxide and specific lead compounds are presented in the following table:

Table 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 / 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** CAS No 7440-43-9 EC No 231-152-8 **and its compounds**	For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87 (*). **1. 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]

Designation of substance / group of substances / mixture	Conditions of restriction
	• 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] • 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 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

Designation of substance / group of substances / mixture	Conditions of restriction
	2017. **5. For the purpose of this entry, 'cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface. Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications:** (a) equipment and machinery for: - food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] - agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] - cooling and freezing [8418] - printing and book-binding [8440] [8442] [8443] (b) equipment and machinery for the production of: - household goods [7321] [8421 12] [8450] [8509] [8516] - furniture [8465] [8466] [9401] [9402] [9403] [9404] - sanitary ware [7324] - central heating and air conditioning plant [7322] [8403] [8404] [8415] In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited. **6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below:** (a) equipment and machinery for the production of: - paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] (b) equipment and machinery for the production of: - industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431] - road and agricultural vehicles [chapter 87] - rolling stock [chapter 86] - vessels [chapter 89] **7. However, the restrictions in paragraphs 5 and 6 shall not apply to:** - articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, - electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. **8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01% by weight.** 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:

Designation of substance / group of substances / mixture	Conditions of restriction
	- 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 Appendix 2: **Cadmium oxide**	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: **1. Shall not be placed on the market, or used,** - as substances, - as constituents of other substances, or, - in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: - either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, - the relevant concentration specified in Directive 1999/45/EC. 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.
30 Toxic to reproduction: category 1A or 1B or toxic to reproduction category 1 or 2 According to Appendix 5: Lead compounds with the exception of those specified elsewhere in this Annex, […] **Lead acetate** […]	

Additionally, on 19 April 2012, Sweden registered the intention at ECHA[4] to propose the restriction (Annex XVII) of "Lead and lead compounds in articles intended for consumer use".

The proposal for restriction must be submitted until 19 April 2013.

This proposal stems from the recent forthcomings deeming lead as a non-threshold toxic substance associated with 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 value, Sweden sees reason to impose restrictions on the use of lead in additional applications.

[4] 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)

Additionally, ECHA launched a consultation for contributions concerning the proposal of 54 substances for the List of Substances of Very High Concern (SVHC) on the 3rd of September. This list refers among others to 21 lead compounds and the various risks related to them.

As at present, it cannot be foreseen if and when new restrictions will be implemented as a result of these proposals, their implications have not been considered in the review of the exemption requests dealt with in this report, however for the sake of future reviews, process forthcomings and results shall be followed and carefully considered where relevant.

The following table shows the check of substitutes and alternative material of 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

Table 3: In Progress: Check of specific provisions under REACH, such as conditions of restriction in REACH Annex XVII and Annex XIV for substitutes and alternative material in the exemption requests

Request no.	Substance or compounds	Specific provisions under REACH
1	Silver	None
	Tin Oxide	None
	Zinc Oxide	None
3	System substitution (digital detectors): thallium doped caesium iodide (CsI:Tl) or	None
	Cadmium zinc telluride (CdZnTe)	See entry 23. Cadmium and its compounds, Table 2
6	Thallium	None
12	Titanium or niobium oxides	None
16	Tin and Antimony based lead free solders	None
18	Tin and gold coatings	None

6 Exemption request no. 3

"Cadmium in phosphor coatings in image intensifiers for X-ray images"

6.1 Description of requested exemption

The applicant requests an exemption for cadmium in phosphor coatings in image intensifiers for X-ray images. Cadmium is a constituent of phosphors used in image intensifiers, usually applying silver doped cadmium zinc sulphide (ZnCdS:Ag). Image intensifiers are used to amplify very weak X-ray signals that pass through patients to create bright images that can be recorded with digital cameras. The phosphors cannot be replaced during the lifetime of the image intensifier, so the lifetime of the phosphor coating is equal to the lifetime of the image intensifier, which is estimated to range around 3-4 years for devices used for fluoroscopy applications and 7 years for other equipment (COCIR 2012).

Although material recovery from end-of-life image intensifiers is technically feasible, the amount of phosphor per X-ray device is too low for recycling purposes. Thus, cadmium containing image intensifiers are usually disposed as hazardous waste.

According to the applicant, the total annual use of cadmium for X-ray image intensifier systems in the EU sums up to 10 g (COCIR 2011).

The applicant requests an exemption for "cadmium in phosphor coatings in image intensifiers for X-ray images until 31 December 2019 and in spare parts for x-ray systems placed on the EU market before 1 Jan 2020".

6.2 Applicants justification for exemption

According to COCIR (2011), cadmium-based phosphors are used because they produce brighter images than other output phosphors using the same radiation dose. Comparing the most commonly used P20 phosphor (ZnCdS:Ag) with the best available cadmium-free alternative P43 ($Gd_2O_2S:Tb^{3+}$), output light intensity is about 10% lower with P43.

According to the applicant, several cadmium-free phosphors with similar light output colour have been developed but all require higher x-ray doses (around 10% higher) to obtain suitable images. As there is scientific evidence that the level of radiation doses correlates with cancer rates, this means that all substitutes would have direct negative health impacts on patients undergoing X-ray surgery.

Another way to substitute cadmium-based phosphors in X-ray applications is the general substitution of phosphors by using digital detector systems. Although digital detector systems have a market share of 55% of new X-ray systems sold in the EU, they – according to the applicant – have some disadvantages in some specific applications:

- Digital detector systems are more fragile than X-ray systems with image intensifiers, thus making it difficult to be used in mobile X-ray systems[5]. According to COCIR (2012) 30% of all X-ray systems are designed and used for mobile use.
- Digital detectors require slightly higher X-ray doses for some applications. Nevertheless, application types and X-ray levels could not be further specified and mostly depend on user behaviour (COCIR 2012).
- Digital detector systems are more costly, with purchasing prices ranging between € 200,000–€ 300,000, while image intensifier systems range between € 100,000-€ 200,000. According to COCIR (2011), this would have negative effects on healthcare as some hospitals in the EU would not be able to buy new X-ray imaging equipment.

In addition, COCIR (2011) stresses that digital detectors require heavy metals to adsorb X-radiation. Here, various compositions are used, which require thallium and caesium (CMOS detectors) or cadmium (CZT detectors). While CMOS detectors typically use amorphous silicon coated with thallium doped caesium iodide (CsI:Tl) to convert X-radiation into visible light, CZT detectors are based on cadmium zinc telluride (CdZnTe) as semiconductor material. For the latter detector type, the cadmium required for one X-ray systems exceeds the amount of cadmium in image intensifier systems by the factor of 1 Million (Cd in CZT detectors: ~6500mg; Cd in image intensifiers: ~0.006mg).

6.3 Critical review

The applicant provides sufficient evidence that cadmium-free phosphors require about 10% higher radiation doses compared with cadmium-based phosphors. As lower radiation doses correspond with lower cancer risks caused by X-ray exposure (Huda et al. 2010), a rapid phase out of cadmium-based phosphors in image intensifiers for X-ray images are likely to increase health risks in the EU caused by X-ray doses in medical surgery – presupposing that cadmium-based phosphors would at least partly be replaced by cadmium-free phosphors[6].

The applicant also argues that a rapid and complete switch to digital detector systems (which do not require any phosphors) would have negative health and socio-economic impacts caused by limitations in its use (e.g. for mobile applications), slightly higher X-ray doses in some applications and higher purchasing prices for new X-ray equipment. While these arguments are generally plausible, it seems even more important that the semiconductors of digital detectors (as systematic substitute of image intensifier X-ray systems) all require

[5] Mobile X-ray systems are required to treat patients unable to move to a stationary X-ray system.

[6] In another scenario, image intensifier system would be completely replaced by digital detector systems. Generally, it is most likely that – in case the exemption would not be granted – both types of substitutes would be applied.

significant amounts of heavy metals such as caesium and thallium (CMOS detectors) or cadmium (CZT detectors). These substances are used in the semiconductors for X-ray detection, thus in a component not present in conventional image intensifier systems.

While the amount of thallium applied in CMOS detectors is estimated at some tens of milligrams per device (COCIR 2012), the use of cadmium in CZT detectors exceeds the use of cadmium in conventional image intensifier systems by the factors of 1 million per X-ray device. Although the use of cadmium in CZT detectors is covered by an existing RoHS exemption (item 1 of Annex IV of the recast), it is plausible that a switch from image intensifier systems to digital detector systems would increase the use of cadmium, caesium and thallium.

6.3.1 Relation to the REACH regulation

The use of cadmium in phosphor coatings in image intensifiers for X-ray images is not subject to any restrictions by REACH. The same holds true for potential substitutes, namely $Gd_2O_2S:Tb^{3+}$ as alternative phosphor and CsI:Tl and CdZnTe used in digital detector systems[7].

6.4 Recommendation

It is recommended to grant the exemption as proposed by the applicant. Regarding the timeline, it has to be considered that a ban of cadmium containing phosphors in X-ray equipment will very likely speed up the transition to digital detector systems. As this transition is very likely not correlated with a reduced use of heavy metals in X-ray equipment, there is – from this perspective – no need to further speed up this transition process. Thus, it is recommended to grant an exemption for the full transition phase towards digital detector systems, which is estimated to be completed some years after 2017 for new equipment.

Therefore, it is recommended to grant the exemption as requested by the applicant:

> *"Cadmium in phosphor coatings in image intensifiers for X-ray images until 31 December 2019 and in spare parts for x-ray systems placed on the EU market before 1 Jan 2020".*

[7] While cadmium and its compounds are covered by REACH Annex XVII, the application in medical equipment is not affected by this entry.

6.5 Specific references

COCIR 2011	Original exemption request document no 3 by European Coordinating Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR); http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_3/3_COCIR_-_Exemption_request_-_Cadmium_in_image_intensifiers.pdf
COCIR 2012	Further information on exemption request no 3 submitted by European Coordinating Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) on 21 May 2012 during evaluation.
Huda et al. 2010	Huda, W.; Rowlett, W.T.; Schoef, U.J.: Radiation dose at cardiac computed tomography: facts and fiction. In: J. Thorac. Imaging, 2010 Aug; 25(3) p. 2014.

7 Exemption request no. 4

"Lead acetate marker for use in stereotactic head frames for use with CT and MRI and in positioning systems for gamma beam and particle therapy equipment"

Abbreviations

$BaSO_4$	Barium Sulphate
IGRT	Image guided radiation therapy
MRI	Magnetic Resonance Imaging
CT	Computer Tomography

COCIR (2011a) has applied for an exemption for "Lead acetate marker for use in stereotactic head frames for use with CT and MRI and in positioning systems for gamma beam and particle therapy equipment"

7.2 Description of requested exemption

Medical procedures, such as brain surgery, the removal of tumours with the use of x-ray, gamma-ray or particle beams and targeted radiation treatment of tumours with particle radiation, require extreme accuracy so that damage to tumour adjacent healthy tissue can be avoided or at least limited. Obtaining a location prior and for use throughout these procedures can be done quite successfully at present with the help of head and body fames that use lead acetate as a clearly recognizable marker in imaging systems such as MRI and CT. The lead acetate marker used with head/body-frames allows for the combination of results of both imaging systems, overcoming the inaccuracy shortcomings that the use of each single system would pose. As no viable substitute has been developed to date, an exemption has been requested to allow the prolonged use of lead within these procedures.

COCIR (2011a) explain in their application that the precise location of features within patients' heads and bodies is very important particularly for treatment of tumours by radiation therapy and also for brain surgery. Tumours can be destroyed by radiation using x-ray, gamma ray and particle beams for example, using linear accelerators or a "gamma knife" which focuses many low dose radiation beams from cobalt 60 isotope onto the tumour, usually within the head. These techniques are able to deliver radiation very precisely so that the tumour is destroyed with a minimal amount of surrounding healthy tissue affected. Radiation damage to healthy tissue may lead to other health problems, including additional cancerous tumours. Modern technology allows the radiation beam shape to precisely match the shape of the tumour and the beam can then be positioned at an accuracy level of less than 1 mm. In this respect, provision of extremely accurate positioning data of the tumour is important for the success of such procedures and for the limitation of subsequent effects on healthy tissue.

There are a few methods used for location and positioning of various features within the body, however when such accuracy is required, positioning is usually performed by compiling imaging data from both MRI and CT systems. MRI systems are very good for imaging soft tissues and tumours, however images can be distorted. CT systems provide very good spatial resolution, but are poor when it comes to the imaging of soft tissues.

The combination of imaging data from both systems thus allows more accurate positioning of tumours, in turn making precise treatment of such features possible. As data from each system must be overlapped to achieve such positioning, markers must be used that are clearly visible in both images, allowing for precise super-positioning and combination of imaging results.

CT markers must contain a high atomic mass element to be relatively dense so as to appear opaque to X-rays.

MRI markers must be a substance viewable to the MRI but not adversely affected by it, i.e. not magnetic. MRI is sensitive to hydrogen atoms, however hydrogen behaves differently in different states, depending on what it is bound to (water, acid solution, etc.). The behaviour of the hydrogen affects the frequency of the signal and the signal intensity so that acid hydrogen ion (H+) signals are relatively weak and occur at high frequencies, whereas hydrogen bonded to oxygen in hydroxyl groups is much stronger and occurs at lower frequency. The signal strength affects the visibility of the element by the MRI, and is very important as it must be noticeable against a background of hydrogen bonded to a variety of molecules in the body. The MRI marker therefore must contain substances with hydrogen atoms that give strong signals such as glycols and acetates.

Under this background, lead acetate is an ideal marker for use with head-frames in procedures requiring precise positioning. It holds the following qualities:

- Lead has a high atomic mass (207) and is relatively dense (11.45 g/cm^3) and therefor opaque to X-rays in CT systems.
- Lead acetate has a high solubility in water and more importantly in glycol solutions, providing sufficient hydrogen atoms bounded to materials that clearly appear in MRI imaging.
- The lead acetate salt remains stable within the solution used in head-frames, preventing precipitation of solids that could result in markers appearing in different places in MRI and CT images and resulting in inaccurate positioning.

COCIR (2011a) estimate that 1 kg of lead is put on the European market every year through this application. This estimation is based on the presumption that there are only two or three suppliers of stereotactic head frames, one of which has an annual lead consumption of 1 litre. It is assumed that around 1 kg lead is the part of the substance in the lead acetate supplied to the European market every year.

The typical lifetime of head and body-frames stated by the applicant is 10 years (COCIR 2011b).

7.3 Applicants justification for exemption

The justification for this exemption, as expressed by the applicant, is that there are no viable substitute designs nor substitute materials that are opaque to X-rays, readily visible by MRI and that are not more hazardous than lead acetate, as will be elaborated below.

Markers located within head-frames and body frames give the best precision which allows radiation treatment of tumours to be used with minimal damage to surrounding healthy tissue.

Regarding the possible substitutes for lead acetate, some alternative metals are very toxic. Other alternatives are only soluble in strongly acidic solutions, which would pose a risk to patients should a leak occur. Additionally, strong acidic solutions have a high hydrogen ion concentration and an extremely low hydroxyl ion concentration, respectfully giving off a weak signal and so not contributing to a clear image.

7.3.1 Possible design alternatives

As explained, lead acetate is used as a marker within head and body frames applied for producing precise imaging and accurate positioning of tumours and other body features, required for specific medical procedures. The applicant mentioned a few alternatives for the performance of marking: gold markers, frameless markers and framed markers.

Gold markers

In the past, gold markers were used for assisting with positioning in CT imaging systems. These were surgically implanted into the body. As gold is invisible to MRI systems, this option could no longer be viable for this application, as positioning would rely on CT imaging alone and would therefor result in less accurate positioning. Additionally, as these markers must be implanted in the body, this alternative also has an inherent risk as does any surgery.

Frameless markers

Frameless markers are circular adhesive pads that are attached to the patient's skin and serve as a means for applying external markers for use with imaging equipment. The pad consists of an outer layer of polymer that is filled with barium-sulphate ($BaSO_4$). $BaSO_4$ is used in the polymer as it is an inert powder that can be used as filler. Inside the layer there is a cavity filled with hydrogel that contains bound water. The $BaSO_4$ is fairly opaque to x-rays, providing a good marker substance for CT imaging and the bound water is visible to MRI.

MRI visibility may vary depending what part of the body is in view: fats, muscle, various organs etc. There are a few techniques which may be used to improve visibility and therefor the ability to see hydrogel markers depends on the area in view and the techniques used to produce the image.

Pads are easy to use and provide a fairly accurate location of features such as tumours and other medical conditions, however they may move in relation to a tumour when attached to the skin due to its flexibility in relation to inner tissues. Additionally this technique may result in less accurate imaging as pads are attached to the body locally and so do not prevent movement resulting from breathing and shaking or fidgeting. The use of adhesive pads for procedures also requires removal of hair from adhesion areas and thus eliminates one of the advantages of radiosurgery in comparison with regular surgery. The adhesive pads may be attached to head and body frames to avoid movement, but as Barium is less opaque to x-

rays, markers appear less clearly and therefore sometimes provide lower grade imaging data.

For all these reasons, frameless markers are reported to be inherently less accurate in comparison to lead acetate markers. They are mainly used for neurosurgery with an optical tracking system that aids in determining their position.

Framed markers

Frame markers are imbedded within a head or body frame structure. This structure is then clamped and sometimes surgically fixed to the body, providing for the marker remaining at a precise location and therefor respectfully ensuring that the feature may be positioned at a precision of less than a millimetre. The marking substance within the frame must clearly appear on both MRI and CT imaging so that the tumour may be precisely located in reference with the markers location.

Other techniques

According to COCIR (2012a), in the last few years the radiotherapy world has started moving towards the so called “frameless mode” or “IGRT (image guided radiation therapy)”. The patient is now positioned using a CT like system and/or ultrasounds and/or surface scan cameras. This new technology doesn’t require frames and provides the necessary precision, if not higher in some cases. According to the information provided by the applicant, this method is coming in to use as an alternative for both head and body-frames.

The downside of this technique is that it is still not widespread. Many hospitals do not have IGRT technologies and so need to rely on frames in order to reach the necessary level of accuracy. COCIR (2012b) further explain that this trend is likely to continue and that complete phase out of the use of lead acetate containing head frames may be complete in as little as 10 years, i.e. by 2022.

7.3.2 Possible substitute alternatives

Lead acetate is an ideal substance for use as a marker within head and body frames used for positioning for radiotherapy and gamma-ray tumour extraction procedures. It is relatively dense and has a high atomic mass making it opaque to x-rays and therefore allowing it to appear clearly in CT imaging. The solution can be clearly seen by MRI due to the hydrogen in hydroxyl groups as well as hydrogen atoms in the methyl group of acetate ions. Lead is abundant in nature and the acetate can be supplied at a concentration high enough to ensure high x-ray opacity. Toxicity issues related to use would only occur should it be released from within the frame (rare). Toxicity issues related to waste management are also of lower concern as lead recycling is straightforward and well controlled in comparison to other heavy metals.

There is a limited choice of metal compounds that can be dissolved in polar solvents for use within the frames, and even fewer of these have stable glycol soluble acetate salts. The applicant demonstrated the various possibilities for use of other metals as markers. The information has been compiled and appears in Table 4 below. In general it can be said that:

- Metals with an atomic mass lower than tantalum and tungsten have a density lower than that of lead and are therefore significantly less opaque to x-rays.
- Solutions must have relatively high concentrations of metals to be opaque to X-rays. Many of the high atomic mass metals can be converted into "complex salts" but these are usually, either insoluble or are only soluble at such low concentrations as to be ineffective.
- The marker solution must be non-hazardous and pH neutral or slightly alkali in order to have high hydroxyl ion concentrations. Metals whose compounds are soluble only in acid solution are unsuitable as hydrogen ions give weak MRI signals.
- It is important that the heavy metal compounds have high solubility because solids dispersed in liquids will usually separate and can move to different regions within the device so that the solid metal compound and the polar solvent could indicate different locations by CT and MRI.

Table 4: Qualities and limitations of alternative metals for use as markers within head and body frames

Metal	**Symbol**	**Atomic mass (lead is 207)**	**Properties**				
			Density, g/cm3 (lead is 11.4 g/cm^3)	**Solubility in materials that clearly appear in MRI**	**Abun-dance**	**Toxicity**	**Opacity to x-ray**
Caesium	Cs	133	1,9	Caesium acetate only slightly soluble in glycols			Much less opaque than lead
Barium	Ba	137	3,5	Barium acetate only slightly soluble in glycols. Barium sulphate is invisible to MRI and insoluble in MRI opaque solvents and so will separate from the fluid so that a different location is indicated by CT and MRI.		Soluble barium compounds are classified as toxic; H phrases H301 – toxic if swallowed and H332 – harmful if inhaled). Due to insolubility, barium sulphate is less toxic but cannot be used in frames.	Much less opaque than lead
Lan-thanum	La	139	6,2	Lanthanide compounds solubility in glycols is too low & so unsuitable			Much less opaque than lead
Hafnium	Hf	178		Does not form water and glycol soluble,			Less opaque than lead

Metal	Symbol	Atomic mass (lead is 207)	Properties				
			Density, g/cm3 (lead is 11.4 g/cm^3)	Solubility in materials that clearly appear in MRI	Abun-dance	Toxicity	Opacity to x-ray
				stable acetate salts			
Tan-talum	Ta	181	16,6	Does not form water and glycol soluble, stable acetate salts	2 ppm in earth crust		
Tung-sten	W	184		Does not form water and glycol soluble, stable acetate salts	~70-100 ppm in earth crust		
Rhe-nium	Re	186		Sodium perrhenate very soluble in water but not in ethanol. Solubility in glycols not published but likely to be lower than in ethanol. Perrhenates are strong oxidising agents likely to cause glycol decomposition	0,0007-0,0026 ppm in earth crust, very rare. No acetate suppliers could be identified	Toxicity not fully understood	
Osmium	Os	190		Does not form water and glycol soluble, stable acetate salts. Stable osmium salts are soluble with excess alkali.	0,0015 ppm in earth crust, very rare	Risk of formation of very toxic osmium tetroxide (dangerous volatile metal). May cause irreversible blindness	
Iridium	Ir	192		Sodium hexachloroirridate is water soluble, stable in acidic and neutral solution but may precipitate or decompose with reducing agents. Most other compounds not soluble or not stable.	0,0004-0,001 ppm in earth crust, very rare. Acetate is commercially available however at a concen-tration too dilute for CT marking	Toxicity is poorly understood	
Platinum	Pt	195		Most compounds insoluble in water, some only in very acidic solutions or unstable in solutions.Sodium chloroplatinate is soluble in water and alcohol.	0,004-0,005 ppm in earth crust		
Gold	Au	197		Cyanide complexes are water soluble. Sodium chloroaurate	0,003-0,004 ppm in earth	Cyanide complexes are very toxic	

Metal	Symbol	Atomic mass (lead is 207)	Properties				
			Density, g/cm3 (lead is 11.4 g/cm^3)	Solubility in materials that clearly appear in MRI	Abun-dance	Toxicity	Opacity to x-ray
				soluble in water and alcohol. Gold acetate has very low water solubility.	crust		
Mercury	Hg	201		Mercury acetate soluble in alcohol but not in water		More toxic than lead	
Thallium		204		Soluble in water but no data on glycol solubility		More toxic than lead	
Lead	Pb	207	11.4	Soluble in water and glycols	14 ppm in earth crust		
Bismuth	Bi	209		Only stable in highly acidic solution	0,009-0,025 ppm in earth crust		
Uranium	U	238		All elements heavier than bismuth are radioactive			

7.3.3 Environmental arguments

Even though no technically viable substitute has been identified at present, COCIR have submitted further information concerning life cycle assessment aspects, to further enhance their argumentation. Information includes reference to the availability of other metals, the energy consumption required for their extraction and refining and information concerning the re-use and recycling of waste. In general, the information submitted concerning these aspects also proves lead to be the most suitable candidate, seeing as:

- It is widely abundant and may be relatively easily extracted.
- Extraction and refinement require less energy by far, in comparison with other metals
- Recycling systems are widespread and the process is straightforward, again entailing less energy in comparison with other metals where recycling is possible only through multi-stage energy intensive processes, sometimes also requiring the use of additional toxic chemicals.

7.3.4 Road map for substitution

As explained above, at present, direct substitution of lead acetate marker is impractical. The applicant has stated that alternative markers have been developed for some medical

treatments, but none of these afford the precision required in the applications mentioned in the context of this exemption. COCIR (2011a) have stated that further research may eventually identify a marking substance that is suitable for use with both MRI and CT systems, however as at this time there are no obvious candidates, it is impossible to predict how long this may take.

In parallel, it seems that the alternative IGRT technique will be able to replace the framed marker technique within the coming years. At this time it is not fully widespread, nor does it seem to be compatible for all procedures in question, but its development may allow for the phase out of lead acetate containing head-frames within about 10 years (COCIR 2012b).

7.4 Critical review

7.4.1 Relation to the REACH regulation

Chapter 5 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. Lead and its compounds are thus listed in Annex XVII, and their use might weaken the environmental and health protection afforded by the REACH Regulation.

In the consultants' understanding, entry 30 of Annex XVII does not apply to the use of lead in stereotactic head frames used for the above mentioned applications. 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 stereotactic head frames 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.

7.4.2 Scientific and technical practicability of lead substitution

COCIR (2011a) claims that lead cannot be eliminated in this application. The main argumentation focuses around the lack of an alternative metal that could serve as a feasible substitute.

The applicant provides a comparison of a number of other metals, concerning various aspects relevant to substitution reliability as well as to possible health and environmental impacts. Details can be found in the sections above (cf. sections 7.3.1 and 7.3.2). For some metals the main argumentation is unreliability or unavailability of a solution suitable for use within the head-frames. Other materials that may serve as possible substances prove to be more toxic than lead and therefore cannot be viewed as feasible substitutes.

One question remains, concerning barium sulphate, which is in use with non-framed marking systems and could thus be regarded as a possible substitute. The main problem with using $BaSO_4$ (used in frameless techniques) as a substitute is that it is not soluble in water and alcohols and therefor would not be available in a solution that would be apparent in MRI

systems. According to the information submitted by the applicant, no other barium containing substances could be identified as suitable for producing a solution apparent in both CT and MRI systems. Therefore without further research in this direction, it cannot be established that Br could be available in a solution compatible to both imaging systems.

IGRT systems are not widespread enough and may not be compatible at present for all procedures; however there is a shift towards these systems that may allow application elimination towards 2022.

The consultants conclude that, in the absence of contrary information, the applicant´s technical arguments plausibly justify that currently the use of lead as a marker in stereotactic head-frames cannot be eliminated, nor is a feasible substitute available.

7.4.3 Environmental arguments

COCIR (2011a and 2012b) present environmental data and statements comparing the life cycles of lead with potential substitutes. As none of the substitutes can actually be used currently, 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.

7.4.4 Conclusion

The applicant's scientific and technical arguments are plausible and comprehensive. Based on the information submitted, the consultants conclude that a scientifically and technically practicable possibility for substitution or elimination of lead in this application is currently not available.

COCIR (2012a) indicated that its members use lead acetate only in head-frames. No additional information was made available during the stakeholder consultation concerning the use of lead acetate in body-frames, and so the consultant recommends using the wording proposed by the applicant in the case that an exemption is approved.

"Lead acetate marker for use in stereotactic head frames for use with CT and MRI and in positioning systems for gamma beam and particle therapy equipment"

As the applicant has affirmed with the provided argumentation, at present no substitutions can be identified for use as the marking substance within stereotactic head frames nor is the applicability of such substances foreseen in the near future.

In parallel, it seems that the radiotherapy world has begun to move towards the use of "IGRT (image guided radiation therapy)". According to the applicant, if this trend should continue, it could lead to the complete phase out of the use of lead acetate containing head-frames within ten years, and so by the end of 2022 (COCIR 2012b).

In this regard and in the absence of substitution and elimination possibilities, as well as knowledge concerning the development of such possibilities, the consultants have no motive to recommend an expiry date prior to the seven years maximum validity of exemptions adopted to Annex IV.

7.5 Recommendation

Based on the documents submitted by the stakeholders and in the absence of contrary information, the requested exemption would be in line with the requirements of Art. 5(1)(a). The consultants therefore recommend adding an exemption to Annex IV of the RoHS Directive with the following wording:

> *"Lead acetate marker for use in stereotactic head frames for use with CT and MRI and in positioning systems for gamma beam and particle therapy equipment"*

As there are at present no possible substitutes and it appears these shall not be available in the near future, the consultants recommend not setting an expiry date prior to the end of the maximum validity period of the exemption in July 2021.

7.6 Specific references

COCIR 2011a	Original exemption request submitted by European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR); http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_4/4_COCIR_-_Exemption_request_-_Lead_acetate_marker_final.pdf
COCIR 2011b	Answers to first clarification questions submitted by the applicant, by the European Coordination Committee of the Radiological, Electro-medical and Healthcare IT Industry (COCIR) on 7 December 2011; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_4/Questionnaire1_Exe-4_answers.pdf
COCIR 2012a	Answers to further questions submitted by the applicant, document no 2 by European Coordination Committee of the Radiological, Electro-medical and Healthcare IT Industry (COCIR) on 23 July 2012
COCIR 2012b	Answers to further questions submitted by the applicant, document no 2 by European Coordination Committee of the Radiological, Electro-medical and Healthcare IT Industry (COCIR) on 9 August 2012

8 Exemption request no. 5

"Lead as an alloying element as a lubricant for bearings and wear surfaces in radiotherapy equipment and radiosurgery equipment and for patient and equipment support systems"

COCIR (2011a) has applied for an exemption for "Lead as an alloying element as a lubricant for bearings and wear surfaces in radiotherapy equipment and radiosurgery equipment and for patient and equipment support systems"

8.1 Description of requested exemption

According to COCIR (2011a) X-ray imaging and radiotherapy equipment has bearings and sliding surfaces of moving parts that are exposed to ionising radiation. Bearings and wear surfaces that are exposed to ionising radiation cannot use grease or oil lubricants as these substances will decompose and cannot easily or safely be replaced. The only dry lubricant material with a long life that does not decompose when exposed to ionising radiation has been found to be alloys that contain particles of lead.

The applicant describes typical examples of where lead is needed as a lubricant in medical device applications as follows COCIR (2011a):

- Bearings used for the doors of multisource radiosurgery equipment. The radiation source used in these products is the radioactive isotope cobalt 60 and the bearings are continuously irradiated. It is essential that the patient entry doors open and close easily to prevent radiation leakage. If an oil or grease lubricant were used, this would need to be regularly replaced as it would degrade due to radiation exposure from the cobalt-60 source. However, replacement of the oil or grease would be a very dangerous operation because of the continuous radiation exposure as the radiation is from a radio-isotope and so cannot be "turned off".
- Lead is also used as a dry lubricant as an alloying addition to aluminium where 5% of lead is added to aluminium. This material is used for the bearings of linear sliders that are used for support systems that allow the patient or parts of the equipment to be moved smoothly to precise locations in angiography, radiotherapy and CT equipment. These bearings need to support very high loads but as they are exposed to ionising radiation, oil and grease lubricants will decompose and be unreliable. This would pose a risk to the patient if failure were to occur during an operation.
- Some types of equipment, such as used for radiotherapy, use telescopic arrangements which require accurate and precise movement to focus the radiation onto the correct location of the patient. Each part of the telescopic assembly has to use lead alloy

bearings as these are exposed to ionising radiation that would degrade oils and greases.

