Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance restrictions in Electrical and Electronic Equipment (RoHS Directive)

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

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Report for:

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Disclaimer

Contents

1.0 Background and objectives

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

Under Framework Contract no. ENV.C.2/FRA/2011/0020, a consortium led by Eunomia Research & Consulting was requested by DG Environment of the European Commission to provide technical and scientific support for the evaluation of exemption requests under the new RoHS 2 regime. The work has been undertaken by the Oeko-Institut, and has been peer reviewed by Eunomia Research & Consulting.

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

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

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

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

function without failure for a period of time comparable to that of the application in which the original substance is included, is lower than for the application itself;

- The negative environmental, health and consumer safety impacts of substitution outweigh the benefits thereof.

Ø Once one of these conditions is fulfilled, the evaluation of exemptions, including an assessment of the duration needed, now has to consider the availability of substitutes and the socio-economic impact of substitution, as well as adverse impacts on innovation, and life cycle analysis concerning the overall impacts of the exemption; and

Ø A new aspect is that all exemptions now need to have an expiry date and that they can only be renewed upon submission of a new application.

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

The Report includes the following Sections:

Section 2.0 Project set-up

Section 3.0 Scope

Section 4.0 Overview of the evaluation results

Section 5.0 Links from the Directive to the REACH Regulation

Section 6.0 Evaluation of the requested exemption handled in the course of this project.

2.0 Project set-up

Assignment of project tasks to Oeko-Institut, started 18 November 2013. The overall project has been led by Carl-Otto Gensch. The project team at Oeko-Institut consists of the technical expert Yifaat Baron. Eunomia, represented by Adrian Gibbs, have the role of ensuring quality management.

3.0 Scope

A single new RoHS exemption request has been evaluated. Through the course of the evaluation, it was further established that Exemption Request 2013-6, originally requested for Cat. 9 applications, was also relevant for medical devices of Cat. 8. This has been taken into consideration in the evaluation of the request. An overview of the exemption request is given in Table 4-1 below.

In the course of the project, a stakeholder consultation was conducted. The stakeholder consultation was originally launched for a duration of 8 weeks, between 20.12.2013 and 28.02.2014. Towards the end of the consultation period, the applicant requested a few changes to the formulation of the existing exemption, including an extension of its scope to all RoHS regulated substances. In coordination with the European Commission, the consultants extended the consultation period to provide stakeholders with sufficient time to contribute information, taking into consideration the requested changes. In total, 6 weeks were added to the consultation period, which ran until 11.04.2014.

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

Information concerning the consultation was provided on the project website, including a general guidance document, the applicant's documents for the exemption request, results of earlier evaluations where relevant, a specific questionnaire and a link to the EU CIRCA website. All non-confidential stakeholder comments, submitted during the consultation, were made available on the RoHS Evaluation website and on the EU CIRCABC website (Communication and Information Resource Centre for Administrations, Businesses and Citizens)[1].

The evaluation of the stakeholder contributions led to further consultation including, *inter alia*, engaging with stakeholders in further discussion, further exchanges in

[1] EU CIRCABC website: https://circabc.europa.eu (Browse categories > European Commission > Environment > RoHS Evaluations, at top left, click on "Library")

order to clarify remaining questions, cross-checking with regard to the accuracy of technical arguments, and checks in respect of confidentiality issues.

The request was evaluated according to the various criteria (Cf. Section 1.0 for details). The evaluation appears in the following chapters. The information provided by the applicant and by stakeholders is summarized in the first sections. This includes a general description of the application and requested exemption, a summary of the arguments made for justifying the exemption, information provided concerning possible alternatives and additional aspects raised by the applicant and other stakeholders. In some cases, reference is also made to information submitted by applicants and stakeholders in previous evaluations, in cases where a similar request has been reviewed or where a renewal has been requested of a request reviewed in the past. The Critical Review follows these sections, in which the submitted information is discussed, to clarify how the consultants evaluate the various information and what conclusions and recommendations have been made. For more detail, the general requirements for the evaluation of exemption requests may be found in the technical specifications of the project.[2]

4.0 Overview of the evaluation results

The exemption request covered in this project and the applicants concerned, as well as the final recommendations and proposed expiry dates are summarized in Table 4-1. The reader is referred to the corresponding section of this report for more details on the evaluation results.

The – not legally binding – recommendations for exemption request no. 2013-6 were submitted to the European Commission by Oeko-Institut and have already been published at the EU CIRCA website on 23 October 2014. So far, the Commission has not adopted any revision of the Annex to Directive 2011/65/EU based on these recommendations.

[2] Cf. under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Project_Description_II_Pack_4.pdf

Table 4-1: Overview of the exemption requests, associated recommendations and expiry dates

No.	Wording	Applicant	Recommendation	Expiry date
2013-6	Lead and hexavalent chromium in reused spare parts, recovered from industrial monitoring and control instruments placed on the global market before 22 July 2017 and used in category 9 equipment placed on the market before July 22 2024, provided that use and reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer.	FEI Company	The use of substances listed in Annex II of the Directive, in reused spare parts, recovered from CE marked EEE, placed on the global market, and used in equipment to be made available on the market: a. provided that reuse takes place in auditable closed-loop business-to-business return systems; and b. that the reuse of parts is notified to the consumer; and c. provided that spare parts comply with Regulation (EC) No 1907/2006. Where "placed on the global market" means making available for the first time globally; and where spare parts are to be used in repair and or refurbishment activities of EEE falling under:	
			i. Annex I Category 8: Medical devices	22 Jul 2021
			ii. Annex I Sub-Category 8: In-vitro diagnostic medical devices	22 Jul 2023
			iii. Electron microscopes and instruments used as accessories and/or as parts of electron microscopes which fall under Annex I Sub-Category 9: Industrial monitoring and control devices	22 Jul 2024

5.0 Links from the Directive to the REACH Regulation

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

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

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

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

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

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

provisions of RoHS. This is essentially the same approach as has already been adopted for the re-evaluation of some existing RoHS exemptions 7(c)-IV, 30, 31 and 40,[3] as well as for the evaluation of a range of requests assessed through previous projects in respect of RoHS 2.[4] Furthermore, substances for which an authorisation or restriction process is already underway are also reviewed, so that future developments may be considered where relevant.

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

- on the list of substances proposed for the adoption to the Candidate List (the Registry of Intentions);
- on the list of substances of very high concern (SVHCs- the Candidate List);
- in the recommendations of substances for Annex XIV (recommended to be added to the Authorisation List);
- listed in REACH Annex XIV itself (The Authorization List); or
- listed in REACH Annex XVII (the List of Restrictions).

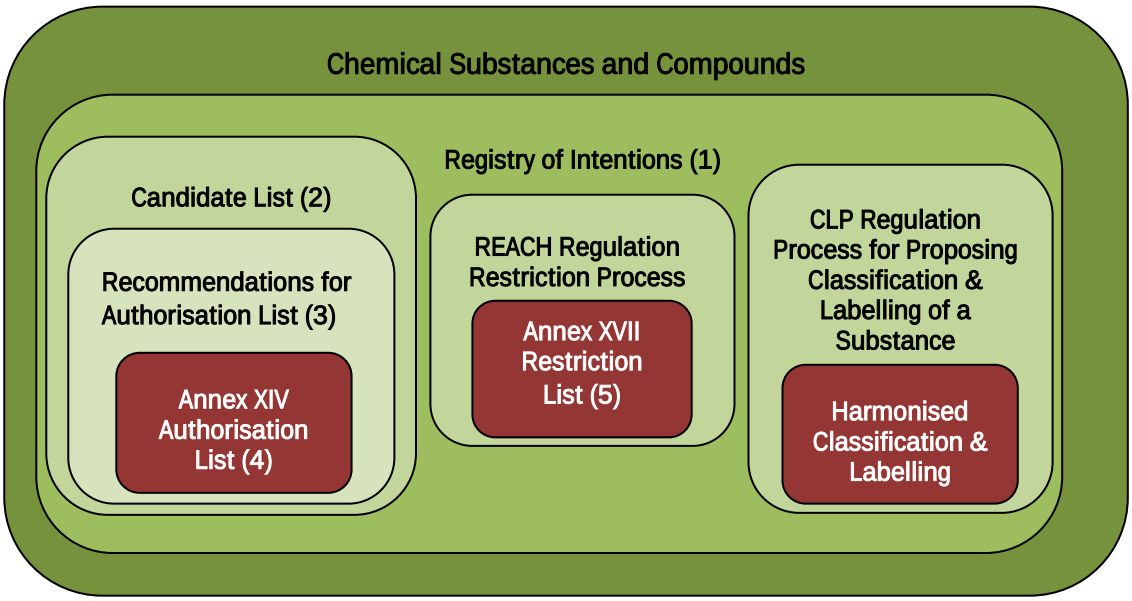
As the European Chemicals Agency (ECHA) is the driving force among regulatory authorities in implementing the EU's chemicals legislation, the ECHA website has been used as the reference point for the aforementioned lists, as well as for the exhaustive register of the Amendments to the REACH Legal Text.