Independently from the single applications there are two types **of grease-free bearing materials** used as lubricants for bearings and wear surfaces in radiotherapy equipment and radiosurgery equipment and for patient and equipment support systems (COCIR 2011a):

- Aluminium containing up to 5% lead.
- Leaded bronzes some of which contain typically 5–20% lead.

Lead metal in these alloys is present always at the bearing surface as fresh particles are continuously exposed as the bronze or aluminium alloy is worn down. The coefficient of friction of leaded bronze against steel with no grease lubricant is typically ~0.1 or a little higher after some wear has occurred. Steel on steel has a coefficient of friction of 1.0.

In its request for exemption COCIR initially estimated that 20 kg of lead is used in the EU per year for use as dry bearings in medical devices. (COCIR 2011a)

The consultant asked the applicant to disclose the assumptions for this quantity. Based on estimations for two particular types of applications (diagnostic radiology, radiotherapy equipment) and additionally taking into account niche applications the applicant raised its estimation to 50 kg of lead per year. (COCIR 2011b)

This amount is comparatively low, compared to the amount of lead used as radiation shielding. According to COCIR (2011b), approximately 1 ton of lead is used as radiation shielding in radiotherapy linear accelerators.

8.2 Applicants justification for exemption

The applicant argues that elimination or substitution of lead via design changes or materials and components which do not require lead is technically impracticable (COCIR 2011a):

- Although alternative types of bearings have been developed in which greases and oils are used as lubricants, these substances degrade when exposed to ionising radiation. Most oils and greases are based on hydrocarbons, fluoro-organics and organo-silicones and are suitable for many types of electrical equipment but are not suitable for applications where they are exposed to ionising radiation. All types of oil and grease degrade when exposed to ionising radiation such as X-rays and γ-radiation and so these are not suitable for bearings and wear surfaces of medical devices where there is exposure to ionising radiation.
- The only existing exemption that is applicable to lead as a lubricant is exemption 9b of Annex III[8]. However, this is limited only to HVACR applications because oils and

[8] Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications.

grease are not effective at low temperature and this exemption does not apply to medical devices.

8.3 Possible substitute alternatives

The applicant provides a set of criteria which are relevant for bearing surfaces to perform consistently and reliably (COCIR 2011a):

- Low coefficient of friction,
- Low rate of wear,
- Adsorb and discard small particles such as dirt and abraded particles,
- Adapt to surface roughness – lead smears over rough surfaces,
- High compressive strength,
- Corrosion resistance – this is important as oxides and corrosion products will have poor lubrication properties,
- Low shear strength (at bearing surface interface) in order to fill irregularities between surfaces,
- Structural uniformity.

Members of COCIR assessed a range of possible alternatives that are not affected by ionising radiation, against these criteria (see COCIR 2011a, page 5 et seqq.) but came to the conclusion that currently, lead is the only known material that is suitable over long periods of use as a dry lubricant where exposure to ionising radiation occurs.

8.4 Environmental arguments

Even though no technically viable substitute has been identified at present, COCIR have submitted further information concerning life cycle assessment aspects, to further enhance its argumentation. Information includes reference to the availability of silver and gold as alternative metals, the energy consumption required for their extraction and refining and information concerning the re-use and recycling of waste. In general, the information submitted concerning these aspects also proves lead to be the most suitable candidate, seeing as:

- It is widely abundant and may be relatively easily extracted.
- Extraction and refinement require less energy by far, in comparison with gold
- Recycling systems are widespread and the process is straightforward, again entailing less energy in comparison with other metals where recycling is possible only through

multi-stage energy intensive processes, sometimes also requiring the use of additional toxic chemicals.

8.5 Road map for substitution

According to the applicant and as explained above, at present, substitution of lead as an alloying element for bearings and wear surfaces under the condition of ionising radiation is impractical. Nevertheless COCIR (2011a) concludes that a potential alternative to lead as a dry lubricant may be graphite loaded alloys. However, these alloys have not yet been evaluated by medical equipment manufacturers.

The applicant summarises the research required to assess this potential substitute as follows:

Design and construction of bearings for each application	1 year (to 2013)
Evaluation of graphite bearing performance using accelerated testing	1 year (to 2014)
If these test results are satisfactory, then re-design medical devices that utilise leaded bearings	At least 2 years to complete (to 2016)
Long term reliability testing of medical equipment constructed with lead-free bearings to simulate 25 year lifetimes	Complete for all types of equipment after 5 years (to 2021)
If long term trials are satisfactory, clinical trials would follow to obtain data for Medical Device Directive approval	Further 1 year (to 2022)
Time required for obtaining medical device directive approval	1 year (to 2023)

The consultant asked the applicant to provide further details especially regarding the above specified period of 5 years for the long term reliability testing of medical equipment. Exemplified for a tube set with wheels (COCIR 2011b) states that it is very important that wear behaviour is thoroughly understood because the wear behaviour has a large influence on the handling and the accuracy of the system. Several intense endurance tests are necessary to study wear behaviour of materials and designs. First, there may be many different materials to be tested. Also, the crowning (e.g. shape), the basic hardness, any wear coatings and the surface roughness all have a significant impact on the behaviour of the material.

The following tests must be carried out in this respect (COCIR 2011b):

- Test with static load (2500N)
- Roller test for continuous operation on a special test (this must cover each roller moving a distance equivalent to about 320km with a 2500N load). This test alone requires a period of approximately 8 months

- Duration of test tube set in rollers (testing as a complete assembly). One material can be tested at a time for wear behaviour to determine the long term behaviour. These tests must also be equivalent to movement over a distance of about 320 km. These tests are required for each material, each taking a period of approximately four months.

Experience has shown that one series of tests is usually not sufficient, but rather that several tests must be repeated. Thus, a period of 5 years is needed for detailed testing.

8.6 Critical review

8.6.1 Relation to the REACH regulation

Chapter 5 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. Lead and its compounds are thus listed in Annex XVII, and their use might weaken the environmental and health protection afforded by the REACH Regulation.

In the consultants' understanding, entry 30 of Annex XVII does not apply to the use of lead as an alloying element for bearings and wear surfaces as the substance is not made available on the market for the general public but rather is present in a specific application used and supplied only to specific professional sectors. 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 as an alloying element for bearings and wear surfaces 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.

8.6.2 Scientific and technical practicability of lead substitution

COCIR (2011a) claims that lead cannot be eliminated in this application. The main argumentation focuses around the lack of an alternative metal that could serve as a feasible substitute.

The applicant provides a comparison of a number of other metals, concerning various aspects relevant to substitution reliability as well as to possible health and environmental impacts. The main argument, the degradation of hydrocarbons as lubricants when exposed to ionising radiation is a commonly known interaction between radiation and material, which is used for example to modify the characteristic of polymers through radiation (cure vs. degradation; see Ehrenstein and Pongratz 2007).

The consultants conclude that, in the absence of contrary information, the applicant´s technical arguments plausibly justify that the current use of lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation cannot be eliminated, nor is a feasible substitute available.

8.6.3 Environmental arguments

COCIR (2011a) presents environmental data and statements comparing the life cycles of lead with potential substitutes, especially gold. As none of the substitutes can actually be used currently, 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.

8.6.4 Conclusion

The applicant's scientific and technical arguments are plausible. Based on the information submitted, the consultants conclude 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, the consultants have no motive to recommend an expiry date prior to the seven years maximum validity of exemptions adopted to Annex IV.

8.7 Recommendation

Based on the documents submitted by the stakeholders and in the absence of contrary information, the requested exemption would be in line with the requirements of Art. 5(1)(a). The consultants therefore recommend adding an exemption to Annex IV of the RoHS Directive.

In order to ensure a simplified but unambiguous wording and to prevent misapplications of this exemption we recommend to change the wording suggested by the applicant as follows:

> *"Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation."*

As there are at present no possible substitutes and it appears these shall not be available in the near future, the consultants recommend not setting an expiry date prior to the end of the maximum validity period of the exemption in July 2021.

8.8 Specific references

COCIR 2011a	Original exemption request submitted by European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) on 29/09/2011: Application for granting new Exemption: Lead as an alloying element as a lubricant for bearings and wear surfaces in radiotherapy equipment and radiosurgery equipment and for patient and equipment support systems.
COCIR 2011b	Answers to first clarification questions submitted by the applicant, by the European Coordination Committee of the Radiological, Electro-medical and Healthcare IT Industry (COCIR) on 19 December 2011
Ehrenstein and Pongratz 2007	Ehrenstein, G.; Pongratz, S.; Beständigkeit von Kunststoffen. Band 1, 527-528. München 2007

9 Exemption request no. 6

"Lead to enable the thermal compression process to make a vacuum tight connection between aluminium and steel for X-ray image intensifiers"

Abbreviations

CZT detectors	cadmium-zinc-telluride detector
FD	flat digital detector
II	image intensifier(s)
K	Kelvin
MRI	magnetic resonance imaging

9.2 Description of requested exemption

COCIR (2012a) asks for an exemption with the following wording:

"Lead to enable thermal compression process to make a vacuum tight connection between aluminium and steel for 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".

Image intensifiers are used in two main types of X-ray imaging equipment:

- mobile X-ray C-arcs

- nearby controlled C-arcs

Mobile X-ray C-arcs are smaller systems that are moved around hospitals to examine patients that cannot be moved, for example if they are receiving emergency treatment or during surgery. These are relatively simple low priced systems but are robust and are not damaged by being moved. Nearby controlled C-arcs are stationary systems where the patient is brought to the equipment (COCIR 2011).

COCIR (2011) explains that image intensifiers amplify the weak images produced by X-ray imaging equipment and are often supplied as integral parts of these products. They must have a permanent high vacuum to function reliably as any gases will reduce the performance and could impair the quality of the image.

According to COCIR (2011), image intensifiers are assembled from different metals. As aluminium has a low atomic mass, it is transparent to X-rays. Aluminium parts are therefore applied where transparency to X-radiation is required, and steel is used for high strength. Steel is also needed where glass-to-metal seals are required because vacuum-tight bonds directly between glass and aluminium cannot be made.

COCIR (2011) explains that lead is used for manufacturing permanent vacuum tight seals between aluminium and steel that reliably work over the long service lives of image intensifiers. Figure 1 illustrates the construction of an image intensifier showing the location of the lead seal between the X-ray transparent aluminium dome and the steel body (COCIR 2011).

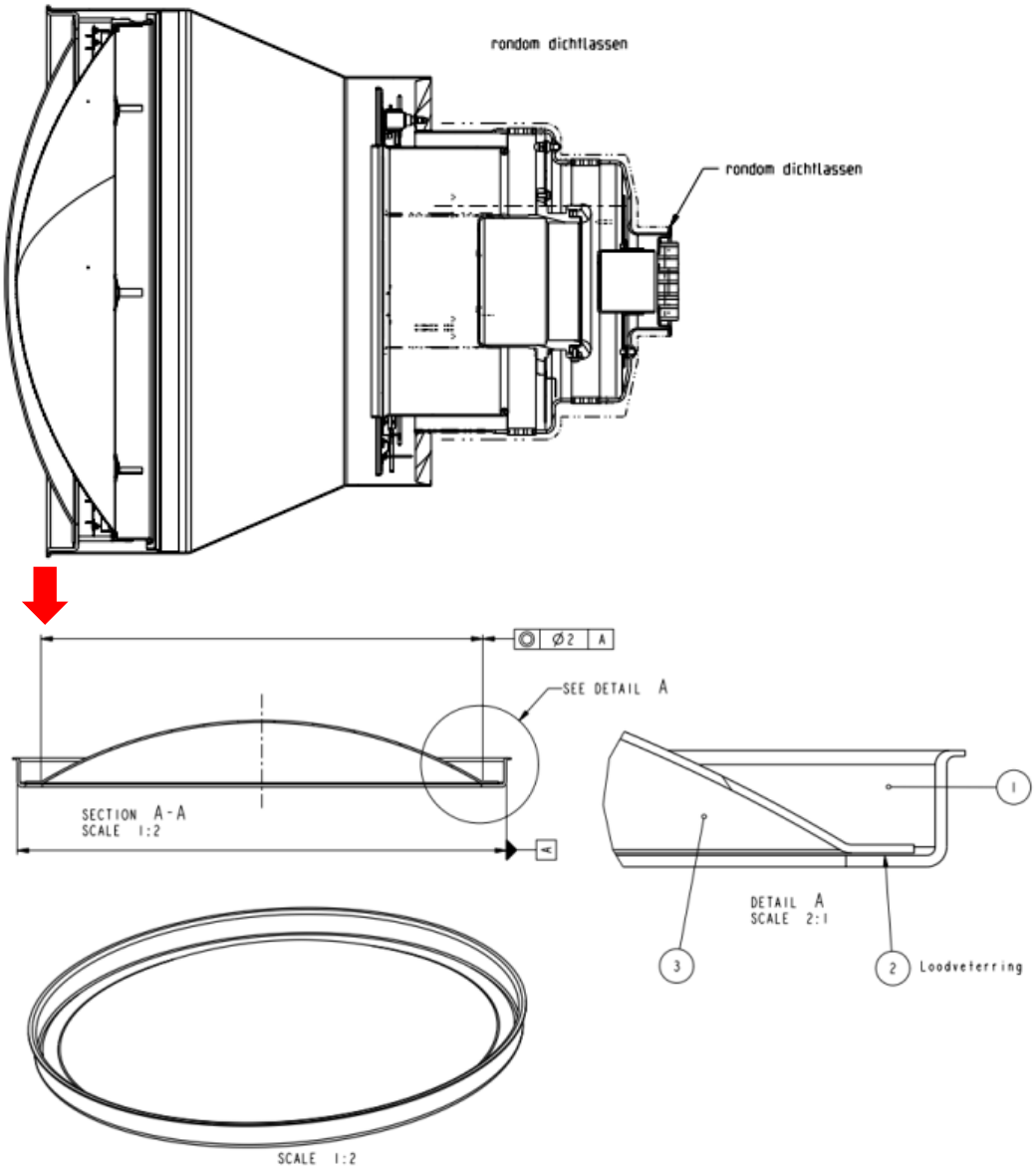

Figure 1: Construction of an image intensifier showing the location of the lead seal (“Loodveterring”) (COCIR 2011)

COCIR (2012b) explains that the lead seal is being positioned in between the two parts. The two parts with lead seal are put in an oven. After reaching the correct temperature the parts with lead seal in between are pressed together in a press for a certain time. After cooling down, the vacuum tight connection is realized. Different from solders, the lead does not form a chemical bond to the surfaces of the joined materials, because it must slide over the surface to allow for thermal expansion mismatch between aluminium and steel.

COCIR (2012a) calculates 33–42 grams of lead used per image intensifier in this application resulting in the use of around 50 kg per year in the EU. COCIR's substantiation of this calculation is shown in the following table.

Table 5: Lead use in image intensifiers (II, source: COCIR 2012b)

Type:	Lead usage	Annual quantity	Total
23 cm II:	33 g	1,100	36.3 kg
31 cm II:	42 g	450	18.9 kg
Total:	75 g	1,550	55.2 kg

COCIR (2012b) estimates that the EU currently uses about 25% of global production resulting in around 14 kg per year put on the EU market.

9.3 Applicant's justification for the exemption

9.3.1 Substitution of lead in image intensifiers

Pure lead is a soft metal which will retain its structural integrity at 200°C and will not emit gases into the high vacuum. The aluminium and steel parts are assembled with a vacuum-tight lead seal. After assembly, a vacuum pump evacuates the interior of the image intensifier. During the evacuation process, the assembly is heated to 200–220°C to remove contaminants inside the assembled image intensifier such as cutting oil residues and extrusion greases. The organic contaminants must be completely removed as otherwise they will slowly evaporate into the high vacuum and degrade the vacuum, which would deteriorate the image intensifier's performance (COCIR 2011).

Because the assembly needs to be heated to over 200°C, the seals need to withstand the temperature of this process and maintain the vacuum in the image intensifier over its entire life time. Ideally, the image intensifier's life time should be the same as that of the X-ray imaging equipment, which is typically 25 years (COCIR 2011).

Soldering to aluminium and steel is difficult as both metals form stable and inert oxides on the surface. Before solder can wet the surface, a very corrosive flux is needed to remove these oxides, and some would remain inside the image intensifier and could cause corrosion and eventual failure. Also, because the units have to be vacuum pumped at ~200°C, only high melting point solders can be used (standard lead-free alloys have too low melting point). All flexible and ductile high melting point solders are lead-based (with >90% lead) so if they could be used they would provide no health or environmental benefit over lead seals. However soldering large area bonds with lead-free solders is very difficult due to the differences in thermal expansion of the two materials, which requires the use of a ductile

solder to prevent the cracking of the seal due to temperature changes. Lead-free solders are, however, considerably more brittle than the ductile lead. Soldering lead-free alloys to aluminium and steel is therefore never carried out. Lead-free high melting point solders exist, such as Au80Sn20 (80% gold and 20% tin) with a melting point of 280°C exist. Suitable fluxes for bonding to aluminium and steel are, however, not available. If these could be developed, they would need to be very corrosive and so might be unsuitable.

COCIR (2012a) puts forward that no tests were carried out with alternative seal metals because none have been identified that have all of the essential characteristics. Tin and Indium have a too low melting point taking into account the required temperature to remove gasses by vacuum baking. Copper is only suitable as a seal for (stainless) steel/steel joints (same thermal expansion coefficient no thermal mismatch). Image intensifiers require a combination of stainless steel / aluminium so movement due to temperature changes is significant. Originally gold was not considered because of its price but is not expected to be suitable because of its cold welding characteristics, which would result in a brittle joint lacking the necessary ductility to compensate the thermal mismatch between steel and aluminium.

Thus, if a leak-free bond could be made with lead-free solders, which is very unlikely, these alloys are hard and very brittle and so are likely to fracture, causing leaks when differential thermal expansion occurs due to temperature changes. This may result in leaks destroying or affecting the vacuum and thus the proper functioning of the II. Such soldered seals additionally would be much more difficult and probably impossible to dismantle and then reassemble the image intensifier should repairs be required (COCIR 2011).

The additional heating of the II during evacuation in order to evaporate organic pollutants is one reason why the lead seal is required. A previous cleaning of the parts prior to their assembly, e.g. through a storage in vacuum at higher temperatures, could in principle be considered. COCIR (2012a) explains that the heating during evacuation is needed to get rid of the organic contamination. Image intensifier manufacturers already perform extensive cleaning (washing, etching, etc) prior to assembly, and parts are stored in a very clean nitrogen environment. This type of cleaning and storage is, however, not sufficient because the parts usually become contaminated after this treatment during handling and storage due to trace organic contaminants in the air that are adsorbed onto the clean surfaces. Vacuum baking is a common process for all types of vacuum equipment and it is necessary to do this whenever high vacuum equipment is assembled or reassembled after repair (COCIR 2011).

9.3.2 Digital detectors as alternative technologies

X-ray image intensifiers are gradually being replaced by digital semiconductor detectors.

Use of toxic substances in digital detectors

COCIR (2011) explains that various types of semiconductor are used in digital detectors depending on the type of imaging technique and the performance that is required. Silicon based types were the first to be introduced and are the most common. As silicon is a light element, it adsorbs X-radiation inefficiently. Silicon detectors therefore usually are coated with an X-radiation sensitive phosphor based on heavy metals. Such coatings adsorb x-radiation efficiently and converts it into visible light, which the silicon sensor then can detect. Thallium doped caesium iodide is the most common type of phosphor coating. The thallium concentration typically is around 1% in the thin phosphor layer. These coatings are typically 6 to 8 microns thick. A 20 mm x 20 mm detector thus contains around 6 µg of thallium (COCIR 2012a). According to COCIR (2012d), thallium iodide is very toxic. However, according to checks of the contractor, no conditions of restrictions or specific provisions under REACH apply to thallium used in silicon detectors (see Table 3). COCIR (2011) says that this type of phosphor is applied only in digital silicon detectors. The phosphor in image intensifiers usually consists of sodium doped caesium iodide because this converts incident X-radiation into light with a maximum wavelength which is the most sensitive for the photocathode.

COCIR (2011) says that recently more efficient types of digital detectors such as cadmium zinc telluride (CZT) detectors 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, exemption 1 in RoHS Annex IV covers this use of cadmium in digital X-ray detectors. COCIR (2012a) estimates that a 20 mm x 20 mm x 6 mm average size CZT detector contains around 6.5 grams of cadmium. An X-ray device, according to COCIR (2012c), normally contains one detector resulting in 6.5 g of cadmium per device.

CZT detectors are new and are difficult to assemble. Only a few manufacturers are able to use them and then only in the more expensive systems. CZT detectors are, however, more sensitive than silicon detectors. They reduce the radiation doses required in examinations and thus improve a weak point of digital detectors.

Diagnostic limitations of digital detectors

Digital detectors have several technical advantages, but also disadvantages, as Table 6 shows.

Table 6: Properties of digital silicon and CZT detectors compared to image intensifiers (COCIR 2012a and 2012b)

Advantages of digital detectors	Disadvantages of digital detectors
Lower radiation dose required for single images	When used for techniques where continuous imaging (diagnostic fluoroscopy) is required, patients are exposed to a larger radiation dose
Better spatial resolution	Currently much more expensive, so smaller hospitals may not be able to buy
Fast frame rate imaging possible so that fast changes and movement can be viewed, but this is possible only with small area detectors and therefore impractical for some procedures	30 frames/second can be achieved only with small area detectors. However large area images are needed for some diagnoses where only slower frame rates are possible and these are too slow to obtain the visual information needed for procedures such as speech pathology diagnostics, which requires >30 frames per second

There is a trend to use digital detectors for producing single X-ray images, while II are applied for real time, fluoroscopy examinations resulting in continuous X-ray exposure such as diagnostic imaging, angiography and radioscopically guided interventional procedures.

For single exposure imaging, high spatial resolution is important. In order to minimise the noise level, higher doses are used to which the patient is exposed for a very short time only. Digital detectors yield the best results in these cases related to an acceptable risk for the patient.

Real-time fluoroscopy imaging requires the patients' continuous X-ray exposition during the duration of the examination. For examinations such as diagnostic imaging, angiography and radioscopically guided interventional procedures it is therefore essential to use very low doses to minimise the risk of potentially lethal side-effects such as cancers. A certain image noise level is acceptable in these cases. Flat digital detectors, having a higher spatial resolution than II systems, need higher radiation doses to overcome their higher noise level. Therefore for these treatments, II systems allow lower radiation doses and hence are the best option considering the diagnostic result and the patient's risk due to the exposition to the carcinogenic X-ray. The flat detector's advantage – higher spatial resolution – thus is of no use in dynamic imaging fluoroscopy.

For single exposure imaging, a high spatial resolution is an advantage and will probably be used with II systems. Such an image would probably be "shot" with three to four times the dose of a dynamic fluoroscopy II image but would have a lower resolution and so may miss fine details such as hairline fractures. For single exposure radiographic exams at full resolution the dose applied for II and digital are thus comparable.

Some dynamic fluoroscopy examinations require high speed imaging. This is possible at good quality with analogue image intensifiers, but is inferior with large area digital systems.

For example, speech pathology studies require imaging at a rate of 30 frames per second which is straightforward with image intensifiers. Current digital detectors can achieve this frame rate only in small areas of up to 15 cm x 15 cm. This is too small for the patient that needs to be examined with around 25 cm to 30 cm.

Mechanical limitations of digital detectors

Besides the diagnostic properties, digital detectors still have mechanical limitations. While II are robust systems, digital detectors are relatively fragile and so there is a risk of damage with mobile systems C-arc systems. They are currently only used in some high-end mobile C-arc systems. Within the EU as a whole, it is therefore predicted that about 75% of mobile C-arc systems put on the market will still use image intensifiers by 2014. Nearby controlled C-arc systems, as they are stationary systems, can be larger and more complex. It is estimated that 85% of these systems in Europe will be equipped with digital detectors by 2014. COCIR (2011 and 2012b) states that those customers who currently buy mobile systems with digital detectors prefer the advantages of these systems and are willing to accept that the digital detector is more fragile.

Socio-economic implications of digital detector equipment

Currently, digital detectors are considerably more expensive and are used only in “high-end” systems. High-end systems have about double prices compared to image intensifier systems. (COCIR 2012a) explains that besides the higher purchasing price, the annual service cost for digital detector systems currently still is more expensive, and the energy consumption is 10 to 15 % higher (COCIR 2012b). The treatment times being similar, the higher cost is a serious limitation for many hospitals in the EU (COCIR 2011).

COCIR (2011) says that even though digital detectors are considerably more expensive than image intensifiers and are used only in “high-end” systems, they are gaining an increasing market share in the EU. In Nordic countries, most new systems have digital detectors whereas some new image intensifier systems are still sold in France, Germany and the UK. Hospitals in southern and eastern European countries currently buy more image intensifier systems than digital systems so that at present in the EU, about 45% of new X-ray systems sold have image intensifiers. There is thus still a large market for lower priced II systems sold to hospitals in countries with smaller budgets. This market is even rapidly growing, e.g. in some south and southeast EU member states. These countries require state of the art systems that are economically attractive enough to invest in. Only II systems currently and in the coming years will fulfil these conditions.

COCIR (2012a) sees a risk to human health where hospitals with limited budgets are forced to retain their older systems for longer if cheap and affordable II systems would not be

available. X-ray systems suppliers cannot sell digital systems at a loss and the price differences are due to the higher costs involved with the manufacturing of digital systems.

9.3.3 Environmental arguments

COCIR (2012a) says that digital detectors are made from either silicon or CZT semi-conductor wafers. Single crystals of semiconductor are fabricated from melts of high purity materials and so is a very energy intensive process. Silicon detectors are coated with thallium doped caesium iodide.

According to COCIR (2012a and 2012b), image intensifiers are recycled or may be re-used in refurbished units. For recycling, the steel and aluminium parts are separated and recycled with very high yields. As the lead does not form a metal-metal bond to either the steel or aluminium, no lead remains on either the steel or aluminium when the image intensifier is disassembled at end of life. As a result, the steel, aluminium and lead are easily separated and all can be recycled. This is one of the advantages of lead over other metals that cold weld to other metals. The high purity lead seal can be melted and recycled in subsequent smelting and refining processes used without need for purification. Large amounts of lead are safely recycled in the EU where strict and effective safety legislation is applied.

COCIR (2012a) presents the below table comparing these materials with those used in image intensifiers.

Table 7: Overview on environmental effects related to FD and II systems

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

COCIR (2011) says that digital detectors have a disadvantage over image intensifiers in that they are very difficult to repair and so if a fault develops, they become waste. The detector panels are silicon which has a low value and so recycling is not carried out commercially. Thallium, as contained in very low amounts (6 µg), will not be recycled. If the electrical waste is treated thermally, this will be emitted as thallium oxide vapour and this should be collected by scrubbers and the scrubber waste would be disposed to landfills as hazardous waste. Due to the extremely small amount, thallium is not monitored specifically. Used detectors

may alternatively be discarded to landfill as silicon has no value. However, digital detectors are relatively new and so none as yet have reached end of life.

9.3.4 Roadmap for substitution and elimination of lead

COCIR (2011) claims that it is very unlikely that an alternative material will be found to substitute lead in II systems for the reasons explained in the exemption request. There is, however, a trend to use digital detectors, thus eliminating the lead by a technological change. Further research into digital detectors is still needed to enable these to use radiation doses that are the same or less than with image intensifiers for all medical treatments and also that they can achieve the same speed. More research into fabrication processes is also needed to reduce the price so that digital detectors can be used in low-end systems that smaller hospitals are able to afford without affecting healthcare. Manufacturers estimate that this work may be complete by ~2018 or possibly a few years later. After this date, image intensifiers will no longer be used in new X-ray imaging systems, and image intensifiers will only be required for as spare parts for the repair of systems placed on the EU market before this date. As research cannot guarantee results, 2018 may be optimistic and 2020 may be a more realistic date.

9.4 Critical review

9.4.1 Relation to the REACH regulation

Chapter 5 of this report lists entries 23 and the entries 28 and 29 restricting the use of cadmium, lead, and their compounds in Annex XVII and the related authorization and restriction processes in the REACH Regulation. Cadmium and lead compounds are thus listed in Annex XVII, and their use might weaken the environmental and health protection afforded by the REACH Regulation.

In the consultants' opinion, however, these entries do not apply to the use of cadmium and lead applied in image intensifiers and in CZT detectors for X-ray devices. Lead or its compounds for use as sealing material, as well as cadmium and its compounds for use in CZT detectors may be considered as substances or mixtures restricted by the above-mentioned restrictions. Putting lead or cadmium in image intensifiers on the market in the reviewers' point of view is not a supply of lead and cadmium and their compounds to the general public. Lead and cadmium are part of an article and as such not covered by entries 23, 28 and 30 of Annex XVII. Additionally, entry 28 only applies to cadmium oxide, and entry 30 to lead acetate. These substances are, however, lead compounds, while lead and cadmium are used in their elementary or possibly ionic form in image intensifiers and in CZT detectors.

The consultants thus conclude that the use of lead and cadmium in these applications complies with the stipulations of the REACH Regulation. An exemption could therefore be granted if the other criteria of Art. 5(1) (a) apply.

9.4.2 Technical, health and environmental arguments

COCIR plausibly explains that substitution of lead in image intensifiers is impossible. No opposing statements are available from other stakeholders. The substitution of lead would result in insufficiently reliable image intensifiers and therefore must be considered as technically impracticable.

The use of silicon-based or CZT digital detectors would allow the elimination of lead. COCIR puts forward that the silicon detectors are less sensitive to x-rays. In dynamic examinations, where the patients are exposed to X-ray over a certain period of time, low doses are of particular importance to reduce the patients´ risk to contract cancer. Additionally, examinations requiring high frame rate imaging in combination with a large area to be examined, digital detectors are still inferior in performance compared to X-ray systems with II.

Cadmium-zinc-telluride (CZT) detectors have a higher sensitivity, but depend on the use of cadmium. Cadmium is, however, restricted in the RoHS Directive, too, even though exemption 1 in RoHS Annex IV allows the use of cadmium in detectors. An X-ray with an II contains 33 g to 75 g of lead depending on its size (see Table 5), while the cadmium in an X-ray with a CZT detector amounts to around 6.5 g. Even though the amount of cadmium is clearly lower than the amount of lead per X-ray device, a comparison of the toxic impacts is impossible in this exemption process, as there is no method authorized by the Commission to weigh the toxic impacts of two substances banned in the RoHS Directive. There is thus no proof that the use of cadmium in CZT detector systems may be environmentally more advantageous than the use of lead in II systems.

To sum up, COCIR explained plausibly that lead in image intensifiers currently can neither be substituted, nor can it be eliminated by using detectors replacing the II systems. Technically and with respect to the health and safety of patients, the continued use of II systems therefore is still required. An exemption would be in line with the requirements of Art. 5(1)(a). Based on the available stakeholder information, and in the absence of contrary evidence, the reviewers therefore recommend granting the exemption.

9.4.3 Setting of the expiry date

COCIR explained in section 9.3.4, that it is very unlikely that a substitute for lead be found in II systems. The digital silicon and CZT detectors need further research to overcome their diagnostic constraints and to reduce the price so that digital detectors can be used in low-

end systems that smaller hospitals are able to afford without affecting healthcare. The manufacturers estimate this work to be completed by ~2018 earliest, but assume that 2020 may be a more realistic date.

In the absence of converse information about the manufacturers' roadmap towards compliance, the reviewers recommend the exemption to expire on 31 December 2019. The remaining time should allow the manufacturers to do the necessary research, and it leaves a small safety margin in case the research is not as successful as planned.

9.5 Recommendation

Based on the available stakeholder information, and in the absence of contrary evidence, the reviewers recommend granting the exemption until end of 2019 with the following wording:

> *"Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers; expires 31 December 2019".*

9.6 Specific references

COCIR 2011 — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Original exemption request document "6-COCIR – Exemption request – Lead in image intensifier thermal compression rings.pdf"; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_6/6-COCIR_-_Exemption_request_-_Lead_in_image_intensifier_thermal_compression_rings_rev.pdf

COCIR 2012a — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Questionnaire1_Exe-6_-answers_rev.pdf" submitted by stakeholder http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_6/Questionnaire1_Exe-6_-answers_rev.pdf

COCIR 2012b — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Questionnaire2_Req-6- Answers.docx", submitted by stakeholder on exemption request no. 6 on 27 April 2012.

COCIR 2012c — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Questionnaire-3_Req-6 answers.doc", submitted by stakeholder on exemption request no. 6 on 11 May 2012.

COCIR 2012d — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Thallium-Iodide_Safety_Data_Sheet.pdf", submitted by stakeholder on exemption request no. 6 on 11 May 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

10 Exemption request no. 7

"Lead used in pin connector systems requiring non-magnetic connectors"

Abbreviations

Bi	bismuth
MEG	magneto-encephalography
Pb	lead
Sn	tin
SQUID	superconducting quantum interference device

COCIR (2011) applies for an exemption for "Lead used in pin connector systems requiring non-magnetic connectors". Gensch et al. (2009) reviewed a request for lead used in compliant pin connector systems. Lead-free substitutes were available or foreseeable, and the Commission granted exemptions 11(a) and 11(b) in RoHS Annex III setting expiry dates for the use of lead in this application:

- *Exemption 11(a)*

  Lead used in C-press compliant pin connector systems for use in spare parts for EEE placed on the market before 24 September 2010
- *Exemption 11(b)*

  Lead used in other than C-press compliant pin connector systems; exemption expires on 1 January 2013 and after that date may be used in spare parts for EEE placed on the market before 1 January 2013

10.2 Description of requested exemption

Magneto-encephalography (MEG) is a fairly new technique that is used to generate three-dimensional maps of the brain by detecting and mapping minute brain signals. These extremely small signals are in the order of femto-teslas (10^{-15}), or around one billionth (1/1,000,000,000,000) of the strength of a typical domestic magnet. One manufacturer's product, for example, has 300 special superconducting quantum interference devices (SQUIDs) used as detectors. The SQUID detectors are cooled to 4K with liquid helium and connected electrically with special non-magnetic connectors. These connectors will be very cold although not superconducting and must be non-magnetic to avoid interfering with the detection of very small brain signals. Figure 2 shows a pin connector system used in MEG.

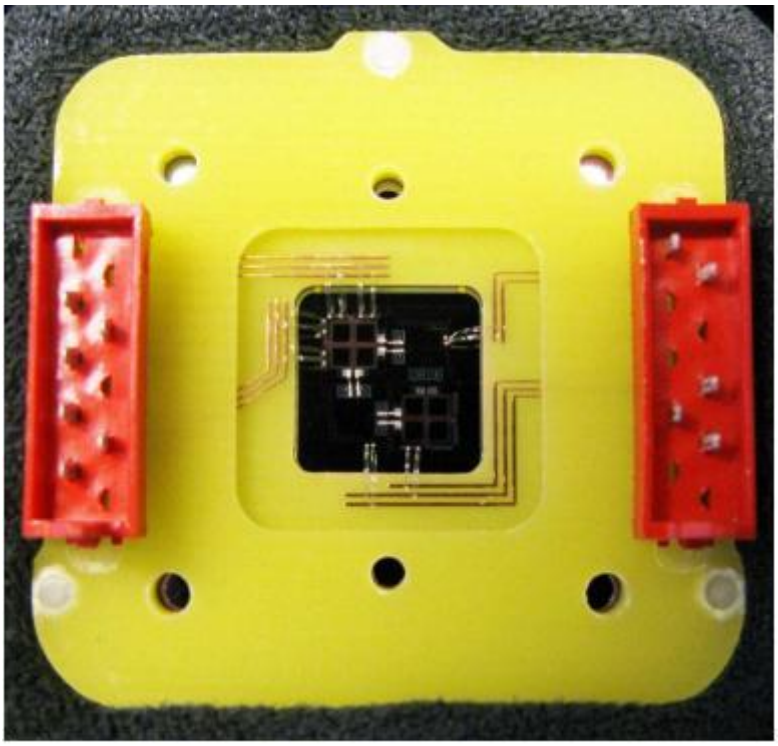

Figure 2: Pin connector system (COCIR 2011)

Copper is used as the base metal for the metal connector terminals because it is physically strong and is an excellent electrical conductor at 4K. As copper tarnishes in air to form an electrical insulator it is coated with tin-lead alloy, which does not tarnish and is a good electrical conductor at 4K. In MEG, the tin-lead alloy is the only appropriate surface coating. No lead-free alternatives are available. (COCIR 2011)

COCIR (2012a) presents the following calculation of the total amount of lead used in this application:

The total pin area of a connector is approximately 200 mm^2 covered by 10 μm of 90Sn10Pb (alloy with 90% weight of tin 10% of lead), which is a conservative estimate. The total volume of 90Sn10Pb thus is 2 mm^3, which corresponds to around 1.5 mg of Pb in a pin connector. Each MEG uses around 1,000 connectors resulting in 1.5 g of lead. Worldwide, around 10 MEG are sold per year, half of this in the EU. The worldwide use of lead in this application thus is around 15 g of lead per year, from which around 7.5 g are put on the EU market.

The calculation of this total amount of lead deviates from the around 100 g of lead use, which COCIR (2011) had calculated for this application. COCIR (2012b) confirmed that the 15 g are the more substantiated and correct figure, while the previous 100 g were just a rough estimate.

10.3 Applicant's justification for the exemption

10.3.1 Technical conditions barring the use of nickel barriers

COCIR (2011) claims that tin-lead is the only connector coating material for connector pins that will not fail prematurely. As MEG SQUID detectors are used to detect extremely small signals, electrical conductivity of the connector coatings must be very high at 4 K, and this conductivity must not deteriorate in use. Any metals or combination of metals whose resistance increases over time will be unsuitable. Gold or silver are most commonly used for the surfaces of the connectors, and an electroplated nickel barrier is applied between the copper alloy pin terminals of the connector and the surface coating. Without nickel, copper rapidly diffuses into gold and silver, and when it reaches the surface, it oxidises causing an increase in electrical resistance. Nickel, however, cannot be used in this application as it is a strongly magnetic metal and so would impair the performance of the MEG. Gold and silver platings therefore are not appropriate either.

Tin in principle could be used without nickel barrier as another lead-free surface coating material. Tin reacts with the copper to form an intermetallic layer at the copper/tin interface. Copper normally does not reach the surface unless the tin coating is very thin or the part is used at 100°C or hotter, where the formation of intermetallic phases is accelerated and all of the tin is consumed. Tin-copper intermetallic formation is, however, extremely slow at 4 K. Tin and most of its alloys nevertheless can't be used because they undergo a phase transformation – tin pest – at low temperatures, which causes the tin coating to form a powder with a high electrical resistance. (COCIR 2011)

Besides the stable high conductivity at 4K, the pin coatings must be ductile to allow connector pins to be inserted into the connector sockets. Brittle metals such as bismuth thus are technically inappropriate. Other possible alternatives are magnetic, which excludes

metals like nickel, iron or cobalt. Tin-lead is the only viable material, as it is ductile, has a high and stable conductivity at 4K, does not produce whiskers and is less sensitive to tin pest. (COCIR 2011)

10.3.2 Tin pest in lead-free tin alloys

Tin coatings suffer from tin pest at low temperature, but the behaviour of tin alloy coatings is less well studied. One researcher[9] showed that 99.99% pure tin suffers complete transformation after only 30 hours at -45°C (228 K).

Research with tin and its alloys has not been carried out at 4K so its performance is not known. Plumbridge[10] at the Open University has shown that tin based solder alloys such as those containing bismuth may be more prone to tin pest than tin-lead alloys. This research, however, was carried out on bulk alloys whereas electroplated coatings may behave differently. After testing a range of commercial alloys at -18°C and -40°C for over 10 years, some alloys such as SnCu suffer tin pest sooner at -18°C whereas others such as SnAg suffer tin pest sooner at -40°C. This research also showed that tin-lead solder also eventually suffers from tin pest at both temperatures although it has been used in applications such as magnetic resonance imaging (MRI) for many decades without problems. This indicates that at the much lower temperatures applied in MRI, the rate of tin pest formation is sufficiently reduced for the solder to survive the normal life of the equipment. However this cannot be certain for any other alloys, especially if they have been shown to suffer from tin pest more quickly than tin-lead. The Open University research is studying SnCu, SnAg, SnAgCu and SnZnBi. All alloys have been studied so far for over 10 years at both temperatures except for SnZnBi with only six years. Table 8 below summarises the results.

Table 8: Tin pest in tin alloys (COCIR 2011)

Alloy	-18°C 8 years	-18°C 10 years	-40°C 8 years	-40°C 10 years
SnPb	none	11.4%	none	37.5%
SnCu	35.8%	71.7%	14%	58.1%
SnAg	3.8%	22.9%	37.3%	98.7%
SnAgCu	24.2%	56.6%	10%	20%
SnZnBi	100% of samples suffered from tin pest at -40°C after six years			

These results show that all of the substitute alloys tested suffer from tin pest much sooner than SnPb, especially the standard lead-free alloys that are now widely used by the electronics industry. This research also shows that a lead-free solder containing bismuth is also unsuitable as it suffered from tin pest after less than 6 years, much sooner than SnPb.

9 "Suppression of Tin Pest in Lead-free Solders" by Keith Sweatman, JEDEX conference, San Jose, USA 2005, referenced in COCIR (2011)

10 W. J. Plumbridge, "Further Observations on tin pest formation in solder alloys", J. Electronic Materials, Vol 39 (4), p 433, 2010, refernced in COCIR (2011)

Evidence that bismuth is less effective than lead supplements to tin coatings is also available from research published in 2009[11]. This describes a case study where electroplated tin connectors suffered from tin pest after low temperature storage. This investigation found that 5% lead addition was effective at preventing tin pest, but 0.5% bismuth or antimony were less effective. A 0.5% bismuth addition is fairly standard for coatings on connector terminals.

The Open University ten years' research is the only long-term work on tin pest at low temperatures. All other research is much shorter. Where this research showed no transformation, the results are of little value as phase transformation may take longer than the tests were carried out and no comparison with tin-lead can be made. Tin pest unlike other physical processes cannot be accelerated because cooling slows the transformation rate and heating up to just below 13°C drastically slows the nucleation rate. No transformation occurs at higher temperatures.

COCIR (2012c) describes "nucleation" as the local initiation of a new thermodynamic phase or state of a material. For the change from the white tin phase to the grey tin phase, the grey tin particles need to start growing. Forming this new phase spontaneously requires much more energy than to start growing at a suitable "nucleation" site which can be a rough surface, scratches, contaminant particle, crystal defects or even due to a cosmic ray. This is the same situation as when ice crystals grow in water at below 0°C. Ice crystals or grey tin particles will be slow to start to grow spontaneously because energy is required for the phase change to occur. However less energy is needed if suitable nucleation sites are present on which new grey tin particles can begin to form. Once very small grey particles have been formed on suitable sites, these can then grow and crystal growth requires less energy than is needed for nucleation. If there are no sites for nucleation, then the time before nucleation occurs will be much longer. For example, if very pure water is cooled to well below 0°C (even down to -20°C) in a very clean container, it "super-cools" and does not form ice crystals. This is because there is no dust or rough surface on which ice crystals can nucleate. If you scratch the side of the container, ice forms immediately as the scratch acts as a nucleation site.

The time before tin pest occurs depends on how long nucleation takes to occur as well as the rate of growth after nucleation, and both of these are dependent on temperature. Grey tin crystal growth slows as the temperature decreases. Lowering temperature should encourage nucleation but this depends on the presence of suitable nucleation sites and alloy

[11] Burns, N.D. "A tin pest failure", J. Failure Analysis and Prevention, Vol. 9(5), p 461, 2009, referenced in COCIR (2011)

composition as well as temperature. It is thus unpredictable. Plumbridge[12] states that "what actually constitutes "nucleation" (of tin pest) is open to debate". Plumbridge also states that the precise role of temperature is unclear at present and that incubation times (time before nucleation occurs) can vary from a few minutes to over 300 years and even the presence of water vapour can be significant as ice crystals have a similar lattice parameter to α-tin. Plumbridge explains that "The vibrational amplitude of individual atoms increases with temperature, so the time to nucleation would be expected to fall at higher temperatures below the transition temperature (13.2°C). Once tin pest has nucleated, different parameters are likely to affect subsequent growth". As a result, it is very difficult to predict how long tin pest will take to start and grow for a specific alloy composition. Plumbridge states that tin pest growth is highly alloy composition specific, especially the effect of trace impurities. (COCIR 2012c)

According to (COCIR 2011), tin alloys used in MEG will experience much lower operating temperatures than the minus 45°C studied in the Open University research. The effect of temperature on tin pest is that with decreasing temperature the thermodynamic energy to start the phase transformation increases, but the rate of physical processes decreases. It is therefore difficult to predict what might happen at much lower temperatures and very little published research is available. The overall rate of transformation depends on both nucleation and transformation. Published research[13] has shown that transformation rates depend on the temperature as illustrated in the Table 9.

Table 9: Transformation rates at different temperatures (COCIR 2011)

Temperature	Theoretical transformation rate m/s
-10°C	1.5×10^{-5}
-20°C	1×10^{-5}
-30°C	0.6×10^{-5}

Nucleation rates depend on many variables including alloy composition, cooling rate, work history, etc., as well as temperature. Overall tin pest failure rates are impossible to predict and so must be measured. (COCIR 2011)

10.3.3 Tin whiskers

Tin whiskers are thin rods of tin that grow spontaneously from electroplated tin coatings. These have been known for many decades and have caused the failure of a wide variety of electrical equipment as a result of short circuits. Intensive research has been carried out only

[12] W.J. Plumbridge "Further Observations on tin pest formation in solder alloys", Journal of Electronic Materials, Vol. 39(4) 2010, p. 433

[13] http://www.electroiq.com/index/display/packaging-article-display.articles.advanced-packaging.volume-15.issue-11.features.tin-pest-in-tin-rich-solders.html, referenced in COCIR (2011)

since the introduction of the RoHS directive, aimed at determining causes and identifying measures to minimise the risk. This research has shown that whiskers form where the tin has compressive stress which can have many different causes. The US organisation International Electronics Manufacturing Initiative (iNEMI) has co-ordinated a lot of research and published guidance[14] on methods to minimise whisker formation. However these recommendations cannot all be adopted with non-magnetic pin connectors. Of the potential substitutes available, only tin and tin alloys electroplated onto copper terminals are viable because non-magnetic metals such as copper tarnish to give a high contact resistance. iNEMI recommend avoiding tin plated onto copper by using gold electroplated onto nickel or tin electroplated onto nickel, but these are not suitable options for this application as nickel is magnetic. iNEMI state that if tin is plated onto copper, it should be baked at 150°C within 24 hours to form a thin uniform intermetallic layer. This is also impractical with connectors containing heat sensitive plastic parts, and tin will still suffer from tin pest. One of the sources of stress is due to the formation of irregular crystals of tin-copper intermetallic phases that grow between copper substrates and tin plated coatings. Barrier layers and heat treatment prevent irregular tin-copper formation but are not options for this application. (COCIR 2011)

COCIR (2011) states that another source of stress in connectors is the deformation of the tin when connector pins are inserted. In this application, this stress is unavoidable. There appears to be no alternatives to lead addition to prevent tin whiskers for this application.

The behaviour of tin whiskers at very low temperatures (close to 4K) is not known and no published research has been found. If very low temperatures increase stress levels in the tin coating, this could increase the risk of whisker formation, but without long-term research this risk is not known. Table 10 sums up the findings for different potential substitute metals.

[14] iNEMI guidance on mitigation measures against tin whiskers, http://thor.inemi.org/webdownload/projects/ese/tin_whiskers/Pb-Free_Finishes_v4.pdf

Table 10: Overview on properties of metals potentially enabling the substitution of lead (COCIR 2011)

Connector terminal coating	Comments
Tin lead alloys	Non-magnetic and stable at liquid helium temperatures. Resistant to tin whiskers. Low electrical resistivity at 4K.
Tin, tin silver and tin copper alloys	Will undergo phase change and disintegrate – "tin pest" (see below) and also susceptible to tin whiskers
Tin bismuth	Bismuth retards tin pest phase transformation but is less effective than lead. Tin bismuth is susceptible to tin whiskers, especially as a nickel barrier layer cannot be used. Not readily available as a coating.
Rhodium	Contact material used in reed relays. Unsuitable as moderately paramagnetic
Silver	Tarnishes to give electrically insulating surfaces and inter-diffuses with copper
Nickel	Unsuitable as strongly ferromagnetic
Gold	Unsuitable without nickel barrier because copper from the terminal will diffuse into gold and then oxidize at the surface to give electrically insulating surface layers
Silver palladium alloy	Alloys with high silver content tarnish. Palladium increases magnetic susceptibility and increases electric contact resistance. Electroplating is very difficult, usually applied as thick film material which is not practical for connectors

According to COCIR (2011), the elimination of lead by using other interconnection technologies than pin connectors is impossible. The connectors allow connecting and disconnecting the SQUID detectors to the electrical measurement system in case of repair. Permanent soldered or brazed connections are unsuitable for this application.

10.3.4 Roadmap for the substitution of lead

COCIR (2011) proposes the following roadmap to develop substitutes although, according to COCIR (2011) no obvious candidate materials are available for evaluation. Any potential materials would be evaluated using test conditions which are representative for the operational conditions. This shall ensure that electrical resistance remains low, that no whiskers form, and that tin pest does not occur. As tin pest cannot be accelerated, this work will take many years with as long as 10 years testing being ideal. Should a suitable lead-free material be found, two years reliability testing in MEG equipment will be needed to collect data that will be needed to gain approval under the medical devices directive (MDD). COCIR (2011) indicates the following timescale:

- Research to identify potential alternatives 1–2 years
- Testing of alternative materials 10 years minimum
- Reliability testing with MEG 2 years
- Submission for MDD approval 1 year

COCIR (2011) says that from research and development starting in 2011, a usable substitute will not be available before 2026. COCIR (2012a) therefore asks for an exemption.

10.3.5 Environmental arguments

COCIR (2011) explains that, even though no technically viable substitutes are available for this application, it still provides life cycle information of the potential lead substitutes

- tin on copper,
- tin alloys on copper, and
- either silver or gold on copper

Mining and refining of metals used to make solders

COCIR (2011) puts forward that tin is widely available as tin ores and production of tin metal is straightforward. Lead is mined in large quantities as a primary metal with about 8 million tonnes per year being produced. Consumption world-wide is increasing despite the RoHS restrictions due to its main uses for batteries and as a building material.

Extraction and refining of lead from its ores is well controlled in most countries so that lead pollution does not occur. Sulphur dioxide is produced as a by-product which is used to make sulphuric acid.

Silver and gold mining, according to COCIR (2011), create large amounts of waste and consume much more energy than tin or lead refining. The quantities of emissions of hazardous substances are far greater than from lead refining. The US EPA has published an extensive life cycle analysis comparing tin-lead with lead-free alloys[15]. This shows that alloys containing silver have much larger environmental impacts than tin-lead in the production phase. Cyanide is used for extraction and refining silver and gold, and accidents causing serious environmental damage have occurred.

COCIR (2011) explains that bismuth arises as a by-product from mining other metals including lead. It is a relatively rare metal occurring at low concentrations so that significant quantities of energy are required to extract and refine this metal. Availability is not an issue.

[15] Life cycle analysis of lead-free and lead-based solders, http://www.epa.gov/dfe/pubs/solder/lca/index.htm; document referenced in COCIR (2011)

Assembly and use of medical equipment

(COCIR 2011) sees no differences during this life cycle phase unless premature failure were to occur due to tin pest or tin whiskers. Reliability with lead-free alloys is uncertain (tin pest and tin whiskers) and there is a risk that they may cause unexpected failures. These failures would have a negative impact on healthcare as the equipment will not be available at hospitals when needed. As MEG are expensive, hospitals will have only one machine available.

End of life

COCIR (2011) claims that at end of life, the pin connectors can be reused or recycled for metals recovery. The standard method for efficient metals recovery used for all types of electrical equipment is smelting and is ideally suited to these components. Copper, tin and lead are recovered with high yields by EU recyclers and emissions are well within the limits imposed by EU legislation.

COCIR (2011) describes the end of life of MEG in more detail for different metals:

- Lead
  Recycling of electrical scrap at end of life can be carried out safely using modern safe processes that are available in the EU and elsewhere. Only if unsafe recycling processes are carried out in developing countries, would lead pose a risk although this is small due to the very small amount of lead used in this application.
- Silver and gold
  It is likely that recyclers will want to recover silver and gold from equipment at end of life. There are safe and very efficient processes used by professional recyclers in the EU and elsewhere but there is a risk that unsafe methods using very hazardous chemicals such as nitric acid and cyanide might be used in developing countries where unsafe recycling occurs.
- Other tin alloy additives
  Other tin alloy additives including bismuth and copper may also be recovered by modern efficient recycling processes but bismuth is difficult to recycle without suitable complex processes and its presence reduces the value of printed circuit board scrap.

10.4 Critical review

10.4.1 Relation to the REACH regulation

Chapter 5 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. Lead and its compounds are thus listed in Annex XVII, and their use might weaken the environmental and health protection afforded by the REACH Regulation.

In the consultants' understanding, entry 30 of Annex XVII does not apply to the use of lead in the surface finishes of pin connectors. Lead and the tin-lead alloy used on the pin connector finish may be considered as substance, as constituent of another substance or a mixture. Putting, however, lead in pin connectors on the market in the reviewers' point of view is not a supply of lead and its compounds to the general public. Lead is part of an article and as such not covered by entry 30 of Annex XVII.

The consultants conclude that the use of lead in surfaces of non-magnetic pin connectors 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.

10.4.2 Scientific and technical practicability of lead substitution

According to COCIR (2011), an investigation (Burns, N.D., "A tin pest failure") found that 5% lead addition was effective at preventing tin pest, but 0.5% of bismuth or antimony were less effective. It may be natural that 5% of lead addition has less effect than 0.5% addition of bismuth. It may thus be possible that higher additions of bismuth solve the problem more effectively. COCIR (2012a) admits that tin alloy electroplated coatings with higher bismuth content can be produced. COCIR (2012a) explains that research at the Open University (cf. Table 8) has shown that tin pest occurs significantly more rapidly with tin-zinc-bismuth alloys having 3% of bismuth than with eutectic SnPb solder. The fact that bismuth is less effective than lead means that the lifetime of coatings at very low temperature made with lead-free alloys is uncertain but will be shorter than with SnPb. Further research is needed to determine if the lifetime is sufficiently long for the safe use of medical devices and this exemption is needed until this work is completed. No research has been carried out at low temperatures with tin having 5% of bismuth and so it is not possible to know if this will have a greater resistance to tin pest than the few tin-bismuth alloys that have been tested.

The applicant was asked whether the results in Table 8 actually prove that bismuth does not prevent tin pest efficiently. The reason that tin pest transformation occurred earlier compared to tin-lead in the examined tin-zinc-bismuth alloy could as well go back to the addition of zinc rather than being cause by bismuth. In SnPb there are only two constituents, while in SnZnBi and other alloys with three and more constituents, each single one besides tin may influence

the tin pest issue. SnBi alloys with a higher content of bismuth, e.g. SnBi58), but without zinc would have the additional advantage of low melting points (less than 140°C in case of SnBi58). This reduces the temperature requirements for the materials used, as the entire device could be soldered at temperatures clearly below 200°C, which is much lower than for lead solders.

COCIR (2012b) explains that no long term test data are available for such a SnBi alloys. The available studies included only SnZnBi, but did not test SnBi as it is not a commonly used solder. As it is not possible to accelerate life testing for tin pest, no useful data is available for this alloy. Another constraint is that alloys with higher bismuth content are more brittle, especially at low temperature, increasing the risk of cracking and delamination. For this reason, these alloys are rarely used. COCIR (2012b) concludes that all the very limited published data indicate that SnPb will survive for considerably longer than any SnBi alloy.

As no data are published on tin pest experiments with high bismuth containing SnBi alloys, and as such data cannot be provided within short periods either, the applicant's above statement is plausible.

The consultants conclude that, in the absence of contrary information, the applicant´s technical arguments plausibly justify that currently, lead in solders cannot be substituted in this application.

10.4.3 Scientific and technical practicability of lead elimination

COCIR (2011) claims that lead cannot be eliminated in this exemption, which raises some additional questions.

COCIR (2011) requests the exemption for non-magnetic pin connectors used below –20°C (253 K), while COCIR justifies the exemption with the operation temperature of minus 269°C (4 K). COCIR (2012a) explains that the current technology utilizes superconductors, which are immersed in liquid helium bath. Inside the cryostat several connectors are needed, part of which are not in liquid Helium bath but in the cold helium gas phase. As the temperature rises gradually from 4.2 K to room temperature at the access opening on top of the cryostat, the temperature range must cover the whole range where tin pest could occur.

This raises the question why the connectors cannot be placed more distant from the cold detector in a warmer zone using, for example, cables. COCIR (2012a) explained why the connectors must be located in the low temperature zones:

- The conductive path from the sensor to room temperature is made of dissimilar materials. For example the portion from RT to liquid helium bath is made of a high-resistive alloy to reduce the thermal conductance along the wires according to Wiedemann-Franz's law. This shall minimize the boid-off of liquid helium. Such high-

resistive materials cannot, however, be used at parts nearest the sensors because of noises disturbing the measurement signal.

- Certain electronic components are needed at the low temperature range end, mounted on printed circuit boards. However, due to noise reasons these components cannot be mounted directly on the sensors themselves.
- The wiring from a whole-head MEG sensor array to room temperature incorporates about 2000 distinct wires (length about 1 m). Having all wiring fixed from sensors to room temperature without any connectors is totally impractical for a field-serviceable unit. As the sensors must be replaceable for service operations (e.g. if a sensor does not meet noise specifications), modularity and low-temperature connectors are unavoidable.

The consultants conclude that, in the absence of contrary information, the applicant´s technical arguments plausibly justify that currently lead in solders cannot be eliminated in this application.

10.4.4 Environmental arguments

COCIR (2011 and 2012a) present environmental data and statements comparing the life cycles of lead with potential substitutes. As none of the substitutes can actually be used currently, these arguments were not reviewed. The consultants would like to point out, however, that this does neither indicate agreement nor disagreement with the applicant's environmental arguments.

10.4.5 Conclusions

The applicant's scientific and technical arguments are plausible. Based on the information submitted, the consultants conclude that a scientifically and technically practicable possibility for substitution or elimination of lead in this application is currently not available. Lead-free solutions in principle are practicable for pin connectors (cf. exemption 11(a) and 11(b) in RoHS Annex III). These solutions cannot, however, be transferred to the application in MEGs and similar devices due to the specific requirements resulting from the use of the pin connectors at extremely low temperatures on the one hand, and the impossibility to use nickel diffusion barriers. As scientifically and technically practicable and sufficiently reliable solutions are not available, the consultants recommend granting the exemption.

In order to narrow the scope of the exemption and to avoid its abuse, the consultants discussed a wording different from the one COCIR (2011) had proposed in its original exemption:

"Lead in the surface coatings of pin connector systems requiring non-magnetic connectors which are used durably at a temperature below -20°C under normal operating and storage conditions"

COCIR (2012d) agreed to this wording proposal for the exemption.

It is not clear whether the research into substitution or elimination of lead in this application would actually require ten years. COCIR puts forward that little research has been conducted on such extreme low temperature applications of tin-based lead-free alloys. It was finally and officially clear in July 2011 – the date of publication of the new RoHS Directive – that the devices of category 8 (medical equipment) of RoHS Annex I will come into the scope of the RoHS Directive, which in the consultants' point of view is the latest point in time when the manufacturers must be expected to start their research and substitution efforts. Thus, with less than one year passed since the adoption of category 8 into the scope of the RoHS Directive, in the absence of substitution and elimination possibilities, and additional time required for reliability testing and qualification of alternative solutions, the consultants have no indication to recommend an expiry date prior to the seven years maximum validity of exemptions adopted to Annex IV.

10.5 Recommendation

Based on the documents submitted by the stakeholders and in the absence of contrary information, the requested exemption would be in line with the requirements of Art. 5(1)(a). The consultants therefore recommend adding an exemption to Annex IV of the RoHS Directive with the following wording:

> *"Lead in the surface coatings of pin connector systems requiring non-magnetic connectors which are used durably at a temperature below -20°C under normal operating and storage conditions"*

The consultants recommend not to set an expiry date prior to the end of the maximum validity period of the exemption in July 2021.