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

[3] See Zangl, S.; Blepp, M.; Deubzer, O. (2012) Adaptation to Scientific and Technical Progress under Directive 2011/65/EU - Transferability of previously reviewed exemptions to Annex III of Directive 2011/65/EU, Final Report, Öko-Institut e. V. and Fraunhofer IZM, February 17, 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Re-evaluations_transfer_RoHS_I_RoHS_II_final.pdf

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

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



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

- Member States Competent Authorities (MSCAs) / the European Chemicals Agency (ECHA), on request by the Commission, may prepare Annex XV dossiers for identification of Substances of Very High Concern (SVHC), Annex XV dossiers for proposing a harmonised Classification and Labelling, or Annex XV dossiers proposing restrictions. The aim of the public Registry of Intentions is to allow interested parties to be aware of the substances for which the authorities intend to submit Annex XV dossiers and, therefore, facilitates timely preparation of the interested parties for commenting later in the process. It is also important to avoid duplication of work and encourage co-operation between Member States when preparing dossiers. Note that the Registry of Intentions is divided into three separate sections: listing new intentions; intentions still subject to the decision making process; and withdrawn intentions. The registry of intentions is available at the ECHA website at: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions;
- The identification of a substance as a Substance of Very High Concern and its inclusion in the Candidate List is the first step in the authorisation procedure. The Candidate List is available at the ECHA website at http://echa.europa.eu/web/guest/candidate-list-table;
- The last step of the procedure, prior to inclusion of a substance into Annex XIV (the Authorisation list), involves ECHA issuing a Recommendation of substances for Annex XIV. The ECHA recommendations for inclusion in the Authorisation List are available at the ECHA website at

http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list;

- Ø Once a decision is made, substances may be added to the Authorisation List available under Annex XIV of the REACH Regulation. The use of substances appearing on this list is prohibited unless an Authorisation for use in a specific application has been approved. The Annex can be found in the consolidated version of the REACH Legal Text (see below);
- Ø In parallel, if a decision is made concerning the Restriction on the use of a substance in a specific article, or concerning the restriction of its provision on the European market, then a restriction is formulated to address the specific terms, and this shall be added to Annex XVII of the REACH Regulation. The Annex can be found in the consolidated version of the REACH Legal Text (see below); and
- Ø As of the 02 of July, 2014, the last amendment of the REACH Legal Text was dated from 08 May 2014 (Commission Regulation (EU) No 474/2014) and so the updated consolidated version of the REACH Legal Text, dated 19 April 2014, was used to check Annex XIV and XVII: The consolidated version is presented at the ECHA website: http://echa.europa.eu/web/guest/regulations/reach/legislation.

Table 5-1 lists those substances appearing in Annex XIV, subject to Authorisation, which are relevant to the RoHS substances dealt with in the requests evaluated in this project. As can be seen, at present, exemptions have not been granted for the use of these substances.

Table 5-1: Relevant entries from Annex XIV: The list of substances subject to authorization

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of)uses
	Latest application date	Sunset date	
10. **Lead chromate** EC No: 231-846-0 CAS No: 7758-97-6	21 Nov 2013	21 May 2015	-
11. **Lead sulfochromate yellow** (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2	21 Nov 2013	21 May 2015	-
12. **Lead chromate molybdate sulphate red** (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8	21 Nov 2013	21 May 2015	-
16. **Chromium trioxide** EC No: 215-607-8 CAS No: 1333-82-0	21 Mar 2016	21 Sep 2017	-

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of)uses
	Latest application date	Sunset date	
17. **Acids generated from chromium trioxide and their oligomers** Group containing: **Chromic acid** EC No: 231-801-5 CAS No: 7738-94-5 **Dichromic acid** EC No: 236-881-5 CAS No: 13530-68-2 **Oligomers of chromic acid and dichromic acid** EC No: not yet assigned CAS No: not yet assigned	21 Mar 2016	21 Sep 2017	-
18. **Sodium dichromate** EC No: 234-190-3 CAS No: 7789-12-0 10588-01-9	21 Mar 2016	21 Sep 2017	-
19. **Potassium dichromate** EC No: 231-906-6 CAS No: 7778-50-9	21 Mar 2016	21 Sep 2017	-
20. **Ammonium dichromate** EC No: 232-143-1 CAS No: 7789-09-5	21 Mar 2016	21 Sep 2017	-
21. **Potassium chromate** EC No: 232-140-5 CAS No: 7789-00-6	21 Mar 2016	21 Sep 2017	
22. **Sodium chromate** EC No: 231-889-5 CAS No: 7775-11-3	21 Mar 2016	21 Sep 2017	