10.6 Specific references

COCIR 2011 — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Original exemption request document "7-COCIR – Exemption request – Lead in nonmagnetic pin connectors"; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_7/7_COCIR_-_Exemption_request_-_Lead_in_nonmagnetic_pin_connectors.pdf

COCIR 2012a — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Questionnaire1_Exe-6_-answers_rev.pdf" submitted by stakeholder on exemption request no. 6 for the stakeholder consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/Questionnaires_Consultation/Questionnaire_Exe_07_Consultation.pdf

COCIR 2012b — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Questionnaire-2_Req-7_-Answers.docx" submitted by stakeholder on exemption request no. 7 on 20 April 2012

COCIR 2012c — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Questionnaire-2_Req-8 Answers.doc", submitted by stakeholder on exemption request no. 8 on 9 May 2012

COCIR 2012d — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Final clarifications.pdf", submitted by stakeholder on exemption requests 7, 8, 9 and 10 on 31 May 2012

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Zangl et al. 2011	Zangl, S.; Blepp, M.; Lui, R.; Moch, K.; Deubzer, O. Adaptation to Scientific and Technical Progress under Directive 2002/95/EC – Evaluation of New Requests for Exemptions and/or Review of Existing Exemptions, Final Report, Öko-Institut e.V. and Fraunhofer IZM, May 2011; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IV/RoHS_final_report_May_2011_final.pdf

11 Exemption request no. 8

"Lead in Solder for Electrical Circuitry that is used at Temperatures below -20°C"

COCIR (2011) requests an exemption for "Lead in Solder for Electrical Circuitry that is used at Temperatures below -20°C".

Abbreviations

Ag	silver
Bi	bismuth
MEG	magneto-encephalography
MRI	magnetic resonance imaging
NMR	nuclear magnetic resonance
Pb	lead
Sn	tin
SQUID	superconducting quantum interference device

11.2 Description of requested exemption

COCIR (2011) explains that exemption 12 in RoHS Annex IV allows the use of "Lead and cadmium in metallic bonds to superconducting materials in Magnetic Resonance Imaging (MRI) and Superconducting Quantum Interference Device (SQUID) detectors". This exemption covers electrically conducting bonds to the MRI superconducting magnet coil and to the SQUID detectors of MEG. Both of these products contain electrical circuits that are very cold but are not superconducting. This circuitry includes

- all of the electrical circuits that sustain the magnetic field,
- the safety shut down circuit,
- the magnet protection circuit,
- the helium monitoring circuit,
- the pressure monitoring and control circuit, etc.

According to COCIR (2012a), MRI magnets generating a magnetic field strength greater than a few tenths of a Tesla rely on superconducting wires (wires with zero electrical resistance) carrying electrical currents of a few hundred Amperes to generate the magnetic field. Use of non-superconducting wires would result in very high energy consumption and heat genera-

tion which would make the MRI magnet extremely costly and impractical. Superconducting wires only have zero electrical resistance at cryogenic temperatures. The actual temperature below which the wire has zero electrical resistance is dependent upon the wire material, operating current and magnetic field. Typical MRI magnets use NbTi superconductors, which must remain at a temperature below ~ 5 K (-268 °C) in order for the magnet to operate. Other superconducting materials do exist which can operate at higher temperatures. The only material available in commercial quantities is Nb_3Sn, which is technically more challenging to work with, significantly more expensive and is not superconducting above ~ 20 K (-253°C). So-called High Temperature Superconductors (HTS) are not expected to become cost competitive with NbTi and they are not produced in the quantities that the MRI industry requires. In addition, many technical challenges have to be overcome to enable their use in whole body MRI magnets and these HTS materials are still limited to operating at temperatures below ~150K (-83°C). No material exists which would allow whole body MRI magnets to operate at temperatures above -20°C.

Some solders are used in the coldest parts of some types of medical and other equipment such as an MRI machine that operates at 4 Kelvin (-269°C). There are several other types of equipment that utilise electrical circuits at very low temperatures including cyclotrons which are used to generate high energy particles and nuclear magnetic resonance (NMR) analysers, which are used for chemical analysis of organic substances. Both use superconducting magnets similar to those used for MRI. Cryogenic oxygen generators are used to make liquid oxygen for medical and other uses and will also have circuitry at low temperatures.

During normal operation, parts of the circuitry are thus exposed to a temperature range of 4 Kelvin to 100 Kelvin (respectively -269°C to -173°C). During ramp up of the magnet, the temperature range in parts of the circuitry can be approximately 100 Kelvin to 200 Kelvin (around -173°C to -73°C). During construction and under certain fault conditions this rises to room temperature values.

The solders used must be stable at these very low temperatures and tin-lead has traditionally been used as it is ductile and does not suffer from a destructive phase transformation known as “tin pest” during the normal life of these products.

COCIR (2011) says that this exemption is needed to allow the use of lead in tin-based solders, which are used, at least for part of their lifetimes, at temperatures below -20°C. COCIR (2012a) calculates the amount of lead used in this application as follows:

- The exemption would be used mainly in MRI systems, but also in NMR, MEG and in cyclotrons for particle therapy, all of which are also liquid helium cooled and have solder bonds under very low temperature conditions for the same reasons as MRI.

- Within the sealed vessel of MRI there are typically 2 to 3 PWB assemblies comprising approximately 100 joints per board. The MRI magnet also contains a number of small wire gauge cable looms which are comprised at one end of various sensors and devices that monitor and/or control the operation of the superconducting magnet, and which are exposed to the external world via hermetic connectors. This results in approximately 100 to 200 joints.
- The magnet also has main current leads (max current approximately 700 A) that are crimped and soldered to form the main current path for ramping up the super-conducting magnet.
- The amount of lead per MRI may differ. One manufacturer calculated approximately 0.5 kg of lead per MRI magnet, another manufacturer indicated approximately 1.8 kg for 1.5 T magnets, 0.97 kg for 1.0 T, and 2.7 kg for 3.0T.
- According to COCIR (2012a) around 700 of such devices are sold worldwide, of them around 280 within the EU. This results in a total use of lead of around 450 kg worldwide and around 180 kg in the EU.

11.3 Applicant's justification for the exemption

The most widely used lead-free solders are tin with silver and copper but it is well known that these alloys cannot be used at very low temperatures. This is due to "tin pest" where the tin undergoes a phase transformation from white "β" tin into grey "α" tin with an associated large change in volume (26%). This phase transformation causes the metal to disintegrate into a fine powder so that the electrical connection is lost. One recent example was of a laptop PC made with a tin/silver/copper solder alloy that was used in the mountains of Afghanistan by the US military. This failed after only a few years because the solder joints disintegrated as a result of the very low temperatures experienced in the field[16]. (COCIR 2011)

Tin pest occurs readily with pure tin and can, in theory, occur at temperatures below +13°C although it is not normally a serious problem with commercial lead-free solders at temperatures above -20°C. Some metal additives reduce the rate at which the phase transformation occurs and metals that dissolve in tin such as lead are effective to some extent.

It is therefore necessary to use lead in solders that are used below -20°C. There are no suitable alternative alloys that have the same or better resistance to tin pest and are known to provide high reliability at very low temperature conditions for the normal lifetimes of the equipment. High reliability is essential for certain types of medical devices such as MRI and

[16] http://www.indium.com/images/blogs/drlasky/files/TinPestPaper0723Final.pdf, referenced in COCIR (2011)

MEG. Unexpected failures pose a risk to the health of patients as the devices are not available when diagnosis or treatment is needed. Electrical circuits used at low temperatures cannot be assembled without soldering with tin-based alloys as will be explained here.

11.3.1 Tin pest

Tin pest has been known for many decades, but most research has been carried out at temperatures between -50 and -30°C because the phase transformation occurs most rapidly within this temperature range. The rate of tin pest transformation depends on two distinct processes:

- The first is nucleation where minute α-phase particles are formed within the β-phase. The driving force for nucleation is the difference in temperature between 13°C and the actual temperature and so the driving force for nucleation increases as the temperature drops. Nucleation usually requires a defect such as a grain boundary or a particle of impurity but the time for nucleation to occur can vary considerably.
- The second process is phase transformation where the α-phase grows from the initial nucleation sites. The rate at which this occurs also varies considerably depending on the alloy composition and its history (as this affects crystal structure) as well as the temperature.

Past research results have been rather confusing due to very inconsistent results, believed to be due to variables that affect the rate at which nucleation occurs as well as the rate of phase transformation, neither of which were understood or adequately controlled. Low levels of impurities are now known to be important but in early research these were not accurately determined because analysis techniques of sufficient accuracy were not available. Other variables that affect rates of both nucleation and transformation include cold working, thermal history, rate of cooling of solder, aging of solder, the effect of creep, all of which have all been found to affect the rate of phase transformation, some to a considerable extent.

Research at the Open University by Plumbridge[17] showed that pre-treatment of solder samples in ways that real solder joints experience gives samples which had a much higher phase transformation rates than samples that were cast and slowly cooled. In the Open University research, tin pest nucleation was found to take many years with some alloys. After nucleation, transformation from white to grey tin occurs as the nucleated particles grow. The rate of phase transformation depends on temperature and as with most chemical and physical processes, this decreases as the temperature drops. The kinetics of tin pest is therefore very complex, but the net result is that the phase transformation is usually fastest between around minus 30°C and minus 50°C.

[17] Plumbridge, W.J. “Further Observations on tin pest formation in solder alloys”, J. Electronic Materials, Vol. 39(4), p. 433, 2010, referenced in COCIR (2011)

Other elements added to tin significantly alter the tin pest behaviour. Some metals such as lead, antimony and bismuth retard tin pest whereas some such as copper and iron appear to increase the transformation rate. Metals that dissolve in tin such as lead usually retard tin pest as the solution of metals is less susceptible whereas metals such as copper that form solid inter-metallic phases increase the rate of transformation possibly due to the inter-metallic crystals acting as nucleation sites.

There is a lot of published research into tin pest, but frequently this provides contradictory results. It is believed that this is because tin pest transformation rates depend on all of the alloying elements including trace impurities present at very low concentrations which are usually not controlled. Research shows that high purity tin with intentional additions can give very fast phase transformations whereas commercial purity solders take much longer due to these trace impurities.

There are two other limitations with published research that is relevant to this exemption request. Firstly, most research is carried out over a period of less than two years (post graduate studies are usually completed with three years), but this is not sufficiently long to determine if and when tin pest will occur with commercial alloys because equipment lifetimes are much longer. Unlike other physical processes, it is not possible to artificially accelerate tin pest. Many physical processes are accelerated by raising the temperature but this is not possible for tin pest because if temperature is increased, nucleation is retarded and no transformation will occur if the temperature exceeds 13°C. Research therefore needs to be carried out for periods that are similar to the lives of the electrical products and for MRI. This can be 30 years. The other problem is the temperature at which research is carried out. The rate of phase transformation slows with decreasing temperature and so most research is carried out between around minus 30°C and minus 50°C to obtain results within the shortest time possible although this still takes many years.

The electronics located in cold regions of MRI are at temperatures as low as 4K which means that the rate of phase transformation will be slower than at minus 30°C and minus 50°C. However it is very difficult to determine by how much the rate is slowed and whether a solder alloy will survive 30 years based on research only at minus 30°C if there is no other data point at very low temperature to allow extrapolation.

Research published by the Open University has shown, after testing a range of commercial alloys at -18°C and -40°C for over 10 years, that some alloys such as SnCu suffer tin pest sooner at -18°C whereas others such as SnAg suffer tin pest sooner at -40°C. This research also showed that tin-lead solder also eventually suffers from tin pest at both temperatures although this alloy has been used in MRI for many decades without problems, which

indicates that at the much lower temperatures, the rate is sufficiently reduced for the solder to survive the life of the MRI. However this cannot be certain for any other alloys, especially if they have been shown to suffer from tin pest more rapidly than tin-lead.

The Open University research is studying SnCu, SnAg, SnAgCu and SnZnBi. All alloys have been studied so far for over 10 years at both temperatures except for SnZnBi with only six years. Table 11 summarises the results.

Table 11: Tin pest in tin alloys (COCIR 2011)

Alloy	-18°C 8 years	-18°C 10 years	-40°C 8 years	-40°C 10 years
SnPb	none	11.4%	none	37.5%
SnCu	35.8%	71.7%	14%	58.1%
SnAg	3.8%	22.9%	37.3%	98.7%
SnAgCu	24.2%	56.6%	10%	20%
SnZnBi	100% of samples suffered from tin pest at -40°C after six years			

These results show that all of the substitute alloys tested suffer from tin pest much sooner than SnPb, especially the standard lead-free alloys that are now widely used by the electronics industry. This research also shows that a lead-free solder containing bismuth is also unsuitable as it suffered from tin pest after less than 6 years, much sooner than SnPb.

Evidence that bismuth is less effective than lead additions to tin coatings is also available from research published in 2009[18]. This describes a case study where electroplated tin connectors suffered from tin pest after low temperature storage. This investigation found that 5% lead addition was effective at preventing tin pest, but 0.5% bismuth or antimony were less effective. A 0.5% bismuth addition is fairly standard for coatings on connector terminals.

The Open University ten years' research is the only long-term work on tin pest at low temperatures. All other research is much shorter. Where this research showed no transformation, the results are of little value as phase transformation may take longer than the duration of the tests and no comparison with tin-lead can be made. Tin pest unlike other physical processes cannot be accelerated because cooling slows the transformation rate and heating up to just below 13°C drastically slows the nucleation rate. No transformation occurs at higher temperatures. For details about nucleation see exemption request 7, section 10.3.2.

COCIR (2011) explains that tin alloys used in MEG will experience much lower operating temperatures than the minus 45°C studied in the Open University research. The effect of temperature on tin pest is that with decreasing temperature the thermodynamic energy to cause the phase transformation increases, but the rate of physical processes decreases. It is therefore difficult to predict what might happen at much lower temperatures and very little

[18] Burns, N.D. "A tin pest failure", J. Failure Analysis and Prevention, Vol. 9(5), p. 461, 2009, referenced in COCIR (2011)

published research is available. The overall rate of transformation depends on both nucleation and transformation. Published research[19] has shown that transformation rates depend on the temperature as illustrated in Table 12.

Table 12: Transformation rates at different temperatures (COCIR 2011)

Temperature	Theoretical transformation rate m/s
-10°C	1.5×10^{-5}
-20°C	1×10^{-5}
-30°C	0.6×10^{-5}

Nucleation rates depend on many variables including alloy composition, cooling rate, work history, etc., as well as temperature. Overall tin pest failure rates are impossible to predict and so must be measured. (COCIR 2011)

Alloy composition is one factor and Plumbridge found that tin pest occurred more quickly with SnCu and SnAgCu at -18°C than at -40°C whereas SnAg and SnPb was more rapid at -40°C than at -18°C. These differences are probably due to differences in both nucleation and transformation rates at these two temperatures and therefore it is impossible to predict how long tin pest will take to occur with lead-free alloys at all of the wide range of temperatures that occur within MRI and MEG cryogenic systems.

Very little research with tin-bismuth solders at very low temperatures could be found except for the work described above that indicates that it will be inferior to tin-lead. The US standard ASTM B545 states that “where electroplated tin coatings are subject to long-term storage or use at very low temperatures, it may be advisable to co-deposit small amounts (<1%) of bismuth, antimony, or lead with the tin. These alloying additions, particularly the first, have been shown to inhibit the transformation”. Also, the US Federal specification QQ-S-571 recommends 0.27% antimony addition to tin to prevent tin pest. The only other possible alloy addition where some research has been carried out is with additions of antimony.

The research described above shows that very low concentrations of antimony are ineffective, but tin-antimony solders with several percent of antimony is described in a patent application for cryogenic pumps as being resistant to tin pest at temperatures as low as 4 K[20]. SnSb solder is also recommended for cryogenic use by Vishay[21]. This states that the “presence of antimony prevents “tin disease”, can be used in cryogenic environments,

[19] http://www.electroiq.com/index/display/packaging-article-display.articles.advanced-packaging.volume-15.issue-11.features.tin-pest-in-tin-rich-solders.html, referenced in COCIR (2011)

[20] Patent Application WO/2009/146120 “Cryogenic pump employing tin-antimony alloys and methods of use”, D. Ball-Difazio, 2009; document referenced in COCIR (2011)

[21] Vishay “Solders and Accessories”, document number 1102319 th October 2004, referenced in COCIR (2011)

although is quite brittle at low temperature" and refers to the alloy with 5% antimony that has a melting temperature of 232–238°C. Sn5%Sb solder is therefore a very poor choice for MRI and MEG for two reasons:

- Its melting range of 232–238°C is 21°C hotter than standard SAC (SnAgCu) solder that melts at 217°C. The typical soldering temperature of SAC is ~260°C which is close to the upper safe limit for many types of electronic components. As 280°C would be needed for Sn5%Sb, this would be too hot for many types of electronic component and is likely to cause other types of defects to the printed circuit board that occur at very high temperature such as CAF (conductive anodic filaments) and board warping as well as destroying many types of component.
- Vishay states that Sn5%Sb is brittle at low temperatures. However there is considerable vibration in MRI machines and the cold electrical circuitry needs to withstand this severe vibration for the life of the equipment. The risk is high that Sn5%Sb would suffer from brittle failure due to this vibration.

11.3.2 Long term reliability of lead-free alloys at low temperatures

COCIR (2011) says that bismuth is used in some less common lead-free alloys but very little research on its low temperature properties has been published. SnSb solders are used as die attach alloys and to bond the pins of pin grid arrays to the IC package, but it is not used for assembling printed circuit boards as its melting point is too high. Table 13 gives an overview on the properties of lead-free alloys.

Table 13: Overview on properties of potential lead-free alloys (COCIR 2011)

Alloy type	Melting range	Tin pest susceptibility	Suitability
Sn5Sb	232 – 240°C	Resistant	Melting point too high
Sn-25Ag-10Sb	233°C	Not known	Melting point too high.
58%Sn42%Bi	138°C	Not known	Low melting temperature but may be too brittle. Bismuth alloys have poor thermal fatigue resistance[8].
57%Sn42%Bi1%Ag	139 – 140°C	Not known	More malleable than 58Sn42Bi. Fatigue resistance concern.
SnAgBi (+others) (Sn3.3Ag4.7Bi, Sn3.5Ag1Bi, various SnAgCuBi)	Typically 208 – 213°C	Not known but probably inferior to SnPb	Uncommon but available lead-free solders that have been used for laptop PCs (SMT only). Fatigue resistance similar to tin/lead but little data on reliability available.
SnAgIn		Test results available only for 20 months at -18°C	Very uncommon solder with little reliability data available
SnCu	227°C	Very susceptible	M.pt. 217°C. Used for wave soldering but too high temp for complex multilayer PCBs with heavy components
SnAg (+Cu)	217°C (eutectic alloy)	Susceptible	Common lead-free used for wave and SMT
Sn9Zn, Sn8Zn3Bi	189 - 199	Inferior to SnPb	Requires very corrosive fluxes which can damage other parts of the equipment. Zinc solders are susceptible to corrosion and so are rarely used
Sn4In3.5Ag0.5Bi	210 - 215	Not known	Patented by Mitsui Metals
Sn8In3.5Ag0.5Bi	197 - 208	Not known	Patented by Matsushita

HP tested 58%BiSn versus 63%SnPb for cyclic thermal fatigue resistance and found that SnBi bonds failed much sooner than SnPb with all of the package types tested.[22]

[22] "Low-temperature Solders", Z. Mei, H. Holder and H A. Vander Plas. H. P Journal, August 1996, referenced in COCIR (2011)

11.3.3 Other issues with lead-free solders at low temperature

COCIR (2011) argues that most research with lead-free solders has been carried out to simulate and accelerate the conditions experienced by consumer, household and IT products although some military-type applications have also been considered. Some of the tests involve brief excursions below 0°C (down to -40°C) but the time at low temperature in total is always relatively short and almost no research has been carried out at the temperatures that exist in cryogenic MRI and MEG applications.

COCIR (2011) concludes that apart from the risk of tin pest, the long term reliability of lead-free solder joints at very low temperatures is not known. Solders become less ductile as the temperature decreases and so at very low temperature they can become very brittle. Lead-free solders are less ductile than tin-lead solders at room temperature, as the Vickers hardness indicates:

- Eutectic tin 37% lead Vickers hardness = 12.9
- Tin 4.7% silver 0.7% copper Vickers hardness = 21.9

COCIR (2011) references research showing that lead-free solders are more susceptible to failure than eutectic tin lead solders when exposed to vibration with high g-forces[23]. The MRI environment is very harsh compared to other industries. The interaction of the strong magnet and gradient field can cause vibration and temperature fluctuations which can have detrimental effects on solder joints. Vibration and temperature cycling typical of consumer and IT equipment has been extensively studied, but there has been no research carried at the low temperatures that occur close to MRI magnets.

COCIR (2012a) argues that MR scanners are expected to be in service with clients for at least 10 years. To simulate actual vibration levels and thermo-mechanical effects for at least 10 years service, the typical test conditions used for MR environment reliability tests are:

- Vibration levels up to 70 G_{rms} for 180 hours, corresponding to 19,000 hours MRI scan time, which, according to COCIR (2012a), is far worse than automotive.
- Number of temperature Cycles (=number of exams on patients) is 6300/year covering 90% of MRI used in the EU. This is, according to COCIR (2012a), far worse than automotive, and comparable with space.

[23] Various research studies, e.g. http://www.jgpp.com/projects/lead_free_soldering/April_4_Exec_Sum_Presentations/JTR%20Reliability%20Conclusions%20March%2028%202006.pdf, referenced in COCIR (2011)

COCIR (2011) concludes that there is therefore an unquantifiable risk that lead-free solders, which are brittle at low temperatures, have a greater risk of failure at very low temperatures due to vibration than more ductile tin-lead solders.

11.3.4 Alternative bonding materials and techniques

COCIR (2011) provide some details about possible alternatives for bonding materials and techniques.

Solder alloys with lead contents below 0.1% of weight

Medical equipment manufacturers have to use commercially available solders and so solder with slightly less than 0.1% lead cannot be easily obtained. The lead content of lead-free commercial solder does, however, vary. Alloys with 0.08% of lead may be found although alloys with 0.03% to 0.05% lead are more common. It is likely that 0.08% lead will give some improved resistance to tin pest compared to no lead, but the resistance is unlikely to be sufficient.

Eutectic SnPb solder contains 37% lead, far more than 0.08%. The Open University research described above used commercial lead-free solder alloys which will contain less than 0.1% of lead, probably around 0.05% as this is typical. This concentration of lead is clearly insufficient and so more than 0.1% lead is needed.

Conductive adhesives as alternatives to solders

An alternative to solders are conducting adhesives. This is, however, only very rarely used to assemble electrical circuitry because its long term reliability and performance (i.e. permanent low electrical resistance) is usually inadequate for most applications. It will not be suitable for use in this application because the bonds to components must be resistant to severe vibration and large temperature changes including very low temperatures where most adhesives will become extremely brittle.

Brazing and welding

Brazing and welding avoids the use of tin so that tin pest is not an issue. However, these bonding techniques cannot be used to build electrical circuitry between copper wire and electronic components because the very high temperatures of more than 500°C for brazing and more than 1,000°C for welding would destroy not just many of the types of components that need to be used, but also the printed circuit board material on which they are to be mounted.

11.3.5 Environmental and resource aspects

Even though no technically viable substitute has been identified at present, COCIR (2011) have submitted further information concerning life cycle aspects, of potential substitutes (bismuth / indium / antimony / silver / zinc) to further enhance their argumentation.

Information includes reference to the availability of other metals, the energy consumption required for their extraction and refining and information concerning the re-use and recycling of waste.

11.3.6 Roadmap for the substitution of lead

Research into lead-free solder alloys for use at low temperatures

It is necessary to gain approvals under the Medical Device Directive after a change has been made to a medical product before the modified product design can be sold in the EU. The change from SnPb solder to lead-free solder is sufficient to require extensive testing and application for approval.

The most time consuming research however is the search for tin pest resistant solders that are suitable for use in MRI, MEG, etc. Research described above shows that at least 10 years testing of potential solders at realistic temperatures for these applications will be needed and this cannot be accelerated. Work published to date has not identified a suitable lead-free alloy and so alternative alloys will need to be evaluated. If this were to begin in 2011, it would not be completed until at least 2021, and ideally longer testing should be carried out.

If a potentially suitable alloy were to be identified, time would be required subsequently to:

- Construct prototype circuit board assemblies and carry out comprehensive reliability testing, which can take two years.
- Build prototype equipment such as MRI using the new alloy (if identified by testing described above) and carry out extensive testing to ensure that accuracy of results and long term reliability are not affected. This can take another two years
- Submit reliability data to Notified Body and request MDD approval. MRI and MEG are complex products so that this could take another year.

These activities will require a further five years after tin pest testing which means that this exemption would be required until at least 2026 with 2030 being realistic, although it is possible that no suitable substitutes will be identified for this very demanding application.

COCIR (2011) concludes that it will clearly be impossible to replace tin-lead with an alternative solder in the period remaining before medical devices are included in the scope of the RoHS Directive and therefore asks for an exemption to be included in Annex IV of the RoHS Directive.

11.4 Critical review

11.4.1 Relation to the REACH regulation

Chapter 5 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. Lead and its compounds are thus listed in Annex XVII, and their use might weaken the environmental and health protection afforded by the REACH Regulation.

In the consultants' understanding, entry 30 of Annex XVII does not apply to the use of lead in solders and termination coatings. Lead and the tin-lead alloy used may be considered as substance, as constituent of another substance or a mixture. Putting, however, lead in solders and finishes on the market in the reviewers' point of view is not a supply of lead and its compounds to the general public. Lead is part of an article and as such not covered by entry 30 of Annex XVII.

The consultants conclude that the use of lead in this requested exemption 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.

11.4.2 Scientific and technical practicability of substitution and elimination of lead

The applicant was asked whether it was not possible to install the printed circuit boards outside the cold zone thus avoiding the tin pest and potential reliability implications at low temperatures. COCIR (2012a) explains that for its operation a superconducting magnet relies on cryogenic. For the control and monitoring of the superconducting magnet, various sensors and devices are exposed to very low temperatures. The magnet would not work without these devices, and a number of these devices are integral to the safety of the magnet system e.g. ensuring uncontrolled high voltages do not appear externally during fault conditions, or that the magnet can be brought to zero field in the event of an emergency.

Furthermore, COCIR (2012a) puts forward that the number of connections between the cryogenic parts of the magnet and the external world (at room temperature) is as small as possible to minimize cooling needs and respectfully, energy consumption and to avoid loss of liquid helium. The connections to each sensor and to the superconducting coil therefore are within the cryogenic sealed vessel which is operated at low temperatures. Solder connections are the only type that will be reliable at such low temperatures. Sensors and other devices are not made with very long leads and if they were, these could not be passed through the wall of the sealed vessel.

There is thus no information showing that the substitution or elimination of lead is possible in this application.

11.4.3 Environmental arguments

The applicant puts forward environmental data and statements comparing the life cycles of lead with potential substitutes. As none of the substitutes can actually be used currently, 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

11.4.4 Conclusions

The applicant's scientific and technical arguments put forward for the justification of the exemption request are plausible. In the absence of contrary information, the consultants conclude that the substitution or elimination of lead is currently not possible in this application.

COCIR puts forward that little research has been conducted on such extreme low temperature applications of tin-based lead-free alloys. It is not clear whether research into viable substitutes actually would take until 2026 however as demonstrated by the applicant, it is clear that besides the time required for research into substitutions, additional time would be required to complete the authorization of use of substitutes in these applications due to their medical purpose.

It was finally and officially clear in July 2011 – the date of publication of the new RoHS Directive – that the devices of category 8 (medical equipment) of RoHS Annex I will come into the scope of the RoHS Directive, which in the consultants' point of view is the latest point in time when the manufacturers had been expected to start their research and substitution efforts. Thus, with less than one year passed since the adoption of category 8 into the scope of the RoHS Directive, in the absence of substitution and elimination possibilities, and in light of the additional time required for reliability testing and qualification of lead-free solutions, the consultants have no indication to recommend an expiry date prior to the seven years maximum validity of exemptions adopted to Annex IV.

To clarify the scope of the exemption, the following wording was agreed with COCIR (2012c):

Lead in

- solders on printed circuit boards,
- termination coatings of electrical and electronic components and coatings of printed circuit boards
- solders for connecting wires and cables,
- solders connecting transducers and sensors,

that are used durably at a temperature below –20°C under normal operating and storage conditions.

11.5 Recommendation

Based on the documents submitted by the stakeholders and in the absence of contrary information, the requested exemption would be in line with the requirements of Art. 5(1)(a). The consultants therefore recommend adding an exemption to Annex IV of the RoHS Directive with the following wording:

Lead in

- *solders on printed circuit boards,*
- *termination coatings of electrical and electronic components and coatings of printed circuit boards*
- *solders for connecting wires and cables,*
- *solders connecting transducers and sensors,*

that are used durably at a temperature below –20°C under normal operating and storage conditions.

The consultants recommend not to set an expiry date prior to the end of the maximum validity period of the exemption in July 2021.

11.6 Specific references

COCIR 2011 — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Original exemption request document "8-COCIR – Exemption request – Lead in solders low temperature.pdf"; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_8/8_COCIR_-_Exemption_request_-_Lead_in_solders_low_temperature.pdf

COCIR 2012a — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Questionnaire1_Exe-6_-answers_rev.pdf" submitted by stakeholder on exemption request no. 6 for the stakeholder consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_8/Questionnaire-1_Exe-8_answers.pdf

COCIR 2012b — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document:

Questionnaire-2_Req-8 Answers.doc", submitted by stakeholder on exemption request no. 8 on 9 May 2012

COCIR 2012c — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Final clarifications.pdf", submitted by stakeholder on exemption requests 7, 8, 9 and 10 on 31 May 2012

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Gensch et al. 2009 — Gensch, C.; Zangl, S.; Groß, R.; Weber, A. K.; Deubzer, O.; 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

Goodman 2006 — Goodman, P. 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 2009 — Goodman, P. 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

RoHS Directive 2003 — Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0095:EN:NOT

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
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12 Exemption request no. 9

"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"

Abbreviation

G_{rms}	unit to specify and compare the energy in repetitive shock vibration systems[24]

12.2 Description of requested exemption

Magnetic Resonance Imaging (MRI), high-end Nuclear Magnetic Resonance (NMR) analysis and cyclotrons for particle therapy utilise very powerful magnets. MRI is a medical technique used to diagnose conditions associated with soft tissue such as detecting tumours,

[24] Doertenbach, Neill, QualMark Corp.: The Calculation of G_{rms}; http://www.dfrsolutions.com/uploads/services/HALT_grms_calculation_ndoertenbach.pdf; last accessed 23 April 2012

blockages in blood vessels and damage to internal organs. MRI uses the very powerful magnetic field of a large very powerful magnet, in which the patient is placed. When patients are examined by MRI, they are exposed to a very powerful magnetic field. “Radio Frequency (RF) send and receive coils” are located around the patient and inside the magnetic field. Coils transmit RF signals which excite magnetised protons in soft tissue of the patient and the protons then emit characteristic signals that are received and measured by these coils. One of the essential characteristics of the coils and the electronic circuitry that is connected to each coil is that these must be non-magnetic because any magnetic materials degrade the weak RF signals resulting in distorted MRI images. (COCIR 2011)

COCIR (2012c) states that in particle therapy, powerful magnets are used in the cyclotron and in the beam transport line. The cyclotron magnets are used to maintain the particles in an accelerated path. This creates a beam of high energy particles, which leaves the cyclotron. Transport magnets direct the beam to the patient who is in a different room, some distance away from the cyclotron. Beam transfer (or beam transport) from the cyclotron to the treatment room happens via a "tunnel" of magnets in which the beam is held inside the magnets. At the end of the beam transport section close to the patient is the "nozzle" which contains a number of powerful scanning magnets that are used to bend and direct the beam accurately in order to focus it onto the patient's tumor. The nozzle controls the beam's final direction.

According to COCIR (2011), circuits that are located close to and within the magnetic field use non-magnetic components where possible, to avoid degradation of the MRI image. This is especially important for the electronic circuits that are within the MRI magnet or are electrically connected to these circuits nearby. Magnetic materials will be strongly attracted by the powerful magnets and so either be damaged by the strong attraction force or they may cause distortion of the magnetic field and thus reduce the image accuracy. The same applies to special patient monitors that are attached to patients and are used inside the MRI for patients who are very ill and need to be constantly monitored during the diagnostic examination.

COCIR (2011) mentions research, which has shown that metals with even very small magnetic susceptibility degrade the image quality reducing the ability to detect small features such as tumours or blood clots (see Figure 4 and Figure 5). The types of components used are the same as in other electrical equipment such as capacitors, inductors and resistors, but special “non-magnetic” versions need to be used. The most common termination coating used for standard electrical components in most electrical products is tin or tin-lead electroplated over a nickel plated barrier layer. Nickel prevents loss of tin coating during storage as tin and copper react to form an unsolderable intermetallic phase. Nickel is, however, strongly ferromagnetic and so cannot be used within the region of the RF coils.

Components used for MRI within the magnetic field or connected to send and receive coils need to be soldered to create the electronic circuits and so components having nickel-free solderable coatings are used. These non-magnetic components are manufactured specifically for MRI and similar applications. The choice of terminal materials is very limited as the metal used for the outer surface must be wetted by solder easily and quickly (COCIR 2011). Soldering non-magnetic components with lead-free solders creates technical difficulties and concerns about the long-term reliability of the solder joints.

Many different components are used for these applications and some, but not all, are available without lead in the termination coatings. Most non-magnetic components of MRI are soldered to flexible printed circuit boards by hand with soldering irons, although surface mount technology is beginning to be used by some manufacturers. Figure 3 shows an example of such a printed circuit board assembled with non-magnetic components.

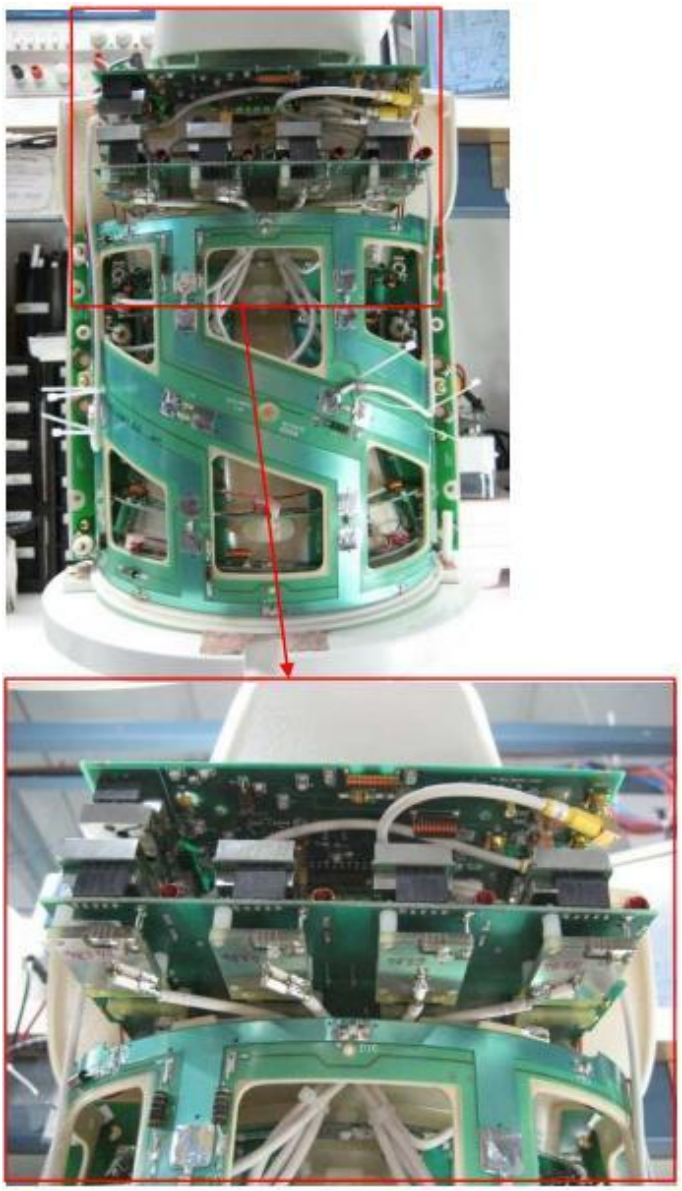

Figure 3: Non-magnetic circuitry of MRI equipment

COCIR (2011) concludes that the use of lead-containing solders and component coatings is therefore still required in MRI, high-end NMR and cyclotrons requiring the use of non-magnetic components. Several applications are thus related to this exemption request:

- Lead in solders used for making connections to non-magnetic components in MRI radio frequency (RF) send and receive coils
- Lead in the solderable coatings of non-magnetic electronic components used in MRI RF send and receive coils.

- Lead in solders and solderable coatings of other electrical circuits, such as in patient monitors, which are used inside MRI magnets or are located sufficiently close to cause distortion of MRI images.
- Lead in solders and solderable coatings of circuits of high-end NMR, cyclotrons and other devices that use superconducting magnets where magnetic materials will degrade performance.

COCIR (2012a) calculates the amount of lead used in these applications as follows:

- Predominantly MRI as scanners and as coils will use this exemption, but also NMR. For RF coils, a head coil is representative. A head coil contains around 18 g of lead.
- An MRI scanner typically has 63 printed circuit boards each with roundabout 2.5 g of lead, and one body coil with an average 4.5 g of lead resulting in around 162 g of lead.
- Annually, the world sales of RF coils amount to 20,000, from which 6,000 (30%) are put on the market in the EU. For MRI scanners, the world market is 2,600 scanners per year, from which 780 units (30%) are sold in the EU.

Based on the above data, COCIR (2012a) calculates a total of around 750 kg of lead applied in this exemption worldwide, with approximately 250 kg (30%) of lead put on the EU market.

12.3 Applicant's justification of the exemption

COCIR (2011) claims that the continued use of lead in this application is required, as its substitution is technically not yet practicable. Lead-free assemblies are difficult to manufacture, and the manufacturers are concerned about long term reliability.

COCIR (2012a) puts forward that the main roadblock to lead-free soldering in these application, in comparison with the use of lead-free soldering in other applications, is the requirement to use non-magnetic components, where the electrical and electronic circuitry is exposed to strong magnetic fields. These components are usually coated with lead solder or alternatively are validated to only be used with solders that are in the lead based temperature range and not the non-lead based temperature range. In addition, many of these components have wires that connect to the component body part, where lead is also used for that termination inside the component. Examples of these components include leaded capacitors, variable capacitors, diodes, inductors, RF connectors, etc. The medical devices industry is the only industry that actually asks for no nickel coating, which can easily be replaced by lead-tin finishes on the terminations.

COCIR (2011) explains that the use of magnetic components is possible only under specific conditions:

- Components containing very small amounts of magnetic metals such as nickel, however, many MRI components, are quite large (see Figure 3 above) so that the magnetic versions would contain large amounts of nickel.
- If many very similar circuits having identical magnetic fields are arranged around the patient cavity, it is possible to design these so that the impact of the magnetic components on the image is minimal. This is not possible with most MRI circuits and so they must use non-magnetic components. For example, there may be only one of a type of module that is located at one side.

COCIR (2011) claims that in most cases, the use of non-magnetic components is indispensable. Figure 4 shows an image of a breast phantom acquired with a breast coil. The coil employed pre-amplifiers which had a voltage regulator containing nickel. The field distortion resulting from the nickel in the pre-amplifier caused a loss of image in the lower right hand corner.

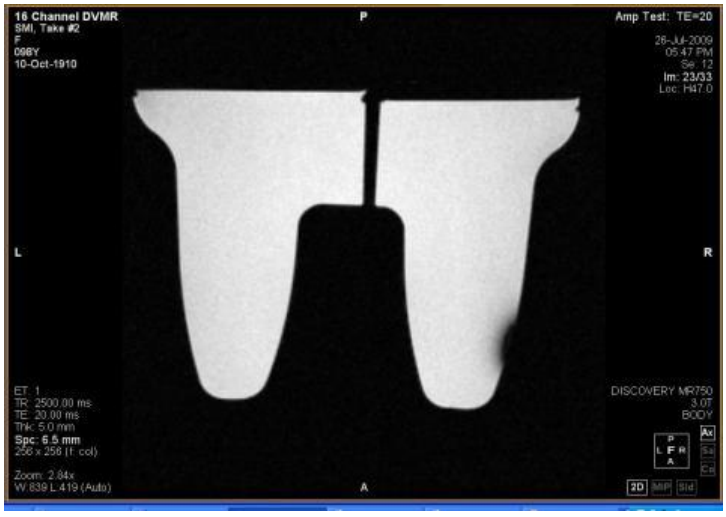

Figure 4: Loss of image in the lower right hand corner due to magnetic field distortion caused by a nickel-containing pre-amplifier (COCIR 2012a)

Figure 5 demonstrates a loss of image on the upper left due to nickel on capacitor terminations.

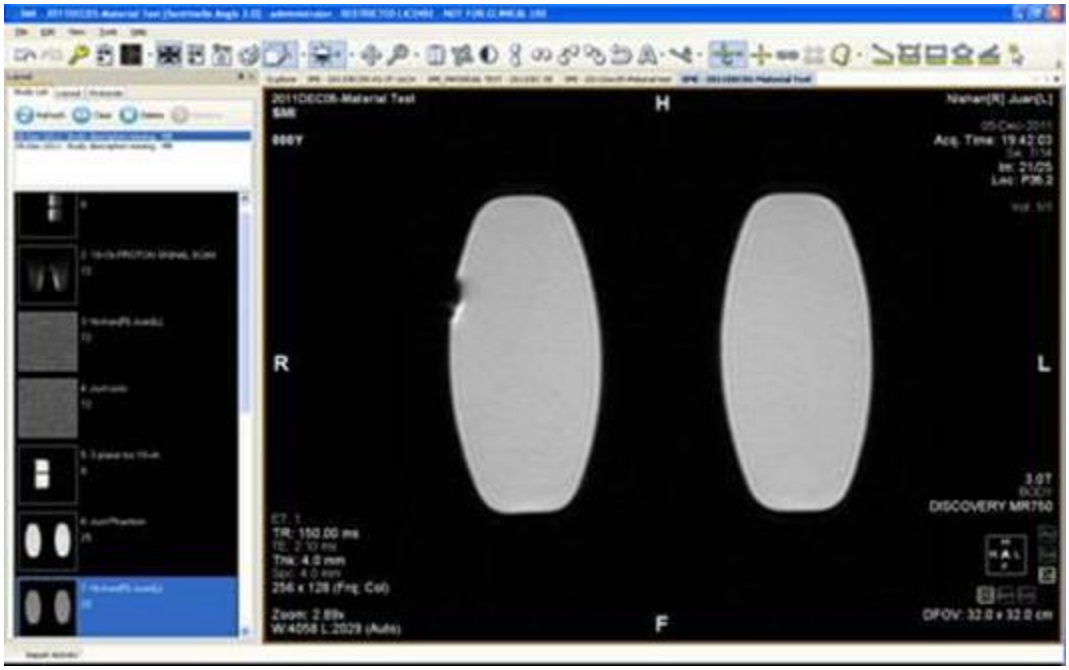

Figure 5: Image loss on the upper left from nickel on capacitor terminations (COCIR 2012a)

Trials to construct non-magnetic (nickel-free) circuit designs with lead-free solders have given very poor yields and testing of lead-free MRI circuits has found poor reliability. This raises concerns that lead-free designs may have a negative impact on reliability and a lot more research is needed to ensure that patient healthcare is not affected. Some of the non-magnetic components are not even available as RoHS compliant versions, which extends the time needed to carry our research and development work for the change to lead-free solders and finishes.

12.3.1 Alternative non-magnetic termination coatings

Goodman (2006) concluded in the ERA report for the EU Commission that temporary exemptions for lead in solders may be required should category 8 and 9 equipment be included into the scope of the RoHS Directive. The report was published in 2006 and since then, research into substitutes has been on-going. The results show that lead-free substitutes are not yet technically viable for this application and can be less reliable.

According to COCIR (2011), standard electrical components have terminations that are most often tin electroplated onto nickel, but as nickel cannot be used for MRI applications within or connected to the magnetic field, alternative types of termination have been developed to achieve non-magnetic components. Metals that can be wetted by solder include tin; tin alloys with lead, copper, silver, some bismuth alloys, gold, silver and silver palladium. COCIR (2011) argues that reliability and solderability issues limit the choice of termination coatings to the following three options:

Tin-lead alloy over copper

This alloy over copper has been used for many years with tin-lead solder and has proven reliability.

Silver-palladium (Ag-Pd)

This metal has been used as a lead-free option, but the wetting properties of Ag-Pd are different to both lead-free and tin-lead solders. The alloy has caused solder leaching and wetting problems.

Tin over copper

This was developed as an alternative to Ag-Pd as it wets easily but it also experiences reliability problems that will be explained here.

COCIR (2011) states that solders can wet further metals as well, but these exhibit other problems:

Gold

Gold forms a brittle intermetallic phase with tin so that bonds fail when exposed to relatively small mechanical forces such as vibration

Copper and bismuth

These metals oxidise in air becoming unsolderable after a few days in storage

Silver

Silver tarnishes in the presence of minute amounts of hydrogen sulphide, which is a very common atmospheric contaminant gas. Tarnished silver cannot easily be soldered.

According to COCIR (2011), the type of component coating depends on the type of electronic component.

- Semiconductor devices such as ICs use lead-frames made of copper or other alloys that are usually electroplated with nickel and then tin or tin-lead, or with nickel and then a thin gold coating. Nickel barriers increase storage life by retarding SnCu intermetallic formation and reduce the risk of tin whiskers. Thin gold coatings cannot be deposited onto copper directly, as these interdiffuse to leave copper that oxidises and thus becomes unsolderable at the surface.
- Chip components such as resistors, capacitor and inductors use “thick-film” pastes consisting of a metal and glass that are heated to melt the glass to bind the metal conductor. Most thick-film pastes are based on silver, silver-palladium alloy or copper.

As these metals all dissolve rapidly in molten solder forming thick and brittle intermetallics, they are usually encapsulated by a nickel layer. As nickel is not solderable, it has to be coated with tin or tin-lead.

- Components with wire connections which include transformers and coils usually have copper wires that are tin plated. The copper wire is normally relatively thick to compensate the higher copper dissolution rate that occurs with lead-free solders with a high tin content. Nickel barriers are not needed therefore. Some of these components, however, have very fine wires where copper dissolution in lead-free solders is an issue, and exemption 33 of RoHS Annex III allows tin-lead solders to be used for soldering very thin wires (<100 micron diameter) of power transformers

Alternative component termination coatings are compared in Table 14:

Table 14: Comparison of different coating materials (COCIR 2011)

Coating material	Advantages and disadvantages
Tin (Sn)	Good solder wetting properties but susceptible to tin whiskers if deposited onto copper without a nickel barrier layer. Not recommended by iNEMI[2]. Very low magnetic susceptibility.
Tin/lead (Sn/Pb)	Good solder wetting, resistant to tin whiskers without nickel barrier layer. Lead also has a very low magnetic susceptibility.
Tin alloys: Tin/copper, tin/silver and tin/bismuth alloys	Susceptible to tin whiskers especially tin/copper. iNEMI recommends tin/silver and tin/bismuth should be used only with nickel barrier layers. SnAg coatings are not thoroughly researched and SnBi has diamagnetic properties that may affect sensitivity.
Gold (Au)	Cannot be deposited as thin coatings on copper as interdiffusion occurs resulting in copper at the surface which oxidises and then cannot be easily soldered. Thick gold coatings cannot be used as gold forms a very brittle intermetallic compound with tin (with all types of tin based solders) which causes rapid bond failure.
Silver (Ag)	Low magnetic susceptibility but tarnishes during storage becoming unsolderable. Also suffers from fairly rapid interdiffusion with copper (see gold above).
Silver/palladium (Ag/Pd)	Applied as thick film material instead of copper and avoids need for an outer coating. Solder wetting is however inferior and there is a risk of weak solder bonds. Palladium also has a relatively high magnetic susceptibility and tests have shown that components with Ag/Pd terminations give inferior sensitivity of the MRI image. The magnetic susceptibility of components with AgPd is about three times that of tin plated copper.

Coating material	Advantages and disadvantages
Copper	Very low magnetic susceptibility but cannot be used without a coating of an oxidation resistant solderable material such as tin or tin/lead because it rapidly oxidises and becomes unsolderable. Copper readily diffuses into tin, gold and silver and so nickel barriers are used when magnetic properties are not important. Electroplated tin deposited onto copper is more susceptible to tin whiskers than where a nickel barrier layer is used.

During soldering, the coating metal dissolves in molten solder at a rate that is proportional to the temperature. The dissolution rate increases with the temperature. Table 15 illustrates the dissolution rates of various alloys.

Table 15: Copper dissolution rates in solders (COCIR 2011[25] [26])

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.)

These results show that the risk of complete loss of copper substrate is higher with lead-free solders than with tin-lead solder. Nickel barrier coatings react with liquid solder much slower but cannot be used in non-magnetic components, and silver and gold dissolve in liquid solder as rapidly as copper.

Table 15 demonstrates the risk to components that have thin termination coatings, as long periods of contact with liquid solder can cause complete dissolution thus leaving an open circuit. This is exacerbated by the higher melting temperature of all types of lead-free solders

[25] 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; referenced in COCIR (2011)

[26] C. Hunt and D. Di Maio, “A Test Methodology for Copper Dissolution in Lead-Free Alloys”, National Physical Laboratory, UK; referenced in COCIR (2011)

(see Table 16) that are used commercially, as the dissolution rate increases with temperature.

Table 16: Melting points of solders (COCIR 2011)

Solder alloy	Melting temperature
SnPb	183 °C
SnCu	227°C (
SnAg	221°C (3.5%Ag)
Sn3.5Ag0.5Cu	217 °C

Lead-free solders are now widely used by the electronics industry, but these have significant disadvantages when soldering to non-magnetic components which do not have nickel barrier coatings. (COCIR 2011)

12.3.2 Influence of the soldering process conditions

In the last few years, manufacturers of electronic components have introduced a wider range of components that are “RoHS compliant”. These manufacturers give advice on soldering their components and claim that soldering with lead-free solder is possible, but there are limitations which are described here. Furthermore, there are still some types of components commonly used in MRI that are not yet available in RoHS compliant versions. (COCIR 2011)

COCIR (2011) says that MRI circuits used, either inside the magnetic field or attached to circuits that are in the field, may be either hand or reflow soldered. Reflow soldering can be well controlled so that components terminations are exposed to a limited maximum peak soldering temperature for a maximum period of time to achieve a reliable solder bond without damaging the components. Whether this time and peak temperature are achievable in practice depends on many variables. These variables include:

- The size of other components on the printed circuit board. Larger ones need more time for wetting so that the smallest components are in contact with liquid solder for much longer.
- Type of flux used; more corrosive fluxes can be faster but can also cause corrosion problems
- Age of circuit board and components; solder wetting times tends to increase as components age due to increased oxidation of coatings

In the reflow process using solder pastes, the circuit boards are held at high temperature for sufficient time to melt the solder and to form the solder bond between the liquid solder and the termination material. In practice, the liquid metal dissolves the termination metal, and so if left for too long, can remove the termination coating completely. The peak temperature required for lead-free solders such as with eutectic tin-silver-copper solder (known as SAC) is higher than that of tin-lead due to its higher melting point (217°C and 183°C respectively).

The actual temperature required depends on the circuit design, component size and the performance of the reflow oven, but it is not uncommon for manufacturers to require 250°C – 260°C and for the solder to be above its melting point for more than 60 seconds. The problem is that liquid tin-based solders dissolve termination coatings at a rate that increases with temperature. This is rapid with tin and copper but much slower with nickel. (COCIR 2011)

COCIR (2011) reports that some manufacturers recommend maximum peak temperatures and time at above melting point with lead-free solders such as SAC and some publish recommended limits for the time exposed to molten solder. The limits published by different manufacturers cannot usually be compared directly as they are measured in different ways, but they are indicative. Table 17 shows a selection of maximum times at reflow temperatures.

Table 17: Published maximum temperatures and peak temperatures for soldering non-magnetic components (COCIR 2011)

Component manufacturer, component and termination coating	Maximum specified reflow temperature	Maximum specified time at peak temperature
Syfer MLCC with Ag/Pd (from Syfer Technical Summary)	240°C	<20 seconds
	260°C	<~7 seconds
Vishay MLCC with Ag/Pd (Tech note TN-0029)	260°C	<40 seconds
Vishay MLCC with Sn/Cu	260°C	As specified in J-STD-020
Temex MLCC Ag/Pd	260°C	< 10 seconds (120 seconds is OK for Sn on nickel barrier)
Temex MLCC Sn/Cu	260°C	10 – 30 seconds
Temex Chip Trim ceramic capacitor (tin terminations)	265°C	Maximum 3 seconds

MLCC = multilayer ceramic capacitors

The maximum times vary considerably between 3 and 40 seconds. Lead-free reflow soldering usually requires at least 30 seconds above the solder melting temperature (and often more than 1 minute) to achieve good wetting of all components on the printed circuit board whereas times above melting point with tin-lead solder tend to be shorter.

Soldering to components with thin termination coatings or to thin wires clearly needs as short a time in contact with liquid solder as possible. Wetting times can also affect the time that terminations are exposed to liquid solder because, when a printed circuit board is soldered, it is necessary to wait until the last bond has formed. This will usually be to the component with the highest thermal mass, which takes longest to reach soldering temperature. Any additional time for wetting to occur extends the time that already wetted bonds are exposed to liquid solder. Wetting time is strongly dependent on the flux composition, but in general, as long as suitable fluxes are used, wetting times for tin-lead solders are shorter than most types of

lead-free solder. Asahi, a solder manufacturer, published tests comparing a variety of alloys by wave soldering a standard printed wiring board at a soldering temperature of 245°C.

Table 18: Wetting Times of Solders at 245 C (COCIR 2011[27])

Alloy composition	Wetting time (seconds)
Tin / lead	0.6
Sn0.7Cu	1.0
Sn3.5Ag	1.4
Sn3.5Ag3.0Bi	1.7
Sn4Ag0.5Cu	1.9

COCIR (2011) admits that it is unrealistic to compare tests at 245°C because SnPb is typically soldered at ~235°C whereas lead-free alloys may be at ~255°C. However, at these temperatures, Asahi's test results show that SnPb has the shortest wetting time:

- SnPb at 235°C ~0.77 seconds
- SnAgCu at 255°C ~1.28 seconds

COCIR (2011) references Asahi stating that the Sn3.5Ag and SnAgCu alloys they tested had wetting times that are too slow for wave soldering. These alloys are used for hand soldering and as solder pastes.

COCIR (2011) presents further results provided by Renasas[28]. The tests illustrate that the effect of the plating layer composition on component terminations when soldered with a SAC lead-free solder is also dependent on termination coating alloy composition:

Table 19: Wetting times of different component packages (COCIR 2011[28])

Component type and termination coating	Average wetting time (secs)	Range of wetting times (secs)
TO package with SnCu	1.33	0.86 – 1.65
TO package with SnPb	0.49	0.43 – 0.60
QFP with SnBi	0.42	0.28 – 0.64
QFP with SnPb	0.24	0.23 – 0.25

Hand soldering of lead-free components with lead-free solders is more challenging than with SnPb solder. Chip-components, especially chip capacitors, are fairly fragile devices and can crack as a result of thermal shock if the soldering iron is placed directly onto the component.

[27] See http://www.asahisolder.com/Publication/Comparative.pdf, referenced in COCIR (2011)

[28] See www.renasas.eu/prod/lead/rt/plating.html, referenced in COCIR (2011)

Standard practice is to place the soldering iron tip onto the printed circuit board near to the component and allow molten solder to make contact with the component's termination. Wetting times are considerably longer with lead-free solders than SnPb unless the operator uses a much higher temperature than is recommended, which can, however, damage the components and the flexible printed circuit board and thus often is not practicable. (COCIR 2011)

Non-magnetic components can withstand only a short time in contact with lead-free solders (as little as 5 seconds) and so there is a high risk that one of the bonds to a component will be defective. With chip capacitors, for example, the assembler would apply solder and heat to each end of the component sequentially. Unless excessive temperature is used, it typically takes about 5 seconds in contact with molten lead-free solder to produce the first bond. The solder from the first bond will however remain molten on very small components while the operator heats the other end to form the other solder bond. The solder at the first end could therefore be molten for about 10 seconds or longer and this may be too long for some types of non-magnetic components. The time to form bonds on larger components will be longer although the first bond is less likely to remain molten while second and subsequent bonds are produced, but they will be hot for longer. The tin-copper intermetallic phase will continue to grow and become more susceptible to failure by cracking of this brittle layer. (COCIR 2011)

Excessive soldering times could at worst cause the end termination material to completely dissolve in the solder so that the bond fails or at least has an increased risk of bond failure due to stresses in service. In surface mount processes, the time that solders are molten is usually longer than by hand soldering so that the risk of damage to the components' copper-tin terminations is increased due to the thicker tin-copper intermetallic phase that forms when nickel barriers cannot be used. (COCIR 2011)

Another issue is the large size of the coil flexible circuits as shown in Figure 3. They have large areas of copper that are a good heat conductor. When bonds are created with a soldering iron, the copper conducts heat away from the bond area so that it can take a significant amount of time before good solder wetting of the copper tracks is achieved. During this time, molten solder is in contact with the non-magnetic component and this can be too long for some types of non-magnetic components. (COCIR 2011)

Low temperature solders are not necessarily a solution as at lower temperatures, the wetting time is much longer and so the component termination is in contact with liquid solder for a

longer period. Moreover, SnBi solder is significantly more susceptible to thermal fatigue than for example SnPb with 5% of lead used in component finishes[29]. (COCIR 2011)

12.3.3 Intermetallic phase formation affecting reliability

Tin from solder and copper terminations reacts to form SnCu intermetallic phases at the interface between the two layers. These compounds grow fairly rapidly while the bonds are being heated by the soldering process. The thickness depends on the soldering time as well as the soldering temperature. SnCu intermetallics are relatively brittle. If they become moderately thick and there is imposed strain from vibration or thermal cycling, both of which occur with MRI, there is an increased risk of failure. Severe vibration occurs as a result of the forces created between the field coil and gradient coils, which are used to produce 3D images. Manufacturers have measured acoustic pressure waves of 145 dB, which will impose severe mechanical stresses. In comparison, 130 dB causes aural pain and a jet engine at 30m is 150dB. Formation of brittle thick layers of SnCu are normally avoided by using nickel barrier layers, as nickel reacts with tin much more slowly than tin with copper so that only very thin and so more flexible SnNi intermetallic layers form. Nickel, however, cannot be used in components exposed to high magnetic field applications. (COCIR 2011)

As tin-copper intermetallic growth rates are temperature dependent, the intermetallic phases are usually thicker after lead-free soldering processes than with tin-lead solder, potentially resulting in lower reliability. Research by JGPP[30] in 2006 showed that lead-free solders are more susceptible to failure as a result of intense vibration than SnPb solders, although this depends on the location of components on a printed circuit board and the type of component. Research has also shown that shock and drop resistance of solder joints is affected by solder alloy composition. Resistance to shock (i.e. being dropped) is relevant to vibration reliability because with severe vibration, the solder bonds are subjected to many high g-force shocks. Drop tests, comparing SnPb with eutectic SnAgCu, show that SnPb has a superior shock resistance with bonds made with Sn3.8Ag0.7Cu failing after fewer drops[31]. This research was carried out with magnetic components, but as the SnCu intermetallic will be thicker on non-magnetic components, shock or vibration induced failures would be more likely to occur. SnAgCu alloys with lower silver content of around 1.0% have been developed

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29 Cf. “Low-Temperature Solders”, Z. Mei, H. Holder and H A. Vander Plas. H. P Journal, August 1996; referenced in COCIR (2011)

30 See http://www.jgpp.com/projects/lead_free_soldering/April_4_Exec_Sum_Presentations/JTR%20Reliability%20Conclusions%20March%2028%202006.pdf, and http://www.jgpp.com/projects/lead_free_soldering/April_4_Exec_Sum_Presentations/040406WoodrowVibThShock.pdf; both sources referenced in COCIR (2011)

31 Greg Heaslip, Claire Ryan, Bryan Rodgers, and Jeff Punch, “Board Level Drop Test Failure Analysis of Ball Grid Array Packages”, Stokes Research Institute, 2005; referenced in COCIR (2011)

(mainly to reduce the cost of silver) and are found to have better drop resistance than eutectic SnAgCu with 3.8% of Ag. However, the melting temperature is higher (~226°C with 1% Ag), which is nearly 10°C hotter than with 3.8% of Ag. This higher temperature will increase the SnCu intermetallic thickness and thicker brittle SnCu intermetallic will make joints more susceptible to thermal fatigue failure. The higher melting temperature will also increase the termination coating dissolution rate in liquid solder which makes manufacture even more difficult or impossible, especially with large thermal mass components. (COCIR 2011)

Intermetallic phases are also formed with tin from solders and AgPd termination coatings consisting of a mixture of SnAg and SnPd phases. Their thickness is proportional to the soldering temperature and time at soldering temperature. With the higher temperature of lead-free solders, these can be sufficiently thick to become relatively brittle so that quite small forces cause them to fracture and the bond fails. There are several publications[32] that show that AgPd thick film coatings are more prone to cracking when soldered with lead-free solders than with tin-lead solder due to the thicker SnPd layer formed with lead-free solders at a higher temperature than when SnPb is used. (COCIR 2011)

12.3.4 Tin whiskers affecting reliability

Increased risk of whiskers related to use of non-magnetic components

Tin whiskers are thin rods of tin that grow spontaneously from electroplated tin coatings. These have been known for many decades and have caused the failure of a wide variety of electrical equipment as a result of short circuits. Only since the introduction of the RoHS Directive has intensive research been carried out to determine its causes and identify measures to minimise the risk. This research has shown that whiskers form where the tin has compressive stress which can have many different causes. The US organisation International Electronics Manufacturing Initiative (iNEMI) has co-ordinated a lot of research and published guidance on methods to minimise whisker formation; however these recommendations cannot all be adopted with non-magnetic circuitry. (COCIR 2011)

One reason is the stress due to the formation of tin/copper intermetallic phases that grow between copper substrates and tin plated coatings. The risk of whisker formation from this source of stress can be significantly reduced by the use of nickel barriers between copper and tin but this is not possible with MRI circuits. A possible alternative is to heat the components to 150°C but this must be carried out within 24 hours of electroplating to be

[32] See for example http://www.europeanleadfree.net/SITE/UPLOAD/Document/Meetings/San%20Sebastian/Belavic_GreenRoSE.pdf, slide 36, and http://extra.ivf.se/eqs/dokument/7%20pet6005.pdf, page 43; both sources referenced in COCIR (2011)

effective. This treatment creates a thin SnCu intermetallic barrier that has been shown in some research to hinder or even prevent tin whisker formation, although research disputes these results. This option relies on the component manufacturer but very few use this process, so many of the components needed are not available with this heat treatment. By the time the medical equipment manufacturer receives the components, it is too late to apply this whisker mitigation technique. (COCIR 2011)

Conformal coating options to reduce risks of whiskers

COCIR (2011) reports about research carried out to determine whether conformal coatings can reduce the risk of tin whiskers. There are several types of conformal coatings available and all have been evaluated. This research has shown, however, that they do not stop the formation of tin whiskers, but delay their formation, some types for longer than others.[33] 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 (2011) lists three ways how short circuits can occur despite of conformal coatings:

- Most types of conformal coatings give fairly thick coatings. 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 however take a longer time than without conformal coatings. To date, no examples of failures due to this mechanism have been reported, although they would be very difficult to detect.
- Whiskers can grow beneath coatings across the surface of printed circuit boards or components to the adjacent electrical conductor. It depends on the adhesion strength and is likely only with poor adhesion.
- 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, which is fairly common.