For the substances currently restricted according to RoHS Annex II: cadmium, hexa-valent chromium, lead, mercury, polybrominated biphenyls and polybrominated diphenyl ethers and their compounds, we have found that some relevant entries are listed in Annex XVII of the REACH Regulation. The conditions of restriction are presented in Table 5-2 below. Additionally, some amendments have been decided upon, and are still to be included in the concise version. These may be seen in Table 5-3.

Table 5-2: Conditions of restriction in REACH Annex XVII for RoHS substances and compounds

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
8. **Polybromobiphenyls; Polybrominatedbiphenyls (PBB)** CAS No 59536-65-1	1. Shall not be used in textile articles, such as garments, under-garments and linen, intended to come into contact with the skin. 2. Articles not complying with paragraph 1 shall not be placed on the market.
16. **Lead carbonates**: (a) Neutral anhydrous carbonate (PbCO 3) CAS No 598-63-0 EC No 209-943-4 (b) Trilead-bis(carbonate)-dihydroxide 2Pb CO 3 -Pb(OH) 2 CAS No 1319-46-6 EC No 215-290-6	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
17. **Lead sulphates:** (a) PbSO 4 CAS No 7446-14-2 EC No 231-198-9 (b) Pb x SO 4 CAS No 15739-80-7 EC No 239-831-0	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
18. **Mercury compounds**	Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use: (a) to prevent the fouling by micro-organisms, plants or animals of: — the hulls of boats, — cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, — any totally or partly submerged appliances or equipment; (b) in the preservation of wood; (c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture; (d) in the treatment of industrial waters, irrespective of their use.
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 Oct 2007; (b) barometers (except barometers within pt. (a)) until 3 Oct 2009.

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	5. The following mercury-containing measuring devices intended for industrial and professional uses shall not be placed on the market after 10 April 2014: (a) barometers; (b) hygrometers; (c) manometers; (d) sphygmomanometers; (e) strain gauges to be used with plethysmographs; (f) tensiometers; (g) thermometers and other non-electrical thermometric applications. The restriction shall also apply to measuring devices under points (a) to (g) which are placed on the market empty if intended to be filled with mercury. 6. The restriction in paragraph 5 shall not apply to: (a) sphygmomanometers to be used: (i) in epidemiological studies which are ongoing on 10 October 2012; (ii) as reference standards in clinical validation studies of mercury-free sphygmomanometers; (b) thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers until 10 October 2017; (c) mercury triple point cells which are used for the calibration of platinum resistance thermometers. 7. The following mercury-using measuring devices intended for professional and industrial uses shall not be placed on the market after 10 April 2014: (a) mercury pycnometers; (b) mercury metering devices for determination of the softening point. 8. The restrictions in paragraphs 5 and 7 shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007; (b) measuring devices which are to be displayed in public exhibitions for cultural and historical purposes.
23. **Cadmium** and its compounds CAS No 7440-43-9 EC No 231-152-8	For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87 (1). 1. Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material): – polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21] – polyurethane (PUR) [3909 50] – low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] – cellulose acetate (CA) [3912 11]

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	— cellulose acetate butyrate (CAB) [3912 11] — epoxy resins [3907 30] — melamine-formaldehyde (MF) resins [3909 20] — urea-formaldehyde (UF) resins [3909 10] — unsaturated polyesters (UP) [3907 91] — polyethylene terephthalate (PET) [3907 60] — polybutylene terephthalate (PBT) — transparent/general-purpose polystyrene [3903 11] — acrylonitrile methylmethacrylate (AMMA) — cross-linked polyethylene (VPE) — high-impact polystyrene — polypropylene (PP) [3902 10] Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material. By way of derogation, the second subparagraph shall not apply to articles placed on the market before 10 December 2011. The first and second subparagraphs apply without prejudice to Council Directive 94/62/EC (13) and acts adopted on its basis. By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be restricted. 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