COCIR (2011) concludes that short circuits caused by tin whiskers are much less likely when a conformal coating is used, but clearly the long term risk is not completely eliminated.

12.3.5 Manufacturability

COCIR (2011) mentions one manufacturer's research that has demonstrated the difficulty of soldering using lead-free processes with non-magnetic components. A circuit was designed for assembly with lead-free solders using non-magnetic RoHS compliant components

[33] http://nepp.nasa.gov/whisker/reference/tech_papers/2006-Woodrow-Conformal-Coating-PartII.pdf, referenced in COCIR (2011)

including small 0402 devices. Reflow soldering trials with this printed circuit board resulted in low yields with poor wetting of the chip components. Assembly of one printed circuit board which includes many non-magnetic chip components and preamplifier ICs was initially carried out using lead-free solder processing but due to poor wetting, this achieved a yield of only 80%, which is unacceptably high. Failures were found to be due to poor solder wetting of component terminations, especially to AgPd terminated components. Solder bonds not sufficing the requirements of industry standard IPC – A 100, which greatly increases the risks of failure in service, and solder joints with “cracks” were observed (cf. Figure 6 below).

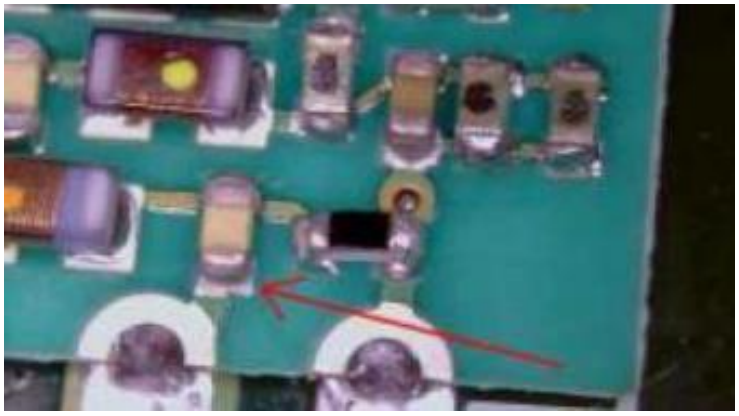

Figure 6: Lead-free soldered printed circuit board of an MRI with poor wetting at arrowed chip capacitor and other components (COCIR 2011)

These defective printed circuit boards could not be reworked as the termination coatings of non-magnetic components have very short maximum times for which they can be exposed to liquid solder as explained above. As it was not possible to achieve a high yield with lead-free solders, soldering with SnPb solder was carried out, which gave yields of 100%. (COCIR 2011)

12.3.6 Reliability test results

COCIR (2011) reports about a manufacturer who achieved better yields in lead-free soldering to RF screen capacitors of a magnet coil, but many of the bonds failed during testing simulating service conditions. Each screen has many capacitors, but one bond failure already causes the failure of the circuit.

COCIR (2012a) argues that MR scanners are expected to be in service with clients for at least 10 years. To simulate actual vibration levels and thermo-mechanical effects for at least 10 years of service, the typical test conditions used for MR environment reliability tests are:

Vibration levels of up to 70 G_{rms} for 180 hours, corresponding to 19,000 hours MRI scan time, which, according to COCIR (2012a), is far worse than automotive.

Number of temperature Cycles (=number of exams on patients) is 6300/year covering 90% of MRI used in the EU. This is, according to COCIR (2012a), far worse than automotive, and comparable with space.

Circuits therefore have to be tested using realistic conditions to simulate the vibration that occurs to MRI circuits. Three types of commercial non-magnetic capacitors were tested and after vibration testing, at worst only 13% survived and at best 63% survived. When capacitors from a different supplier were assembled using tin-lead solder, 100% survival was achieved in the test.

COCIR (2011) concludes that there is therefore an unquantifiable risk that lead-free solders, which are brittle at low temperatures, have a greater risk of failure at very low temperatures due to vibration, than more ductile tin-lead solders.

12.3.7 Environmental aspects

Even though no technically viable substitute has been identified at present, COCIR (2011) have submitted further information concerning life cycle assessment aspects of potential substitutes (tin, copper, silver, palladium, conformal coatings), to further enhance their argumentation. Information includes reference to the availability of other metals, the energy consumption required for their extraction and refining, information concerning production and use and information concerning the re-use and recycling of waste. In general, the information submitted concerning these aspects also supports lead to be the most suitable candidate for this application.

12.3.8 Roadmap for the substitution or elimination of lead

Manufacturers carry out research to identify substitutes. The main approach is to use lead-free solders with non-magnetic components ideally with tin plated copper terminations. Currently this is not yet possible for the reasons described above. Most MRI manufacturers are carrying out research with lead-free solders using the lead-free non-magnetic components that are currently available. A few should be able to produce some lead-free assemblies soon but it will take much longer to convert all of their designs to lead-free versions. The time this will take depends on two variables:

- The number of designs that need to be converted and
- Whether lead-free components are available for current designs.

If no lead-free components are available for the current designs, manufacturers will either have to wait until they are or redesign their circuitry, which will take additional time, typically another 6 months to 1 year longer. Most manufacturers will not complete this work and will not have completed testing and gained approvals before the date when MRI are included into the scope of the RoHS Directive in 2014.

Some manufacturers have many different RF coil designs and identifying suitable processes for all of these will take many years. Once satisfactory soldered assemblies have been constructed, manufacturers must prove that they will be reliable for the expected 10–20 years life of the equipment. This is essential to obtain approval for use in the EU under the Medical Devices Directive. This will require gaining re-approval by a Notified Body for all "significant" changes and requires proof of reliability. It will take up to two years to carry out reliability tests and clinical trials to obtain suitable data and it can then take more than a year to obtain approvals before the new products can be put onto the EU market.

The total timescale for research, modification of all models, testing, trials and approvals will not be complete by 2014 when medical devices are included in the scope of RoHS. The time required could be as much as nine years:

- Research and redesign 3 years, estimated
- Modification of all RF coils 2 years, possibly longer for all models
- Reliability testing and trials ~2 years
- Approvals in EU and worldwide 1–2 years
- Total 8–9 years

COCIR (2012a) indicates that an exemption is needed probably until at least 2020 (9 years from 2011) to allow all MRI manufacturers sufficient time to substitute lead in all of these applications.

12.4 Critical review

12.4.1 Relation to the REACH regulation

Chapter 5 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. Lead and its compounds are thus listed in Annex XVII, and their use might weaken the environmental and health protection afforded by the REACH Regulation.

In the consultants' understanding, entry 30 of Annex XVII does not apply to the uses of lead in the requested exemption. Lead and the tin-lead alloy used may be considered as substance, as constituent of another substance or a mixture. Putting, however, lead in solders and finishes on the market in the consultants' point of view is not a supply of lead and its compounds to the general public. Lead and the lead alloy is part of an article and as such should not be covered by entry 30 of Annex XVII.

The consultants conclude that the use of lead in this requested exemption 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.

12.4.2 Environmental arguments

The applicant presents environmental data and statements comparing the life cycles of lead with potential substitutes. As none of these can be considered a viable substitute at this time, 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.

12.4.3 Technical arguments

The applicant justifies its exemption request with typical technical problems that have to be solved when shifting from soldering with lead to lead-free solders. However, manufacturers of other categories of electrical and electronic equipment have or are about to solve these constraints successfully.

In the applicant's case, the following facts have to be taken into consideration as well:

- Shifting from lead to lead-free soldering requires adapting the printed circuit board design, the soldering process profiles, selecting appropriate material combinations of lead-free solders on the one hand, and component and PCB finishes on the other hand, and possibly components and PCB finishes that can withstand the higher soldering temperatures. These adaptations need time.
- The need to use non-magnetic components to maintain the homogeneity of the magnetic field restricts the options for lead-free solutions.
- The combination of long life time of MRIs, the harsh environment due to strong vibrations, and the high reliability requirements not to endanger patients' health and safety aggravate the situation.

The combination of the above specific requirements makes it plausible that additional time is required allowing manufacturers to find reliable and safe lead-free solutions. It was only clear in July 2011 – the date of publication of the new RoHS Directive – that the devices of category 8 (medical equipment) of RoHS Annex I will come into the scope of the RoHS Directive. Thus, granting additional time for researching, testing and qualifying lead-free solutions is justified.

The applicant explains that nine years will be needed. The consultants have no information justifying an earlier expiry date.

The wording COCIR (2011) had originally proposed was changed. The terms "circuitry" and "strong magnetic fields" were found to be not sufficiently clear. Strong magnetic fields require

the use of non-magnetic components. The distance to the magnetic field was therefore selected for specification, and the various parts requiring the use of lead were specified in the exemption in order to clarify the exemption's scope:

"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

The proposed expiration date for this exemption is 30 June 2020."

COCIR (2012c) agreed to the above wording.

12.5 Recommendation

Based on the submitted information, the consultants recommend granting the exemption and adopting it 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).

The consultants recommend the following wording:

"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

The exemption expires on 30 June 2020"

12.6 Specific references

COCIR 2011 — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Original exemption request document "6-COCIR – Exemption request – Lead in image intensifier thermal compression rings.pdf"; retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_9/9_COCIR_-_Exemption_request_-_Lead_solder_magnetic_field.pdf

COCIR 2012a — Stakeholder document "9_COCIR_-_Exemption_request_-_Lead_solder_magnetic_field.pdf" submitted by COCIR on exemption request no. 9 in March 2012 within the consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_9/Questionnaire-1_Exe-9_answers.pdf

COCIR 2012b — Stakeholder document "Questionnaire-1_Exe-9_answers.docx" submitted by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) on exemption request no. 9 on 21 December 2011

COCIR 2012c — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Final clarifications.pdf", submitted by stakeholder on exemption requests 7, 8, 9 and 10 on 31 May 2012

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RoHS Directive 2003 — Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment;
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0095:EN:NOT

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

Zangl et al. 2010 — Zangl, S.; Hendel, M.; Blepp, M.; Liu, R.; Gensch, C.; Deubzer, O. Adaptation to scientific and technical process of Annex II to Directive 2000/53/EC (ELV) and of the Annex to Directive 2002/95/EC (RoHS); Final Report, Öko-Institut e.V. and Fraunhofer IZM, June 2010;
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13 Exemption request no. 10

"Lead in solders to PCBs for mounting cadmium telluride and cadmium zinc telluride digital array detectors"

Abbreviations

Ag	silver
Bi	bismuth
Cd	cadmium
CTE	coefficient of thermal mismatch
CZT	cadmium-zinc-telluride
PET	positron emission tomography
Sn	tin
SPECT	single-photon emission computed tomography
Te	tellurium
Zn	zinc

13.2 Description of requested exemption

COCIR (2011) explains that cadmium zinc telluride (CZT) is a relatively new semiconductor used to produce high resolution digital images. Cadmium telluride (CdTe) is also a semiconductor candidate for the same applications and has similar mechanical and electrical properties like CZT. Hereafter, CZT is used to indicate Cadmium Zinc Telluride with different zinc concentrations including no-zinc commonly known as cadmium telluride.

According to COCIR (2011), the CZT detectors are more compact than traditional detectors and provide higher spatial and energy resolution. The semiconductor detectors have fast speed and can provide photon counting capability to high flux rates. These materials are used in nuclear medicine as the detector in positron emission tomography (PET) and also as the X-ray detector in Computed Tomography (CT). Dental and bone-mineral densitometry medical exams are also carried out using a CZT detector.

COCIR (2011) explicates that CZT detectors are used because of their very high sensitivity to X-ray and other ionising radiation (e.g. gamma ray) compared to other types of detectors such as image intensifiers with optical detectors and also silicon array X-ray detectors. CZT also has an advantage that it operates at room temperature whereas some types of silicon detectors must be cooled to low temperature and so consume far more energy to operate.

The higher sensitivity of CZT allows patients to receive lower X-ray doses which results in a lower risk of harmful side-effects such as cancer. The semiconductor wafer must be mounted onto a PCB-type substrate in order to make the detector device in an imaging system; there is no other way of making the many hundreds of electrical connections.

COCIR (2011) describes that single crystal wafers of CZT are fabricated into detectors by mounting them onto printed circuit boards (PCBs) with eutectic tin/lead solder to make the many hundreds of electrical connections. One electrical connection is needed for each pixel of the image. CZT is a very fragile and brittle material which is easily damaged, particularly through stress imposed by the assembly process. CZT detectors are relatively new and each manufacturer uses its own unique design. As these designs and the capabilities vary, the method used to assemble detectors also varies. Figure 7 illustrates the typical assembly process of applying metal contacts to the wafer and the assembly of the detector module.

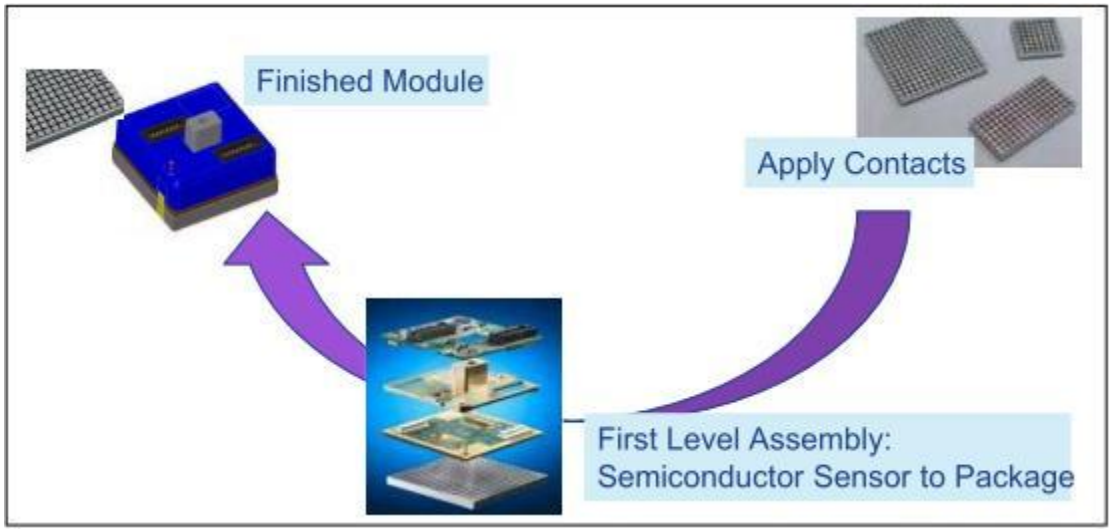

Figure 7: Assembly process for CZT detector modules

Solder is used either as small solder balls or as reflowed solder paste to form the electrical connections between the CZT and the PCB substrate as depicted in Figure 8:

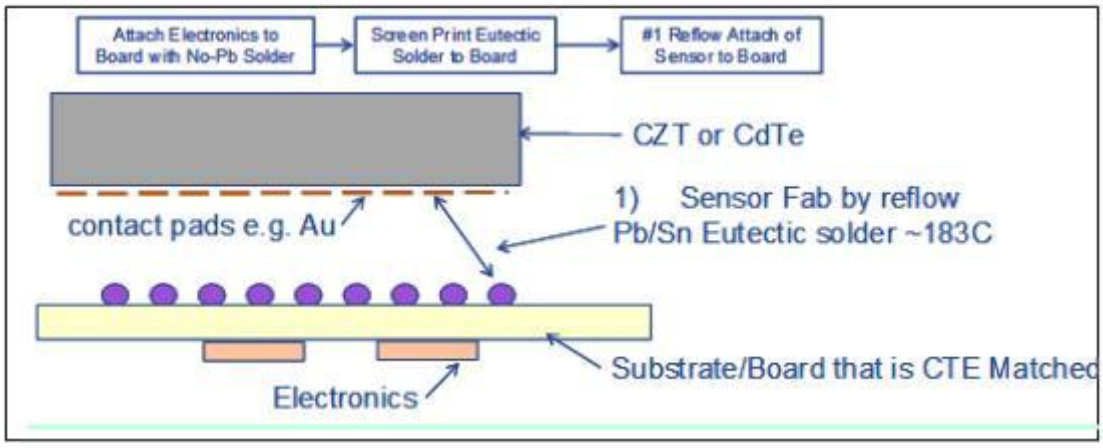

Figure 8: Solder connects in CZT detectors

According to COCIR (2012a), tin-lead solders with 37% weight of lead (SnPb37) are used for reflow soldering of the sensor to the printed circuit board. Each detector module applies around 0.2 g of lead. CT is probably the only equipment that will use this exemption initially, although it could potentially also be used for other imaging technologies such as positron emission tomography (PET) and single-photon emission computed tomography (SPECT. A CT contains 57 detector modules so that the total weight of lead in each system will be around 11.4 g. COCIR (2012a) estimates that 500 systems are put on the market worldwide and around 100 units in EU. The total use of lead in this application will hence be around 5.7 kg per year, from which around 1.1 kg will be put on the market in the EU.

13.3 Applicant's justification of the exemption

Lead-free solders, conductive adhesives, and alternative printed circuit board laminates are principal possibilities to enable the substitution of lead in solders.

13.3.1 Limitations of lead-free solders

Lead-free solders

The lead-free solders that are widely used for many types of electrical equipment all have melting temperatures higher than eutectic tin-lead. The most commonly used alloys are compared with eutectic tin/lead in Table 20:

Table 20: Melting points of tin-lead and lead-free solder alloys (COCIR 2011)

Solder alloy	Melting temperature
SnPb	183 °C
SnCu	227°C
SnAg	221°C (3.5%Ag)
Sn3.5Ag0.5Cu	217 °C
Sn-3.5Ag-3Bi	206 – 213°C

The melting points of lead-free solders tend to be ~30–40°C hotter compared to tin-lead solder. This higher temperature has a variety of effects on electrical assemblies.

Warping of printed circuit boards

COCIR (2011) explains that, in order to avoid stresses on the CZT, which could cause bond failure or damage to the detector, the PCB must be perfectly flat throughout the manufacturing process. The PCBs used for CZT assembly are complex multilayer boards with a high density of internal vias. Polymer PCB laminates tend to distort and warp when they are fabricated, especially complex boards of this type. Distortion occurs during reflow soldering when electrical components and the CZT detector wafer are bonded with solder to the PCB. It is a general rule for any type of laminate that the amount of distortion increases with temperature. Distortion of laminates will be greater on average during and sometimes also after lead-free reflow than during and after reflow soldering with tin-lead solders due to the 20–40°C temperature difference (see Table 20). The conductors and components attached to each side of the laminate will be different and subsequently the thermal expansion of metals on each side will be different in comparison with the laminate material (usually smaller); this difference in expansion will tend to distort the laminate. The extent of distortion is proportional to the laminate's rigidity, which decreases with temperature as well as the differential thermal expansion which increases with temperature. Another effect of high temperature is that heavy components can distort the laminate when it softens and this effect also increases with reflow temperature.[34]

COCIR (2011) reports that at least one manufacturer's trials have shown that the proportion of defective detector modules made with lead-free solders is higher than those made with tin-lead solder. Due to this significant difference, lead-free soldered modules cannot be used in new medical devices until these have been approved under the medical devices directive and this will not be granted until long term reliability has been demonstrated. This will require lengthy testing to simulate a lifetime in use of well over 20 years.

[34] See NPL report, page 8, available from http://publications.npl.co.uk/npl_web/pdf/matc91.pdf; source referenced in COCIR (2011)

Hardness of lead-free solders

COCIR (2011) says that a great deal of reliability testing of lead-free soldered consumer and IT products has been carried out and published, but that the soldering of CZT detectors has many significant differences.

The main difference is that it uses unusually brittle and fragile CZT semiconductors with an uncommon TCE matched laminate. The main risk is the fracture of the CZT. The risk of damage to the CZT is likely to be greater when standard lead-free solders are used as these are harder and less ductile than tin-lead and so where stresses are imposed; these are less likely to be relieved by deformation of the solder. Solder hardness depends on its thermal history, so it is not always straightforward to compare published values. Most lead-free solders are, however, are harder and so less ductile than SnPb.

Table 21: Vickers hardness of solders[35]:

Solder alloy	Vickers hardness
SnPb	12.9 (not annealed)
Sn3.5Ag	17.9 (or 13.9 for annealed)
Sn3.8Ag0.7Cu	21.9
Sn4.7Ag1.7Cu	(12.45 for annealed)
Sn3Ag3Zn	21.9
Sn3Ag3In	21.3

COCIR (2011) explains that SnAgZn and SnAgIn alloys are not standard alloy. They are nevertheless included in the above table to show that they are equally hard as compared to SnAgCu and SnAg, although they are lower melting point alloys.

Lower melting point solders are available but, according to COCIR (2011), are not suitable for a variety of reasons. Some are susceptible to corrosion and some are too hard and brittle and so will cause increased stresses to the CZT. The melting points of some alloys are too low so that they could melt in service.

Table 22: Melting points of low melting point solders with tin-lead as reference (COCIR 2011)

Alloy	Melting point °C
63Sn37Pb	183
52In48Sn	118
58Bi42Sn	138
Sn9Zn, Sn8Zn3Bi	189 - 199
Sn20In2.8Ag	175 - 187

[35] From http://www.boulder.nist.gov/div853/lead_free/props01.html except Sn3.9Ag0.7Cu which is from Elfnet; source referenced in COCIR (2011)

COCIR (2011) explains why the low melting point lead-free solders cannot be used.

Tin-zinc alloys are susceptible to corrosion. The alloy is suitable only for consumer products that have short life-periods and where high reliability is not required. Corrosive fluxes must be used whose residues are difficult to remove from the printed circuit boards after soldering and so pose a risk of corrosion to other parts of the equipment as well as the solder.

The melting points of tin-bismuth alloys are too low for some types of PCBs. Solder joints could melt if the equipment or individual components on the PCB such as power semiconductors were to operate at elevated temperature. Bismuth alloys are difficult and sometimes impossible to repair and rework as producing bismuth solder wires is burdensome. SnBi alloys are very hard and brittle and so any stresses will be transferred to the fragile CZT semiconductor. Bismuth also increases the complexity of waste electrical equipment recycling processes as it combines with gold and other elements. (COCIR 2011)

COCIR (2011) references comparative tests of SnBi with SnPb showing that SnBi is more susceptible to thermal fatigue failure, i.e. it fails after fewer stress cycles. Hewlett Packard tested 58%BiSn with 63%SnPb for cyclic thermal fatigue resistance and found that SnBi bonds failed much sooner than SnPb with all package types tested. [36] Stresses will be imposed on solder bonds of electrical components attached to the circuit board because they will have different thermal expansion coefficients (TCE) as compared with the PCB. The PCB's TCE is matched to the CZT's TCE but will not match the TCE of most other components.

Tin-indium alloys are relatively soft and ductile and have a low melting point so are susceptible to bond failure if the equipment were to become hot, similar to the situation with SnBi alloys. As this is a very unusual solder, there is almost no reliability data available and so approval under the Medical Device Directive may not be possible. Solder pastes are unstable due to particles corroding or cold welding and solder balls can be made, but readily cold weld to each other and so are difficult to use. Additionally, indium is a scarce metal with limited availability. (COCIR 2011)

Finally, tin-indium-silver alloys such as Sn20In2.8Ag are patented by Indium Corporation. The availability of indium is an issue. This alloy is expensive due to the high indium content and so is rarely used and very little reliability data has been published. It is also susceptible to corrosion under high humidity conditions. (COCIR 2011)

COCIR (2011) sums up that lead-free solders give poor yields. Development work by one manufacturer found that after fabrication with a SnPb soldering process, the yield of good

[36] Z. Mei, H. Holder and H A. Vander Plas: Low-Temperature Solders; H. P Journal, August 1996; source referenced in COCIR (2011)

detectors was better than 98%. However, on PCBs produced with lead-free processes, there were 5–10% defective assemblies. This level of failure is high and creates unnecessary waste. COCIR (2011) is additionally concerned that the internal stresses induced by the greater laminate distortion during the soldering process results in more uneven pad dimensions that could also cause more failures to occur after several years in service. The availability of reliability test data with CZT and lead-free solders is very limited as these devices are relatively new. The data are therefore insufficient for obtaining approval for the Medical Devices Directive.

13.3.2 Elimination of lead solders

In principle, lead in solders can be eliminated by using conductive adhesives instead of solders, changing the substrate materials of PCBs to avoid warping, or switching to silicon digital sensors.

Conductive adhesives

CZT detectors can be bonded to PCBs using a special electrically conducting adhesive. Conductive adhesives are not widely used as an alternative to solders. Their long term reliability can be inferior. In many applications, the interconnection resistance must be lower than is achievable with these adhesives, or there are performance issues making the use of conducting adhesives problematic.

Using conducting adhesives to populate the PCB instead of soldering may be suitable for a few applications. The contact resistance tends to increase over time mainly due to surface oxidation of PCB pads, as the copper of the circuit diffuses to the surface where it rapidly forms electrically insulating copper oxide. The conductor particles in some types of adhesive can also oxidise or corrode. If precious metal particles are used, these can form a galvanic cell with the substrate copper accelerating its oxidation and increasing the electrical resistance. Any added resistance in the pathway from the CZT sensor to the readout electronics adds error and affects the clarity of the image. In most applications where CZT detectors are used, only a low resistance interconnect path will enable proper detector performance. (COCIR 2011)

Figure 9 shows two PCB pads bonded with conducting adhesives to the CZT detector. The images illustrate the large difference in thickness of adhesive that is caused by PCB distortion caused by soldering other components resulting in failures or cracks in the CZT semiconductor.

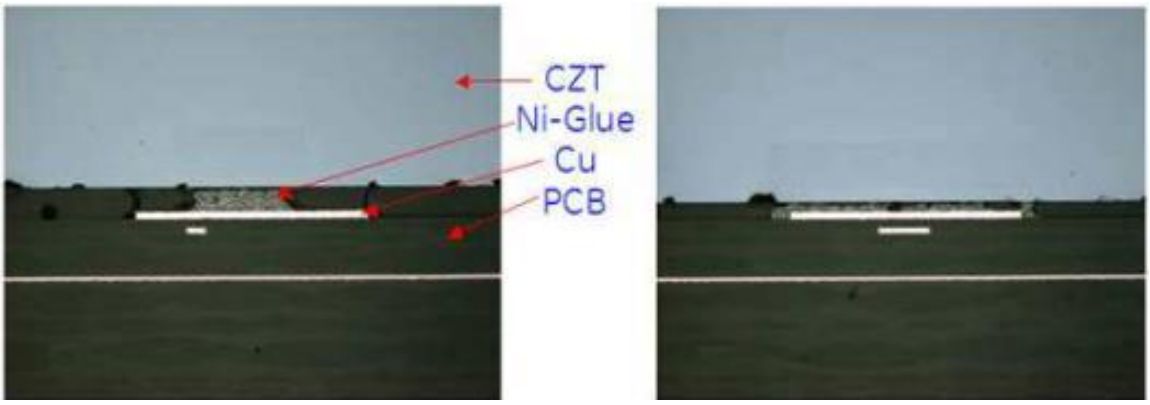

Figure 9: Cross-section through the bonds of a CZT detector with thick (left) and thin (right) layer of adhesive due to PCB warpage

Non-planar board substrates and warping of substrates cause gaps that cannot easily be filled with epoxy. There is a difficult balance with epoxy resins as these require good flow rheology and wetting of contact surfaces during part placement but prevent slumping during the slow curing cycle. Precise solder paste printing is straightforward, even with extremely fine pitch and solders have a wetting force on contact surfaces. Solder is also more ductile than epoxy and can withstand substrate warping that may occur during further thermal processes, e.g. from the attaching of other components. (COCIR 2011)

As additional reasons why conducting adhesives are not suitable as substitutes COCIR (2011) puts forward that the dynamic, high frequency resistive and dielectric properties of conductive epoxies are not the best long term solution for high bandwidth signals of photon counting. Finally, all types of adhesives degrade when exposed to ionising radiation and so bond failure in this application is highly likely. (COCIR 2011)

Use of alternative PCB laminates

As the CZT for the detectors is a very fragile material, the PCB laminate must have the same thermal expansion coefficient as CZT. Additionally, the laminate must allow a sufficiently high interconnect density. This limits the choice of laminate materials significantly. Rigid ceramic thick-film circuits, which will not distort during reflow have a relatively low TCE close to that of the CZT detector, but it is not possible to construct them with a sufficiently high interconnect density. As a result detectors with ceramic substrates would not provide sufficient spatial resolution for many medical imaging applications. Standard PCB laminates are unsuitable as their TCE is too large and so do not match that of the CZT detectors. Thus, very few choices of laminates are suitable and all of these are susceptible to warping at high temperature. (COCIR 2011)

The evaluation of some types of laminates using lead-free solders to attach the detector found delamination or cracking in the CZT especially where there is a mismatch in the

coefficient of thermal expansion (CTE). The higher temperature associated with lead-free solders results in larger differential expansion and therefore more stress in the CZT than with SnPb, whatever the laminate material used. (COCIR 2011)

Replacement of CZT detectors by silicon digital detectors

CZT detectors replace silicon digital detectors because of their superior sensitivity to radiation. Silicon is a light element so most radiation passes through undetected. Silicon detectors therefore usually have a surface layer of thallium doped caesium iodide. These heavy elements efficiently adsorb radiation and then convert this to light which is detected by the silicon photodetector array. (COCIR 2011)

Cadmium and tellurium are moderately heavy elements which adsorb most of the radiation and so directly convert this into a digital image. If silicon were to be used, patients would need to be exposed to higher radiation doses to achieve the same image quality. In particular during computer tomography (CT), patients are exposed to relatively high doses of x-ray. The detectors should hence be as sensitive as possible to minimise the risk of harm from radiation. According to COCIR (2012) the X-ray dose can be reduced to around 50% due to much better detection efficiency and lower electronic noise if the current sensors including both scintillator and the silicon photodiode are replaced by CZT detectors in a CT. There is a linear relationship between radiation dose and risk of cancer. Typical CT doses cause about 1 person in 1,000 (0.12%) to have cancer. In this case, a 10% increase in radiation dose will cause statistically one additional person in 10,000 to have cancer.[37] Positron Emission Tomography (PET) patients ingest or are injected with radioisotopes which migrate to specific parts of the body, where they can be viewed by the radiation detector. As CZT is more sensitive than silicon, lower radioisotope doses can be given which is safer for patients. (COCIR 2011)

COCIR (2011) states that it is important to minimise radiation doses. The “Directive 97/43/Euratom – Medical Exposures Directive” requires that all patient exposures are optimised. If the implementation of RoHS were to result in higher doses, this would conflict with existing EU legislation.