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	of newly produced PVC in compliance with paragraph 1 above. Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: '*Contains recovered PVC*' or with the following pictogram:  In accordance with Article 69 of this Regulation, the derogation granted in paragraph 4 will be reviewed, in particular with a view to reducing the limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e), by 31 December 2017. 5. For the purpose of this entry, 'cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface. Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications: (a) equipment and machinery for: – food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] – agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] – cooling and freezing [8418] – printing and book-binding [8440] [8442] [8443] (b) equipment and machinery for the production of: – household goods [7321] [8421 12] [8450] [8509] [8516] – furniture [8465] [8466] [9401] [9402] [9403] [9404] – sanitary ware [7324] – central heating and air conditioning plant [7322] [8403] [8404] [8415] In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited. 6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below: (a) equipment and machinery for the production of: – paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] (b) equipment and machinery for the production of: – industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431]

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	— road and agricultural vehicles [chapter 87] — rolling stock [chapter 86] — vessels [chapter 89] 7. However, the restrictions in paragraphs 5 and 6 shall not apply to: — articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. 8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C. 9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons. 10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in: (i) metal beads and other metal components for jewellery making; (ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including: — bracelets, necklaces and rings, — piercing jewellery, — wrist-watches and wrist-wear, — brooches and cufflinks. 11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011.
28. Carcinogen category 1A or 1B or carcinogen category 1 or 2 According to Appendices 1 and 2: **Cadmium oxide** **Cadmium chloride** **Cadmium fluoride** **Cadmium Sulphate** **Cadmium sulphide** **Cadmium (pyrophoric)** **Chromium (VI) trioxide** **Zinc chromates including zinc potassium chromate**	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
Nickel Chromate **Nickel dichromate** **Potassium dichromate** **Ammonium dichromate** **Sodium dichromate** **Chromyl dichloride; chromic oxychloride** **Potassium chromate** **Calcium chromate** **Strontium chromate** **Chromium III chromate; chromic chromate** **Sodium chromate** **Lead Chromate** **Lead hydrogen arsenate** **Lead Nickel Salt** **Lead sulfochromate yellow; C.I. Pigment Yellow 34;** **Lead chromate molybdate sulfate red; C.I. Pigment Red 104;**	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; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.
29. Mutagens: category 1B or category 2 According to Appendices 3 and 4: **Cadmium chloride** **Cadmium fluoride** **Cadmium Sulphate** **Chromium (VI) trioxide** **Potassium dichromate** **Ammonium dichromate** **Sodium dichromate** **Chromyl dichloride; chromic oxychloride** **Potassium chromate** **Sodium chromate**	
30. Toxic to reproduction: category 1A or 1B or toxic to reproduction category 1 or 2 According to Appendices 5 and 6: **Cadmium chloride** **Cadmium fluoride** **Cadmium Sulphate** **Potassium dichromate** **Ammonium dichromate** **Sodium dichromate**	

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
Sodium chromate **Nickel dichromate** **Lead compounds with the exception of those specified elsewhere in this Annex** **Lead Arsenate** **Lead acetate** **Lead alkyls** **Lead azide** **Lead Chromate** **Lead di(acetate)** **Lead hydrogen arsenate** **Lead 2,4,6-trinitroresorcinoxide, lead styphnate** **Lead(II) methane- sulphonate** **Trilead bis- (orthophosphate)** **Lead hexa-fluorosilicate** **Mercury** **Silicic acid, lead nickel salt**	
47. **Chromium VI** compounds	1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002 %) soluble chromium VI of the total dry weight of the cement. 2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1. 3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin. 4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1.
63. **Lead** and its compounds CAS No 7439-92-1 EC No 231-100-4	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight. 2. For the purposes of paragraph 1: (i) 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear;

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	(d) brooches and cufflinks; (ii) 'any individual part' shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (14); (b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C. 5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961. 6. By 9 October 2017, the Commission shall re-evaluate this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly.