13.3.3 Environmental aspects

COCIR (2011) puts forward environmental life cycle aspects related to the use of metals in lead-free and lead-containing solders. Information includes reference to the availability of other metals, the energy consumption required for their extraction and refining and information concerning the re-use and recycling of waste.

[37] W. Huda, W. T. Rowlett and U. J. Schoef: Radiation dose at cardiac computed tomography: facts and fiction; J. Thorac. Imaging, 2010 Aug; 25(3), p 2014

13.3.4 Applicant's roadmap for the substitution and elimination of lead

The only potential alternative to lead in solders are lead-free solders. Manufacturers are carrying out research to find alloys and processes that give high yields. This work is likely to require evaluation of less commonly used alloys which are more ductile than the lead-free alloys most often used in consumer and IT electronics such as tin/silver/copper. If high yield processes can be identified, then the assembled detectors will need to be tested using realistic conditions to determine whether these alloys will be reliable for long-term use. Reliability testing of new alloys must be thorough for medical devices as this data is needed before applying for approval under the Medical Devices Directive. To gain approval, it will be necessary to show that the alternative alloys are not less reliable than lead-based solders and so do not pose a risk to patients. The likely time-scales are:

- Evaluation of alternative alloys and processes 2 – 3 years
- Reliability testing of assemblies made with high yields at least 2 years
- Submission for MDD approval 1 year
- Total timescale minimum 5 years

This exemption is therefore likely to be needed until 2018 at least. COCIR (2011) proposes the following wording:

"Lead in solders used on PCBs for mounting cadmium telluride and cadmium zinc telluride digital array detectors."

13.4 Critical review

13.4.1 Relation to the REACH regulation

Chapter 5 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. Lead and its compounds are thus listed in Annex XVII, and their use might weaken the environmental and health protection afforded by the REACH Regulation.

In the consultants' understanding, entry 30 of Annex XVII does not apply to the uses of lead in the requested exemption. Lead and the tin-lead alloy used may be considered as substance, as constituent of another substance or a mixture. Putting, however, lead in solders and finishes on the market in the consultants' point of view is not a supply of lead and its compounds to the general public. Lead and the lead alloy used in this exemption is part of an article and as such should not be covered by entry 30 of Annex XVII.

The consultants conclude that the use of lead in this requested exemption 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.

13.4.2 Environmental arguments

COCIR (2011) presents environmental data and statements comparing the life cycles of lead with potential substitutes. As none of the substitutes can actually be used currently, 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.

13.4.3 Technical arguments

The applicant explains that the use of lead-free solders for soldering CZT detectors to the substrate may result in fractures of the detectors. It is a well-known effect that the less ductile and stiffer lead-free solders change the failure mechanism. While the more ductile tin-lead soldered solder joints mitigate the stress of thermal mismatch (CTE) on the components, reducing their break over time, lead-free soldered solder joints cannot relax this stress, and thus direct it into the components, which therefore may break. This effect is a general problem with the use of lead-free solders, which manufacturers of other equipment in the scope of the RoHS Directive in most cases could solve by adapting the components, soldering processes, printed circuit board designs, and by selecting appropriate combinations of lead-free solders and finishes.

With fragile components, this problem is more difficult to overcome, and for larger size fragile components the problems have not been finally solved. An example is the continued use of lead-containing solders in flip chip packages (exemption 15, lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages, see Gensch et al. 2009). The use of conductive adhesives is not an alternative, as they cannot withstand the exposure to X-ray, and because they have higher electrical resistances.

One part of the justification of this exemption is the warping of the printed circuit board during reflow soldering. The PCBs become uneven, and some of the balls of the CZT module lose contact with the PCB. The PCB used is a multilayer ceramic PCBs. Ceramic boards, however, normally do not warp during soldering. Warping is an effect well known from organic PCBs, such as FR4 boards, but not from ceramic PCBs. For ceramic boards, as they are brittle, warping might result in breakage of the PCB. The applicant was asked to explain this in further details.

COCIR (2012c) agrees that in general the ceramic substrates should not warp which is one of the main reasons they are selected over an organic substrate. However, these ceramic

substrates are also a laminate structure as they are made in layers and depending on the amount of refractory metal routing in each layer there can be small differences between the layers so that warping can occur. This is more severe at higher lead-free reflow temperatures than at the lower tin/lead soldering temperature. If the substrate manufacturer's design rules are followed for each layer, warping is not a problem. The ceramic substrates thus are not the issue, but the electrical assembly with the ceramic substrates has organic (plastic packaged) components which have a relatively high CTE on one side of the ceramic substrate and a low CTE on the other side, and this creates the obvious CTE mismatch and potential for warping.

The elimination of lead by replacing CZT detectors by silicon detectors does not make sense as the silicon detectors require higher X-ray radiation doses endangering patients' health. The use of lead-free solders in this application requires time for research and testing, as it is more difficult to find appropriate solutions granting the necessary high reliability over the long life times of medical equipment such as CRTs. The applicant's arguments are hence plausible, and no converse information is available about viable lead-free solutions for the bonding of CZT detectors. The applicant requests the exemption for a minimum of five years. It was finally and officially clear in July 2011 – the date of publication of the new RoHS Directive – that the devices of category 8 (medical equipment) of RoHS Annex I will come into the scope of the RoHS Directive, which in the consultants' point of view was the latest point in time when the manufacturers were expected to start their research and substitution efforts. Thus, with less than one year passed since the official adoption of category 8 into the scope of the RoHS Directive, in the absence of viable substitutes and elimination possibilities, and due to additional time required for reliability testing and qualification of alternative solutions, the consultants have no indication to recommend an expiry date prior to the five years period proposed by the applicant.

13.5 Recommendation

Based on the applicant's arguments, and in the absence of contrary information, the consultants' recommend granting the exemption and adopting it to Annex IV of the RoHS Directive. Technically, lead cannot be substituted or eliminated in this application. As requested, the exemption should be granted for five years. The consultants propose the following wording for this exemption, which has been agreed with COCIR (2012b):

> *"Lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards; expires on 31 December 2017"*

13.6 Specific references

COCIR 2011 — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Original exemption request document "6-COCIR – Exemption request – Lead in image intensifier thermal compression rings.pdf"; retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_10/10_COCIR_-_Exemption_request_-_Lead_soldering_CdZnTe_detector.pdf

COCIR 2012a — Stakeholder document "9_COCIR_-_Exemption_request_-_Lead_solder_magnetic_field.pdf" submitted by COCIR on exemption request no. 9 in March 2012 within the consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/Questionnaires_Consultation/Questionnaire_Exe_10_Consultation.pdf

COCIR 2012b — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Final clarifications.pdf", submitted by stakeholder on exemption requests 7, 8, 9 and 10 on 31 May 2012

COCIR 2012c — European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Final clarifications.pdf", submitted by stakeholder on exemption requests 7, 8, 9 and 10 on 31 May 2012

Gensch et al. 2006 — Gensch, C.; Zangl, S.; Möller, M.; Lohse, J.; Müller, J.; Schischke, K.; Deubzer, O. Adaptation to Scientific and Technical Progress under Directive 2002/95/EC, Final Report, Öko-Institut e.V. and Fraunhofer IZM, July 2006; http://ec.europa.eu/environment/waste/weee/pdf/rohs_report.pdf.

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Goodman 2006 — Goodman, P. 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 2009 — Goodman, P. 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

RoHS Directive 2003	Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0095:EN:NOT
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
Zangl et al. 2010	Zangl, S.; Hendel, M.; Blepp, M.; Liu, R.; Gensch, C.; Deubzer, O. Adaptation to scientific and technical process of Annex II to Directive 2000/53/EC (ELV) and of the Annex to Directive 2002/95/EC (RoHS); Final Report, Öko-Institut e.V. and Fraunhofer IZM, June 2010; http://circa.europa.eu/Public/irc/env/elv_4/library?l=/reports/final_rohs_2010pdf/_EN_1.0_&a=d
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14 Exemption request no. 13

"Lead and cadmium in metallic bonds creating superconducting magnetic circuits"

14.1 Description of requested exemption

A superconductor occurs only below a maximum critical temperature. Above this temperature the material will act as normal conductor. In principle, superconductors can allow electrical current to flow without any energy loss or a power source. In contrast a conventional conductor has a finite resistance (ohmic resistance) and electrical current will dissipate typically in the form of heat.

A superconductor magnet coil loses all electrical resistance when cooled by a cryogenic fluid (conventionally liquid helium) to a few degrees Kelvin up to 4 K or –269°C. Electrical connections are made to the coils using special wire alloys which are also superconductors to the low temperature. The alloy contains lead and cadmium and metallic bonds are connecting superconducting wires together forming a superconducting electromagnet to create a magnetic field. This magnetic field generated by the superconducting magnet is not limited to use in Magnetic Resonance Imaging (MRI) applications. The superconducting quantum interference devices (SQUID) are also used for detecting small signals produced by the brain, the heart and other organs (Goodman 2006).

According to the applicant, the exemption is necessary for MRI applications and SQUID sensors. Additional applications to MRI are Fourier Transform Mass Spectrometer (FTMS) and Nuclear Magnetic Resonance (NMR) for several special chemical analyses[38], which are very hard to analyse with any other devices. NMR and FTMS equipment is used in science laboratories, pharmaceuticals, hard drive manufacture, silicon wafer manufacture and industrial magnetic separation.

MRI is actually a branch of NMR used specifically for imaging. The technology is essentially the same as the core item is a superconducting magnet. The main difference is that MRI magnets are horizontally mounted whereas NMR products such as FTMS in category 9 are normally mounted vertically.

According to TMC (2012), currently two materials are used for metallic bonds creating superconducting circuits:

- "Woods"[39] alloy Bi (50%) Pb (27%);Sn(13%) Cd(10%) estimated annual use 140 kg,
- Superconducting Solder Pb(60%) Bi(40%) estimated annual use 42 kg.

[38] NMR is very widely used and enables analysis of solids, liquids, liquid crystals and even nano materials as well gels, resins or tissue samples (TMC 2012).

[39] See also Goodman (2006)

These are the estimated annual weights used in the manufacture of superconducting electromagnets and represent approximately 30% of the global NMR market. Finally, this is resulting in <0.03% Pb by weight to the final product.

The applicant claims that the description of exemption 12[40] in Annex IV of Directive 2011/65/EU is limited to medical uses (category 8) and do not cover the uses for monitoring and control instruments (category 9). Thus, the applicant requires that the description of the exemption should be revised or a new one granted for category 9 products.

The applicant requests that the exemption applies until 2021 for all monitoring and control products and suggests the following wording:

"Lead and cadmium in metallic bonds creating superconducting magnetic circuits".

14.2 Applicant's justification for exemption

The applicant's arguments to justify the request can be summarised as follows:

- Electrical connections are made to the coils using low temperature melting alloys which are also superconductors at 4 K. The alloy of choice contains lead and cadmium and remains superconducting in the very strong magnetic field of the superconducting coil.
- For these applications a soft ductile metal is required. Only lead is practical used in metallic bonds for superconductors at a temperature of 4 K and a melting alloy point at –200°C and less.
- Fundamentally superconducting magnets have this exemption for MRI use but not for NMR use. The purpose of this request is to have a new or amended exemption for NMR use in category 9 products using superconducting magnets.
- No feasible substitutes are available. For instance, potential substitutes are bismuth or indium tin (InSn) solders, however these will not work satisfactorily since superconductivity is degraded in the presence of strong magnetic fields.

Other involved stakeholders participating to the consultation support the proposed exemption (JEOL 2012 and JBCE 2012). Both stakeholders state that they do not have information on available substitutes and do not yet have any alternative methods. Both stakeholders agree with the expiry date until 2021. The stakeholders claim that the substitution of lead and/or cadmium can be technically achieved in this timeframe.

[40] Exemption 12 in Annex IV of RoHS Directive 2011/65/EU: *"Lead and cadmium in metallic bonds to superconducting materials MRI and SQUID detectors".*

14.2.1 Substitutes from a technical point of view

Receiving effective solders to MRI, NMR magnets or SQUID sensors a soft ductile and flexible metal is required which superconducts at 4 K. Moreover the solders must be stable and resistance to oxidation at these low temperatures. All high chemical and physical requirements together do only fulfil lead. A further aspect is that lead also benefits as a thermal conductor at liquid helium temperatures for NMR appliances (Goodman 2006).

Although the applicant refers to the ERA study report (Goodman 2006) where it is reported that several materials might be used for substitutes are available (e.g. cadmium free alloys based on lead bismuth (PbBi), lead free alloys by using indium tin (InSn) or indium bismuth tin (InBiSn)) but that they do not ensure sufficient superconductivity of metallic bonds[41]. For instance InSn and InBiSn are low melting point solder alloys which have a critical temperature ≥ 4 K and therefore sufficient for the use of these application (Goodman 2006). However, these alloys are unlikely not suitable for high magnetic fields and for which the development and acceptance has not yet been evaluated in 2006 (Goodman 2006). In addition, solders using tin[42] are impractical as the tin undergoes a phase transformation with an associated large change in volume. This causes the metal to disintegrate into a fine powder so that the electrical connection is lost; this phenomenon is known as tin-pest (TMC 2011 and COHIR 2009). Due to this phenomenon tin based solders in metallic bonds for superconductors are only used at a temperature above 4K.

Moreover, it should be noted that superconducting magnets are commonly in operation for 10–20 years and long term reliability is critical (Goodman 2006). The time needed to develop, qualify and implement Pb-free metallic bonds in these products had been projected not to be completed until 2021, which the applicant proposes as the expiry date for this exemption. The process and materials used are key business technologies, and as a result there are no lead and cadmium free accessible alternatives from other sector players. Agilent Technologies (2012) does not yet have any alternative methods that allow the business to move away from the use of lead in these processes; however according the applicant they are making progress in cadmium free bonds that may take several years to complete depending on the magnet design specifications.

14.2.2 Environmental concerns

The applicant stated that the NMR technique is sufficiently flexible to be used for example to measure the water/fat ratio in foods, monitor the flow of corrosive fluids in pipes, or to study the structure of catalysts. Industrial applications can be divided into chemical, biological, drug

[41] In section 10.11.3, Goodman (2006) provides an overview with properties of materials that might be used for bonding

[42] Tin is namely similar to lead electrochemically but when it oxidises, it forms an inert protective oxide coating which is not useful for these applications.

research, paramedical, data processing, and non-destructive testing. This is not exhaustive, but it gives an overview on the range of the applications. The socio-economic impact of not having these NMR systems is far reaching across many sectors worldwide (TMC 2012b).

The environmental impact is minimized by the extended potential life time of 10-20 years for the superconducting magnets, and the small quantities of material used in this low volume product. Category 9 products are produced in vastly smaller quantities compared to categories already in scope of RoHS. The entirety of category 9 product volumes in total are representative of less than 0.25% of e-waste (TMC 2012b). Furthermore super conducting magnets are large products (ranging from 0.5 to 100 tons) that are installed and decommissioned at end of life by professionals ensuring that they are treated without environmental impact in the waste phase.

14.2.3 Use in category 9

If the exemption is not granted for category 9, TMC (2012) foresee that the unavailability of this substance exemption would cause withdrawal of products from the EU market. This would have very serious consequences, not only for category 9 producers, but also on client industries which are of key importance for the EU economy and competitiveness (TMC 2012).

14.3 Critical review

14.3.1 Substitution technically and scientifically

The applicant argues that there are no technically and scientifically available substitutes known for lead and cadmium and that there is no direct replacement for these specialised components that does not contain trace amounts of lead and cadmium.

Lead and cadmium in metallic bonds creating superconducting magnetic circuits operate at the temperature limit of 4K. According to Goodman (2006), there are even some alternative methods that are theoretically sufficient for superconducting electrical connection. The argument against the use of these potential substitutes was at that date that indium tin alloys was a new material for these applications and it will be needed time for a technical and market development.

Other materials are used for connections with higher temperatures, but neither are superconductors at 4K. Moreover, some materials are not able to implement all the high chemical and physical requirements. For example gold is not possible as there is not superconducted at any temperature. Therefore, it can thus be concluded that currently exemption is technically still justified.

However, the due to the lack of present comparable and verifiable supporting evidence[43] during the stakeholder consultation, it can scientifically not be concluded whether lead and especially cadmium free solutions could have a potential overall benefit compared to current technologies. It is very unclear what level of technical equivalence must be achieved by substitutes to superconducting magnetic.

14.3.2 Market developments

Beyond these technical and scientific aspects, the exemption request raises principal questions around information on current research activities

A key distinction between medical devices and consumer / household products is that improvements in performance to medical products can save lives. Therefore the timescales required for research and development in medical devices takes three times as long as for consumer products (Goodman 2006).

The consultants mentioned that since ERA completed its study in 2006 (Goodman 2006), the medical industry had sufficient time to carry out research on substitutes (e.g indium tin alloys) which were already known at that time. Furthermore the consultants have questioned this issue to a first completeness and plausibility check before the online consultation. Unfortunately, the applicant did not provide results or protocols on research and development activities.

The applicant indicates a minimum of 10 years from this time on to prepare and start up a full production. The path to finding a lead and cadmium free proven reliable alternative is unknown at this time and they cannot predict if such a substitute can be found far less widely available in ten years

Regarding cadmium, one stakeholder have making some progress in cadmium free bonds that may take several years to complete depending on the magnet design specifications (TMC 2012b). Therefore the applicant stated that there is a high probability that by 2021 cadmium free but not lead free material for metallic bonding will be sufficient for superconducting magnets.

14.3.3 Relation to the REACH regulation

The use of lead and cadmium in metallic bonds creating superconducting magnetic circuits of monitoring and control instruments are not subject to any restrictions under REACH. The same holds true for potential substitutes, namely indium, tin or bismuth.

14.3.4 Relation to existing exemption

Superconducting magnets include the current phrasing of Annex IV exemption 12 (RoHS 2 Directive 2011/85/EU) for MRI use (category 8) but not for NMR (category 8) use. Unfortu-

[43] Neither applicant nor other stakeholders

nately, this evidence was missed by ERA (Goodman 2006). During the decision of the RoHS recast the applicant attempted political correction of this error but it was not considered part of the political process and had to be considered as a new request after category 9 officially came into scope with publication of RoHS 2. Posing the question as which applications are part under the scope of this existing exemption it will make sense to amend the exemption for category 8 and 9 equipment.

14.4 Recommendation

Evaluating the above-mentioned arguments and reflecting all evidence supplied by applicant and the stakeholders, the following can be concluded:

Substitutes for lead and cadmium alloys exceeding the temperature limit of 4K and other necessary properties for superconducting magnetic circuits is at that time not foreseeable to the specific applications MRI, SQUID, NMR, and FTMS. However, an overview about the timeframe regarding research and market penetrations of alternatives was provided only rudimentary and could not be verified on scientific basis.

In this case, the exemption would need to be limited to the mentioned above specific applications and the consultants therefore propose to expand the wording of the existing exemption no.12 as follows:

> *"Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR, FTMS detectors"*

The consultants recommend not to set an expiry date prior to the end of the maximum validity period of the exemption in July 2021.

14.5 Specific references

Agilent Technologies 2011	Press release introduction to NMR. Attachment to original exemption request by Test and Measurement Coalition (TMC); http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_13/press_release_nmr.pdf
Goodman 2006	Goodman, P. 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 2009	Goodman, P. 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
JBCE 2012	Stakeholder document submitted by Japan Business Council in Europe (JBCE). on 20 March 2012 within the consultation; https://circabc.europa.eu/d/d/workspace/SpacesStore/e351e36f-94eb-4c36-be97-1c64ac3aa111/JBCE_contribution_request_13_submitted_20032012.pdf
JEOL 2012	Stakeholder document submitted by JEOL RESONANCE Inc. on 01 March 2012 within the consultation; https://circabc.europa.eu/d/d/workspace/SpacesStore/dd56e843-51c2-412c-85f0-a61e3bbaefe7/JEOL_Resonance_contribution_request_13_submitted_01032012.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
TMC 2011	Original exemption request by Test and Measurement Coalition (TMC). http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_13/13_Lead_and_cadmium_in_metallic_bonds_to_superconducting_magnetic_circuits.pdf
TMC 2012	Further information from applicant; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_13/Questionnaire1_Exe-13_Pb_TMC.pdf
TMC 2012b	Stakeholder document submitted by TMC on 19 March 2012 within the consultation; https://circabc.europa.eu/d/d/workspace/SpacesStore/93188b88-e37c-45d7-b072-39de9e87a1c0/TMC_contribution_request_1_12_13_14_15_16_17_18_20_submitted_19032012.pdf

15 Exemption request no. 14

"Lead in alloys as a superconductor and thermal conductor in devices that depend on superconductivity for their operation"

15.1 Description of requested exemption

The Test and Measurement Coalition (TMC 2011a) have requested an exemption for the use of lead in alloys needed for superconductor and thermal conductor applications. They elaborate that such an exemption exist for MRI devices, However the same application of the material is utilized in many superconducting devices with applications including but not limited to Nuclear Magnetic Resonance (NMR) and Fourier Transform Mass Spectrometer (FTMS) instruments. For this reason they request an exemption for such applications that would enable the use of lead when they are used in category 9 products (monitoring and control instruments).

TMC (2011a) explain that in such applications, cryogenic equipment is used to cool powerful superconducting magnets which are cooled to 4 K in liquid helium. Lead is used as a heat sink to cool and therewith regenerate the helium and is chosen as most other metals become brittle at these extremely low temperatures.

According to further information submitted in the stakeholder consultation by COCIR (2012), the products are far from being mass-market applications and health benefits of MEG clearly outweigh the environmental and health risks associated with the use of the small amounts of lead in this exemption.

Regarding the substitutes, the applicant argues that currently there are no viable lead-free devices available on the market for the above mentioned applications.

The applicant requests that the exemption applies until 2021 for all Monitoring and Control products and with the following wording:

"Lead in alloys as a superconductor and thermal conductor in devices that depend on superconductivity for their operation"

Furthermore, the applicant claims that the description of exemption no. 11 in Annex IV of Directive 2011/65/EU is currently limited to category 8 uses (i.e. MRI) and does not cover the above mentioned uses of category 9 monitoring and control instruments. Thus, the descriptt-ion of the existing exemption should be revised or a new one granted for category 9 products.

During the stakeholder consultation, COCIR (2012) submitted a contribution that has served to substantially support and elaborate the original information provided in the TMC's

application (TMC 2011a). Information summarized in this review is therefore widely based on both documents and is respectfully annotated where relevant.

15.2 Applicant's justification for exemption

The applicant puts forward the following main arguments (TMC 2011a):

The refrigeration unit (cryo-cooler) in NMR (nuclear magnetic resonance) or MRI (magnetic resonance imaging) is used to cool powerful superconducting magnets and thermal conductors which are cooled to 4K with liquid helium. Lead is used as a heat sink to cool the helium and is chosen as most other metals become brittle at these extremely low temperatures and so is resistant to damage.

Possible substitutes for all the thermal conductors are rare earth metals but those are difficult to fabricate, would be difficult to recycle and are not commercially viable. Finally, the applicant stated that no feasible substitutes are available. For the justification the applicant refers mainly to the two review reports for the RoHS exemptions needed for category 8 and 9 (Goodman 2006 and 2009).

Two stakeholders have contributed information during the stakeholder consultation in agreement of the scope and in support of the proposed exemption (JEOL 2012; JBCE 2012). Furthermore, both stakeholders say they do not have information on available substitutes and are in compliance with the proposed expiry date in 2021. The stakeholders claimed that technically, the substitution of lead may be achieved in this timeframe.

A third involved stakeholder has also supported the exemption request and provided additional evidence for understanding the issue at hand (COCIR 2012).

COCIR (2012) claims that cryo-coolers used for the MRI technology are also based on lead cold heads. A cold head is fitted with a regenerator in which the thermodynamic circulation process is carried out to generate cold. Besides retaining the cold temperatures required to ensure superconducting and thermal conduction, this process also regenerates helium, thus eliminating the need for frequent helium replenishing and substantially reducing the amount of helium, a limited natural resources, required for operation.

15.2.1 Substitutes from a technical point of view

It can be summarised that the applicant and the stakeholders put forward the following main arguments:

Cryo-coolers are the devices used to reach cold temperatures by cycling certain gases, mainly helium[44]. The cryo-coolers material must have high thermal conductivity and specific

[44] With helium it is possible to reach and maintain 4K temperature at which several metals are superconductors COCIR (2012)

heat capacity at liquid helium temperatures because the thermal properties of materials at ambient conditions are very different to those at 4K. Commonly used metals as copper produced for domestic refrigerators and freezers are not suitable at 4K and make them useless for the applications under the scope of this request for exemption. Lead is a good superconductor at 4K and has a very high thermal conductivity at very low temperature and is resilient to large changes in temperature (COCIR 2012). Most other materials become too brittle and thus are unusable.

The applicant and stakeholders state that rare earth alloys (i.e. erbium nickel alloys (ErNi)) have reasonably high volumetric specific heat values and so are possible candidates as regenerator materials for cryo-coolers. One type of material that has been researched is the rare earth metal erbium. This metal is classified as a critical material because world supply is limited so that a large increase in consumption may not be possible in the short term (COCIR 2012).

- A few arguments were put forward regarding disadvantages of the possible substitutes and advantages of the continued use of lead in this application: Several adverse effects should be noted against the substitutes. NMR, MRI and MEG are extremely sensitive to magnetic materials. All rare earth metals are paramagnetic and nickel is also magnetic and so could be disadvantageous to the sensitivity of these machines[45] (COCIR 2012).
- Further, erbium the most promising candidate is available only in extremely small quantities (COCIR 2012).
- Rare earth compounds with nickel such as ErNi are very brittle and so are very difficult to produce in the useful shapes needed for cryo-coolers unlike lead[46]. Erbium itself however is fairly ductile although it is more difficult to fabricate than lead (COCIR 2012).
- Other lead-free substitutes such as tin with silver or copper cannot be used at very low temperatures close to 4K as the tin undergoes a phase transformation (“tin pest”, see section 11.3.1) and so they have higher specific heat values than lead (Goodman 2009).
- One stakeholder (COCIR 2012) states that another important criterion concerns the helium as a rare and expensive element with very limited natural occurrence. So it is necessary to prevent losses. This can be done through a regeneration process that uses compact and efficient cooling devices where lead is used so that helium loss is avoided and a 4 K temperature is retained for the application.

[45] Cannot be used within the detection zones of the instruments

[46] Lead is relatively ductile and so is resistant to damage.

Furthermore the applicant states that medical equipment and analytical instrument manufacturers can only use cryo-coolers that are commercially available and these currently contain lead thermal conductors (TMC 2011a).

Information on current research activities on substitutions for lead in “superconductor and thermal conductor in devices that depend on superconductivity” submitted by the applicant provides that substitutes will be available and practicably proven for use in mentioned applications before 2020 (TMC 2011b).

15.2.2 Environmental concerns

COCIR (2012) stated that currently, at the end of life, units using lead are returned to the supplier for reprocessing so the units do not enter the waste stream. It is not known if potential substitutes can be easily recycled, re-used or if the negative environmental, health and/or consumer safety impacts caused by alternatives outweigh the benefits of leaded cryo-coolers. It is important to note the function of a cryo-cooler is to condense and recycle helium so that none is lost, and is considered a further environmental benefit of this application.

COCIR (2012) assumes that alternative technologies provide inferior precision leading to following further implications: Helium, which is considered an irreplaceable natural resource, is evaporated and lost to the atmosphere. Although not commercially used yet in MEG, the availability of reasonably priced closed cycle cryo-coolers offers a possibility to this end. In MRI, closed-cycle cryo-coolers are widely used for this purpose.

15.2.3 Roadmap for substitution and elimination of lead

The applicant proposes no roadmap to develop substitutes. However, COCIR (2012) states that at least one manufacturer is currently carrying out research into substitutes and is planning to launch the first lead-free cryo-cooler in 2014. However, if this lead-free device can be developed for evaluation by medical device manufacturers, the time required for evaluation, reliability testing, clinical trials and approval under the Medical Devices Directive 93/42/EEC [47] could be up to 6 years (COCIR 2012). Thus, 2020 may be a realistic date to develop substitutes.

15.2.4 Use in category 9

According to the applicant the existing exemption does not cover category 9 monitoring and control instruments. The unavailability of this substance exemption would cause withdrawal of products from the EU market. This would have very serious consequences, not only for category 9 producers, but also on client industries e.g. hospitals (TMC 2011a).

[47] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:en:PDF

15.3 Critical review

15.3.1 Scientific and technical practicability of lead substitution

The applicant argues that there are no technically and scientifically available substitutes known for lead and that there is no direct replacement for these specialised components. No further evidence was submitted during the stakeholder consultation to further support the notion that the substitution of lead in alloys as superconductor and thermal conductor is technically practicable in this application.

The argument against the use of these potential substitutes was that time will be needed for technical and market development. Here too, the applicant neither provided evidence on the point of time that investigations on substitutes were started on his behalf nor on details regarding the schedule of a substitution roadmap.

The requested exemption strongly relates to very similar applications as discussed in exemption request no. 13 in this report. The applicant also refers to the ERA study report (Goodman 2006) where it was reported that several materials that might be used as substitutes are available.

Goodman (2006) provides several reservations concerning rare earth metal substitutes that are all strongly paramagnetic and so would be highly detrimental to the sensitivity of these machines.

COCIR (2012) provides further information in the consultation beyond the justification of the applicant. For instance, COCIR (2012) provides several disadvantages of using rare materials as substitutes, which can be followed and verified by the consultant. Moreover, the technical impracticability of substitution is described detail and with comprehensive arguments.

The consultants conclude that, despite the absence of sufficient information submitted by the applicant, the stakeholder technical arguments plausibly justify that currently lead used as a superconductor cannot be substituted in this application.

15.3.2 Environmental arguments

Due to the fact that the applications are far from being mass-market and thus, in total, small amounts of lead are needed at present, it may be understood that the subsequent environmental effects are not extensive. The cryo-cooler cold head is one part of these large applications and so would be recycled with the other parts using traditional metals as steel, aluminium or copper recovery processes. The lead in the cold head is contained in confined closed modules where it can also be effectively removed and recycled at end-of life phase.

That is to say, waste equipment from categories 8 and 9 is very likely to be recycled by professional recyclers using well controlled safe processes.

15.3.3 Relation to the REACH regulation

The use of lead in alloys as a superconductor and thermal conductor as part of a monitoring and control instrument is not subject to any restrictions under REACH. The same holds true for potential substitutes, namely erbium and nickel alloys.

15.3.4 Relation to existing exemption

Annex IV exemption 11 (RoHS 2 Directive 2011/85/EU) is intended to exempt the use of lead when used as a superconductor and also when used in cryo-coolers as a thermal conductor used for MRI systems (category 8). The same designs of cryo-coolers are also used for category 8 equipment such as MEG, NMR and cyclotrons. Unfortunately it seems this information was not brought to the attention of ERA (Goodman 2006).

As decisions were made concerning the RoHS 1 recast, the applicant attempted to correct this error but as it was not considered part of the political process, it had to be processed as a new request after category 9 officially came into scope with the publication of RoHS 2. In light of the question as to which applications fall under the scope of the existing exemption, it makes sense to amend exemption 11 to include both category 8 as well as category 9 equipment.

15.3.5 Conclusion

TMC 2011 requests the exemption for superconductor and thermal conductor devices that depend on superconductivity for their operation, while COCIR (2012) justifies the exemption for cyro-cooler cold heads in any equipment that require cryo-coolers. Both statements explain that the current technology utilizes superconductors, which are immersed in liquid helium and the electrical conductivity of the connector coatings must be very high at 4 K.

According to the consultant the technical arguments plausibly justify that cryo-cooler materials must be good thermal conductors and that this conductivity must withstand the extreme conditions of use of this application.

Therefore, the consultants could comprehend the new proposed COCIR (2012) wording for Annex IV covering the use of lead as a superconductor in cold heads of cryo-coolers.

However, it is not clear whether the research into substitution or elimination of lead in this application actually would require ten years. COCIR puts forward that some research has been conducted by one of the manufacturers. One cold head manufacturer is currently carrying out research into substitutes for lead and is planning to launch the first lead-free cryo-cooler in 2012. However, COCIR (2012) state that it is not yet possible to achieve the performance that is achieved with lead and additionally, once the substitute element is launched, it will still require reliability testing and authorization before it can become available for use on the market. As this line of argumentation is relevant only for medical applications (category 8) and for industrial monitoring and control instruments (part of category 9), and as

no other information has been submitted concerning the need of this exemption for other categories, the consultants propose to modify the exemption wording, so as to limit it to applications where redesign, reliability testing and requalification of products would require an additional period of time before products could become available on the market.

Following verification with the applicant, to ensure that the proposed change of wording sufficiently covers applications for which this exemption has been requested, it was verified that lead alloys are also used in cold probes, as well as in equipotential bonding systems used in the various systems under cryo-genic conditions. As the argumentation for the use of lead alloys in these mechanisms follows that of the main exemption, the consultants have adapted the scope of the exemption to encompass these two applications.

Thus, with less than one year passed since the adoption of category 8 and 9 into the scope of the RoHS Directive, in the absence of substitution and elimination possibilities, and in light of the additional time required for reliability testing and qualification of alternative solutions, the consultants have no indication to recommend an expiry date earlier to the seven years maximum validity of exemptions adopted to Annex IV.

15.4 Recommendation

Based on the documents submitted by the stakeholders and in the absence of contrary information, the requested exemption would be in line with the requirements of Art. 5(1)(a). The consultants therefore recommend adding an exemption to Annex IV of the RoHS Directive with the following wording:

> *"Lead in alloys, as a superconductor or as a thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and /or in industrial monitoring and control instruments"*

The consultants recommend not to set an expiry date prior to the end of the maximum validity period of the exemption in July 2021.

15.5 Specific references

COCIR 2012	Stakeholder document submitted by European Coordination Committee of the Radiological, Electronical and Healthcare IT Industry (COCIR). on 15 February 2012 within the consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_14/COCIR_contribution_request_14_submitted_15022012.pdf
Goodman 2006	Goodman, P. 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 2009	Goodman, P. 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
JBCE 2012	Stakeholder document submitted by Japan Business Council in Europe (JBCE). on 20 March 2012 within the consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_14/JBCE_contribution_request_14_submitted_20032012.pdf
JEOL 2012	Stakeholder document submitted by JEOL RESONANCE Inc. on 01 March 2012 within the consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_14/JEOL_Resonance_contribution_request_14_submitted_01032012.pdf
RoHS Directive 2003	Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0095:EN:NOT
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
TMC 2011a	Original exemption request no.14 by Test and Measurement Coalition (TMC). http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_14/14_Lead_in_alloys_as_a_superconductor_and_thermal_conductor.pdf
TMC 2011b	Applicant answers to clarification questions, submitted on 20 December 2011 by the Test and Measurement Coalition (TMC); http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_14/Questionnaire_Exe-14_TMC.pdf
TMC 2012	Further information from applicant; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_14/Questionnaire_Exe-14_TMC.pdf
TMC 2012b	Stakeholder document submitted by TMC on 19 March 2012 within the consultation; https://circabc.europa.eu/d/d/workspace/SpacesStore/93188b88-e37c-45d7-b072-

39de9e87a1c0/TMC_contribution_request_1_12_13_14_15_16_17_18_20_submitted_19032012.pdf

A.1 Annex: GUIDANCE DOCUMENT

Standard application format and guidance document for RoHS exemption requests on the basis of Article 5(8) Directive 2011/65/EU

A.1.1 For whom this document is intended

This document is intended for economic operators of establishments responsible for putting electrical and electronic equipment on the European market, as well as establishments active in the development of materials and applications that may be used as part of such equipment. Economic operators may include:

- Manufacturers of electrical and electronic equipment and parts thereof
- Representatives authorized to act on behalf of manufacturers
- Distributors of electrical and electronic equipment
- Importers of electrical and electronic equipment

A.1.2 Do RoHS exemptions concern me?

The 2011/65/EU Directive[48] (henceforth RoHS 2) restricts the use of certain hazardous substances in electrical and electronic equipment placed on the European market. If an article falls under the scope of equipment given in the RoHS 2 directive, it should be regulated accordingly, thus ensuring that it does not include one of the restricted substances above a prescribed amount. The regulated substances are listed in Annex 2 of the Directive as well as the maximum tolerated amount of the substance permitted in any homogenous material from which the application is comprised. At present the list of substances and tolerated values includes:

- Lead (Pb), (0.1%)
- Mercury (Hg), (0.1%)
- Cadmium (Cd), (0.01%)
- Hexavalent chromium (chromium VI, Cr^{+6}), (0.1%)
- Polybrominated biphenyls (PBB), (0.1%)
- Polybrominated diphenyl ethers (PBDE), (0.1%)

You should be aware that legislation may provide for adjustments of the list of substances and/or tolerated amounts from time to time, in correspondence with available scientific and technological developments.

[48] Directive 2002/95/EC on the Restriction of Hazardous Substances came into force in January 2003 and was known as the RoHS directive. A recent recast in the form of Directive 2011/65/EU has brought into force the RoHS 2 regime, to which this document refers if not explicitly stating otherwise.

Homogeneous material means a material that cannot be mechanically disjointed or separated into different materials, by use of actions such as unscrewing, cutting, crushing, grinding and abrasive processes. A few examples[49] are listed below:

- A plastic cover is a "homogeneous material" if it consists of one type of plastic that is not coated with or has attached to it or inside it any other kinds of materials. In this case the limit values of the directive would apply to the plastic.
- An electric cable that consists of metal wires surrounded by non-metallic insulation materials is an example of a "non-homogeneous material" because the different materials could be separated by mechanical processes. In this case the limit values of the directive would apply to each of the separated materials individually.
- A semi-conductor package contains many homogeneous materials which include: plastic moulding material, tin-electroplating coatings on the lead frame, the lead frame alloy and gold-bonding wires.

Anyone who is involved with the production of such an article, be it for purposes of putting such equipment onto the market, for research activities concerning substitutes or for (legal) services around these issues, should be aware of the RoHS Directive.

In most cases, it will be companies that want to have legal certainty for their products that will need to check whether an existing exemption either applies or whether a new or amended one should be pursued. Also, some companies or research institutions might be involved in developing substitutes and would hence like to increase the incentives for them to be used, which is why they may like to apply for the deletion of an exemption.

If you would like to check whether your application falls under the RoHS 2 scope, you may find some guidance within the Frequently Asked Questions (FAQ) draft from 15 June, 2012 mentioned in section A.1.8 of this document. Further questions may be referred to the European Commission by e-mail or post

contact details

or to the national authorities. A list of national authorities can be found here:

http://ec.europa.eu/environment/waste/weee/pdf/contacts_ms_rohs.pdf

If you have found your application to be under the scope of RoHS 2, you may want to check if the criteria for exemption are applicable, to see if you have grounds for submitting a request for exemption. This should also be done if an exemption already exists but requires renewal or change of wording to cover additional similar applications, as well as in cases

[49] Examples are cited from: European Commission Directorate General Environment, 2006, “Frequently Asked Questions Document on Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)”, cf. under http://ec.europa.eu/environment/waste/pdf/faq_weee.pdf

where you would like to apply for the revoke of an exemption, due to recent scientific or technical developments.

A.1.3 Criteria for exemptions

The directive[50] includes a few criteria according to which RoHS 2 exemptions can be justified. This means that under specific circumstances, temporary permission, for placing EEE, which contains the RoHS 2 banned substances, on the EU market, may be granted. Such exemptions are then listed under Annexes III and IV of the directive. The following excerpt demonstrates how exemptions are listed in the directive annexes:

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

	Exemption	Scope and dates of applicability
33	Lead in solders for the soldering of thin copper wires of 100 µm diameter and less in power transformers	
34	Lead in cermet-based trimmer potentiometer elements	
36	Mercury used as a cathode sputtering inhibitor in DC plasma displays with a content up to 30 mg per display	Expired on 1 July 2010
37	Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body	
38	Cadmium and cadmium oxide in thick film pastes used on aluminium bonded beryllium oxide	
39	Cadmium in colour converting II-VI LEDs (< 10 µg Cd per mm² of light-emitting area) for use in solid state illumination or display systems	Expires on 1 July 2014

It should be noted that the criteria mentioned in the directive do not automatically justify an exemption but may rather be understood as the framework for your argumentation towards exemption justification. Assuming it can be shown that some of the criteria apply towards a certain application, the European Commission will still have the right of discretion in deciding if and under what circumstances the exemption should be granted.

One should also not assume that any single criteria can be seen as a minimum threshold that an exemption request must reach, but rather that respective argumentation towards the various points will be weighed and considered during the decision process.

Exemptions can be requested:

- First and foremost for applications, which contain RoHS 2 restricted substances above the amounts prescribed in Annex II of the directive (cf. section A.1.2) – At present this is mainly relevant for applications previously considered out of scope and soon to be included, however if an in scope product is to newly be made available on the market

[50] Directive 2011/65/EU, article 5(1)(a)

or if you have just now recognized that your application is under the RoHS 2 scope it would also be relevant in your case.

- In cases where a change of wording of an existing exemption could be made to include a similar application with the same inherent compliance issues
- In cases where an exemption exists but is due to expire within ca. 18 months.

You should keep in mind that the scope of RoHS was changed in the last recast and it is possible that an application that was previously exempt is now included in the scope. In such cases, a product that is already available on the market might require undertaking action for the approval of an exemption. Furthermore, the existing list of exemptions and the scope of RoHS 2 are always subject to changes. As a company you are always in the duty of keeping yourself updated in this respect and of verifying whether action is needed.

The directive states[51] that exemptions may also be deleted from the Annexes if the conditions established through applicable criteria are no longer fulfilled. A request for deletion would then argue that the various criteria are no longer met. This could be relevant for you if your enterprise has developed or is representing a developer of possible substitutes for an application currently exempt.

The following diagram will take you through the various criteria, to help you understand if you have grounds for requesting an exemption for your application.

This diagram may also be of assistance if you would like to apply for the renewal of an exemption that is close to the end of its validity; to apply for changing the wording of an on-going exemption so that it may cover additional similar applications or; to apply for the deletion of an existing exemption.

[51] Directive 2011/65/EU, article 5(1)(b)

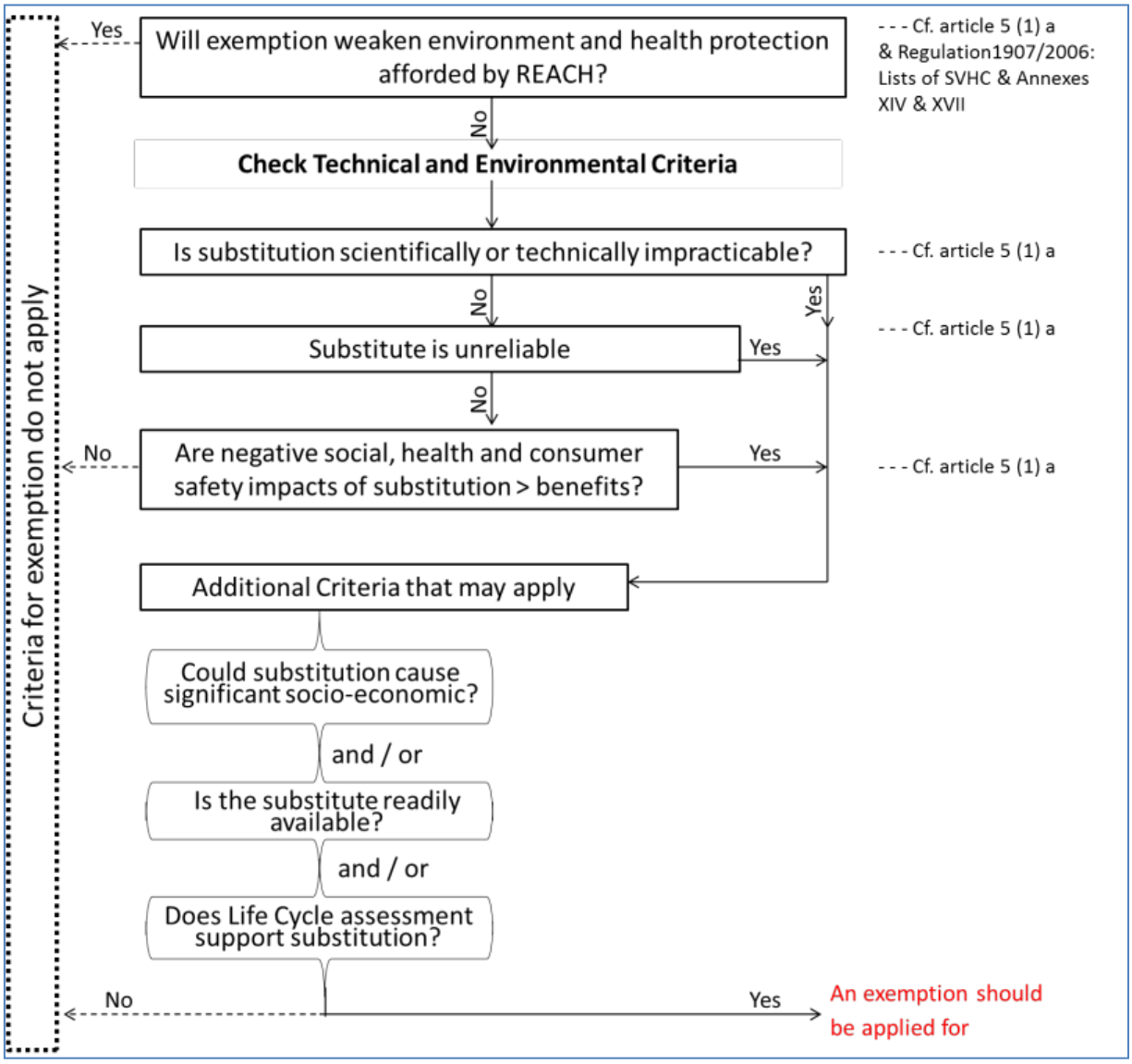

Figure A-1: Grounds for establishing if a product or article may qualify for a temporary exemption

In order to be fully in line with REACH methodology and provisions, applicants for exemptions must follow the methodologies outlined in the ECHA Guidances on application for authorisation and socio-economic Analysis available under:

http://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf

and

http://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf

These documents outline the criteria and tests to follow to determine the availability of substitutes and to assess socio-economic impact of substitution").

The directive also requires that impacts of an exemption on future innovation be considered when deciding on the duration of exemptions.

Table A-2 below contains some further information as to how the various criteria should be understood:

Table A-2: Definition of RoHS 2 exemption criteria

Element	Explanation
Threshold Criteria	
Exemption may weaken REACH afforded environmental and health protection	An exemption may weaken REACH afforded environmental and health protection where REACH regulation already includes restrictions for the use of the substance in the application in question. Restrictions for substances and for specific uses of substances should be checked: ▪ In the list of substances of very high concern (SVHC) and its respective candidate lists ▪ In Annex XIV of the REACH regulation that lists substances requiring authorization ▪ In Annex XVII of the REACH regulation that lists the restrictions of use for various substances Note that REACH regulation may be updated from time to time to contain further annexes that may be relevant for checking existing restrictions.
Criteria	
Substitution is scientifically or technically impracticable	A substitute material, or a substitute for the application in which the restricted substance is used, is yet to be discovered, developed and approved for use in the specific application (approval would be needed for example for the use of a substitute in medical devices).
Reliability of a substitute	The probability that EEE using the substitute will perform the required function without failure for a period of time comparable to that of the application in which the original substance is in use.
Negative environmental, health and consumer safety impacts of substitution outweigh benefits thereof	The impacts of substitution stand to be significantly higher than those attributed to the use of the restricted substance in the application in question, where environmental, health and consumer safety aspects are considered.
Additional Parameters	
Socio-economic impacts of substitution	Substitution could cause adverse socio-economic impacts that should be considered in the evaluation of an exemption. A good example would be the impact of substitution for an application that is manufactured by big enterprises as well as small and medium ones. In such a case, the costs of substitution may have adverse effects on the market for the application, caused by the impacts on competitiveness and this may in turn affect employment in some regions.
Availability of a substitute	The availability of a substitute to be produced and delivered within reasonable time in comparison with the substance originally used in the application. This includes the time required for manufacturing the application in which the original substance is in use. This could apply when a substitute exists “in the lab” but is still not available for use in the required amounts or qualities.
Life Cycle assessment on impacts of exemption	A life cycle assessment of the exemption would compare the consumption of various resources and the environmental impacts attributed to the use of the restricted substance and its possible

Element	Explanation
	substitutes in the various life stages of the application: production, distribution, use and waste management at end of product lifetime.
Impacts on innovation	Impacts that the duration of an exemption may have on future efforts for developing possible substitutes.

A.1.4 How do I apply for an exemption?

Once you have decided that you either want to request an exemption or the renewal, the amendment or the deletion of an existing exemption, you will have to do the following:

1. Use the checklist below to understand what information and data you need to compile before handing in a request.
2. Fill out the application form
3. Send the application form along with further documentation to the European Commission by e-mail or post:

contact details

4. Be ready to answer questions related to your request.

Checklist documentation

Research and provide documentation such as:

- Test results on the suitability of substitutes and any other technical / scientific documentation supporting your request – if possible and available, this documentation should be third party certified.
- Third party verified documentation such as life cycle assessment according to ISO 14040, ISO 14044, PCF, CBA etc.
- Roadmaps for the further technical development of RoHS 2 compliant substitute applications.
- REACH-relevant documentation such as registration, application for authorization etc.
- Documentation from suppliers on the availability or non-availability of substitutes
- Socio-economic data in as much detail as possible (see application form in Appendix 1 for the necessary categories and level of detail) and if possible and available, with third party certification.

A.1.5 What happens once I apply for an exemption?

Once you have handed in your request it will be processed in a standardized manner which is briefly described in this section.

First of all the request will be subject to a first check by the European Commission. Then the request will be technically and scientifically evaluated (this may be prepared by an external

consultant). Finally the request will go through a formal procedure within the EU institutions, in which a decision shall be made concerning it approval.

The directive[52] describes in detail the procedure stages that need to be followed concerning requests for exemptions. These include:

(a) The Commissions will acknowledge receipt of an application in writing within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(b) The Commissions will inform the Member States of the application without delay and provide them with the application and any supplementary information;

(c) The Commissions shall make a summary of the application available to the public;

(d) The Commissions will evaluate the application and its justification

The evaluation of your request will include the following steps:

1. Completeness check (duly filled out application format, availability of all necessary documentation, contact details available).
2. First technical and scientific check (comprehension of request, validity of provided argumentation and information, identification of missing information).
3. Compilation of questions to the applicant if necessary.
4. Once the requested additional information has been received, the submitted information will be prepared for an online stakeholder consultation (compilation the application and additional information, references to former evaluations if applicable, questions to stakeholders, and preparation of consultation website). Note that a stakeholder consultation is usually held for a number of exemption requests in parallel and therefore will not necessarily take place adjacent to the completion of initial information.
5. Minimum of 8 weeks online stakeholder consultation with the goal to collect additional data and information and to inform stakeholders about the request.
6. Evaluation of consultation results and results of additional rounds of questions to the applicant and other stakeholders.
7. Drafting of a recommendation including the evaluation results and a justification on whether the request should be accepted or not.

Once the recommendation has been prepared, the European Commission will have to decide whether it follows the recommendation which could lead to an amendment of Annex III or IV (cf. Table A-1 above). In this case, a draft Commission Delegation Regulation will be submitted according to the following steps:

[52] Directive 2011/65/EU, article 5 (4)

(A) Preparation of legal measure;

(B) Consultation of Member States expert group for RoHS 2 delegated acts;

(C) COM internal consultation and translation;

(D) Notification of Council and Parliament;

(E) Publication of legal measure in the Official Journal of the European Union.

It should be noted that The European Parliament and the European Council may object to a delegated act, and so to the decision concerning an exemption within 2 months of notification. This period may be extended to up to 4 months.

A.1.6 Everything you need to know about timelines for exemptions

How long do I need to wait for a decision concerning my application for exemption?

Once you have handed in a request it may take up to one and a half years before the procedure has been completed. You thus need to hand in a request in due time to make sure that you have legal certainty as soon as possible in order to be able to put your product onto the market.

The directive[53] also lays down the obligation of the Commission to decide on an application for renewal of an exemption no later than 6 months before the expiry date of the existing exemption unless specific circumstances justify other deadlines. The existing exemption shall remain valid until a decision on the renewal application is taken by the Commission.

In case an exemption is to be deleted from the Annex, be it because the application for its renewal has been rejected or because the exemption is revoked, the directive[54] specifies that it shall expire at the earliest 12 months, and at the latest 18 months, after the date of the decision. I.e. a transition period is foreseen to allow stakeholders to take appropriate action.

You should consider how these timeframes may affect the production and the placing of application on the European market in deciding when at latest to submit an application for exemption, should applicable substitutes not be available.

When at latest should I apply for an exemption?

If you are applying for a **new exemption**, you should apply no later than 18 months (cf. above); procedure completion may take a year and a half) before your application comes under the RoHS 2 scope. You should additionally consider how much time you will need to adapt production processes for the use of substitutes, should your exemption not be

53 Directive 2011/65/EU, article 5 (5)

54 Directive 2011/65/EU, article 5 (6)

approved, so as to avoid taking products off the market or postponing the distribution of a new application in the EU market.

If you would like to request the **renewal of an exemption**, the directive[55] sets the maximum time limit for the application for exemption renewal at no later than 18 months before the exemption expires.

If you would like to **change the wording of an existing exemption** you should take notice of the validity period as mentioned above, especially if there exist, within the exemption, a few clauses setting unique validity periods that depend on application specifics (for example voltage, size, material components, etc.).

If applying for the **revoke of an existing exemption**, you may apply immediately, so long as substitutes will be ready and approved for use in applications, should the request be approved. Though the procedure for reviewing and reaching a decision concerning a request may take up to 18 months, it could also take less and then an additional 12-18 months would be granted as transition period for manufactures to update production lines for the use of applicable substitutes.

How long will an exemption be valid?

The directive[56] regulates the maximum validity period of exemptions:

Table A-3: Maximum validity period of exemptions under RoHS 2 as of 21 July 2011 unless a shorter period is specified

Category Annex I	**Maximum validity period for new exemptions**	**Validity period for existing exemptions where no expiry date is specified**	**Validity period for existing exemptions where an expiry date is specified**
1-7, 10, 11 (not applicable to Annex IV exemption)	5 years	22 July 2011 - 21 July 2016	22 July 2011 - specified date
8, 9 (medical and monitoring and control devices)	7 years	22 July 2014 - 21 July 2021	22 July 2014 - specified date
8 (in vitro diagnostic medical devices)		22 July 2016 - 21 July 2023	22 July 2016 - specified date
9 (industrial monitoring and control instruments)		22 July 2017 - 21 July 2024	22 July 2017 - specified date

Assuming that the conditions set out in the exemption criteria are still fulfilled, the validity period of an existing exemption may be renewed by means of application for renewal.

55 Directive 2011/65/EU, article 5 (5)

56 Directive 2011/65/EU, article 5(2)

You should also be aware that if your application is to be included into the RoHS scope in the near future, the granted validity period only starts "running" once the application comes into scope.

A.1.7 Application format and elaboration of necessary documentation for submitting an exemption request

The application form can be found in the attachment below [### in final document it is perhaps better to add a link in case of updates ###]. It has been formulated to assist applicants in understanding the various details that should be included in an application.

Applications should be submitted in digital format.

It should be specified if parts of an application, or parts of further information supplied throughout the evaluation process, are confidential. It is strongly recommended to submit confidential and non-confidential material in separate documents. Additionally, it should be noted that as confidential material cannot serve as official information in support of an exemption request (or its renewal, amendment or deletion), where possible, it should be refrained from.

A.1.8 Further resources

In 2012 a RoHS Frequently Asked Questions (FAQ) document draft was published by the European Commission. It includes information that may be of assistance concerning various issues such as:

- The main changes introduced by the recast of RoHS (RoHS 2 regime)
- Information concerning the transposition of the directive into force
- Clarifications concerning the RoHS 2 scope, terms and definitions and other specific issues
- Questions concerning compliance

The document may be found under:

http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf

A.1.9 Example

###Perhaps include an example that can be followed by the applicant (this may be located in an appendix)###

A.1.10 Contacts

###Name and contact information of an official Commission contact###

Exemption Request Form

Date of submission: _____

1. Name and contact details

1) Name and contact details of applicant:

Company:	_____	Tel.:	_____
Name:	_____	E-Mail:	_____
Function:	_____	Address:	_____

2) Name and contact details of responsible person for this application (if different from above):

Company:	_____	Tel.:	_____
Name:	_____	E-Mail:	_____
Function:	_____	Address:	_____

---

2. Reason for application:

Please indicate where relevant:

- ☐ Request for new exemption in:
- ☐ Request for amendment of existing exemption in
- ☐ Request for extension of existing exemption in
- ☐ Request for deletion of existing exemption in:
- ☐ Provision of information referring to an existing specific exemption in:
  - ☐ Annex III ☐ Annex IV

No. of exemption in Annex III or IV where applicable: _____

Proposed or existing wording: _____

Duration where applicable: _____

☐ Other: _____

3. Summary of the exemption request / revocation request

_____

---

4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

   Name of applications or products: _____

a. List of relevant categories: (mark more than one where applicable)

☐ 1	☐ 7
☐ 2	☐ 8
☐ 3	☐ 9
☐ 4	☐ 10
☐ 5	☐ 11
☐ 6	

b. Please specify if application is in use in other categories to which the exemption request does not refer: _____

c. Please specify for equipment of category 8 and 9:

The requested exemption will be applied in

☐ monitoring and control instruments in industry

☐ in-vitro diagnostics

☐ other medical devices or other monitoring and control instruments than those in industry

2. Which of the six substances is in use in the application/product?

   (Indicate more than one where applicable)

   ☐ Pb ☐ Cd ☐ Hg ☐ Cr-VI ☐ PBB ☐ PBDE

3. Function of the substance: _____

4. Content of substance in homogeneous material (%weight): _____

5. Amount of substance entering the EU market annually through application for which the exemption is requested: _____

   Please supply information and calculations to support stated figure.

6. Name of material/component: _____

7. Environmental Assessment: _____

   LCA: ☐ Yes

   ☐ No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

_____

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

_____

---

5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

1) Please indicate if a closed loop system exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

_____

2) Please indicate where relevant:

☐ Article is collected and sent without dismantling for recycling
☐ Article is collected and completely refurbished for reuse
☐ Article is collected and dismantled:
  ☐ The following parts are refurbished for use as spare parts: _____
  ☐ The following parts are subsequently recycled: _____
☐ Article cannot be recycled and is therefore:
  ☐ Sent for energy return
  ☐ Landfilled

3) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:

☐ In articles which are refurbished _____
☐ In articles which are recycled _____
☐ In articles which are sent for energy return _____
☐ In articles which are landfilled _____

---

6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

_____

(B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

_____

---

7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

_____

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

_____

---

8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

- ☐ Authorisation
  - ☐ SVHC
  - ☐ Candidate list
  - ☐ Proposal inclusion Annex XIV
  - ☐ Annex XIV
- ☐ Restriction
  - ☐ Annex XVII
  - ☐ Registry of intentions
- ☐ Registration

2) Provide REACH-relevant information received through the supply chain.
Name of document: _____

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?
   - ☐ Yes. Consequences? _____
   - ☐ No. Justification: _____
2. Can the substance named under 4.(A)1 be substituted?
   - ☐ Yes.
     - ☐ Design changes:
     - ☐ Other materials:
     - ☐ Other substance:
   - ☐ No.

     Justification: _____
3. Give details on the reliability of substitutes (technical data + information):_____
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
   1) Environmental impacts: _____
   2) Health impacts: _____
   3) Consumer safety impacts: _____

⇨ Do impacts of substitution outweigh benefits thereof?
Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

a) Describe supply sources for substitutes: _____
b) Have you encountered problems with the availability? Describe: _____
c) Do you consider the price of the substitute to be a problem for the availability?
   ☐ Yes ☐ No
d) What conditions need to be fulfilled to ensure the availability? _____

(D) Socio-economic impact of substitution:

⇨ What kind of economic effects do you consider related to substitution?

- ☐ Increase in direct production costs
- ☐ Increase in fixed costs
- ☐ Increase in overhead
- ☐ Possible social impacts within the EU
- ☐ Possible social impacts external to the EU
- ☐ Other: _____

⇨ Provide sufficient evidence (third-party verified) to support your statement: _____

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

_____

---

10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:

_____