Table 5-3: Summary of relevant amendments to Annexes not updated in the last concise version of the REACH Regulation

Designation of the substance, of the group of sub-stances, or of the mixture	Conditions of restriction	Amended Annex	Amendment date
Addition of **Entry 62** concerning: (a) **Phenylmercury acetate** EC No: 200-532-5 CAS No: 62-38-4 (b) **Phenylmercury propionate** EC No: 203-094-3 CAS No: 103-27-5 (c) **Phenylmercury 2-ethylhexanoate** EC No: 236-326-7	1. Shall not be manufactured, placed on the market or used as substances or in mixtures after 10 October 2017 if the concentration of mercury in the mixtures is equal to or greater than 0,01% by weight. 2. Articles or any parts thereof containing one or more of these substances shall not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than 0,01% by weight.'	Annex XVII, entry 62	20 Sep 2012

Designation of the substance, of the group of sub-stances, or of the mixture	Conditions of restriction	Amended Annex	Amendment date
CAS No: 13302-00-6 (d) **Phenylmercury octanoate** EC No: - CAS No: 13864-38-5 (e) **Phenylmercury neodecanoate** EC No: 247-783-7 CAS No: 26545-49-3			
Addition of items 5-7 to entry 47. **Chromium VI** compounds	5.Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather. 6.Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part. 7.Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.'	Annex XVII, entry 47	27 March 2014. The amendment shall apply from 1 May 2015.

As of 1 July 2014, the REACH Regulation Candidate list includes those substances relevant for RoHS listed in Table 5-4. Proceedings concerning the addition of these substances to the Authorisation list (Annex XIV) have begun and shall be followed by the evaluation team to determine possible discrepancies with future requests of exemption from RoHS (new exemptions, renewals and revokals).[5]

[5] Updated according to http://echa.europa.eu/web/guest/candidate-list-table

Table 5-4: Summary of relevant substances currently on the REACH Candidate List

Substance name	EC No.	CAS No.	Date of inclusion	Reason for inclusion
Cadmium chloride	233-296-7	10108-64-2	16 June 2014	Carcinogenic (Article 57a);
Cadmium sulphide	215-147-8	1306-23-6	16 Dec 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Lead di(acetate)	206-104-4	301-04-2	16 Dec 2013	Toxic for reproduction (Article 57 c);
Cadmium	231-152-8	7440-43-9	20 Jun 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Cadmium oxide	215-146-2	1306-19-0	20 Jun 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Pyrochlore, antimony lead yellow	232-382-1	8012-00-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead bis(tetrafluoroborate)	237-486-0	13814-96-5	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead dinitrate	233-245-9	10099-74-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Silicic acid, lead salt	234-363-3	11120-22-2	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead titanium zirconium oxide	235-727-4	12626-81-2	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead monoxide (lead oxide)	215-267-0	1317-36-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Silicic acid ($H_2Si_2O_5$), barium salt (1:1), lead-doped *[with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]*	272-271-5	68784-75-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Trilead bis(carbonate)dihydroxide	215-290-6	1319-46-6	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead oxide sulfate	234-853-7	12036-76-9	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead titanium trioxide	235-038-9	12060-00-3	19 Dec 2012	Toxic for reproduction (Article 57 c)

Substance name	EC No.	CAS No.	Date of inclusion	Reason for inclusion
Acetic acid, lead salt, basic	257-175-3	51404-69-4	19 Dec 2012	Toxic for reproduction (Article 57 c)
[Phthalato(2-)]dioxotrilead	273-688-5	69011-06-9	19 Dec 2012	Toxic for reproduction (Article 57 c)
Tetralead trioxide sulphate	235-380-9	12202-17-4	19 Dec 2012	Toxic for reproduction (Article 57 c)
Dioxobis(stearato)trilead	235-702-8	12578-12-0	19 Dec 2012	Toxic for reproduction (Article 57 c)
Tetraethyllead	201-075-4	78-00-2	19 Dec 2012	Toxic for reproduction (Article 57 c)
Pentalead tetraoxide sulphate	235-067-7	12065-90-6	19 Dec 2012	Toxic for reproduction (Article 57 c)
Trilead dioxide phosphonate	235-252-2	12141-20-7	19 Dec 2012	Toxic for reproduction (Article 57 c)
Orange lead (lead tetroxide)	215-235-6	1314-41-6	19 Dec 2012	Toxic for reproduction (Article 57 c)
Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead cyanamidate	244-073-9	20837-86-9	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead(II) bis(methanesulfonate)	401-750-5	17570-76-2	18 Jun 2012	Toxic for reproduction (Article 57 c)
Lead diazide, Lead azide	236-542-1	13424-46-9	19 Dec 2011	Toxic for reproduction (article 57 c),
Lead dipicrate	229-335-2	6477-64-1	19 Dec 2011	Toxic for reproduction (article 57 c)
Dichromium tris(chromate)	246-356-2	24613-89-6	19 Dec 2011	Carcinogenic (article 57 a)
Pentazinc chromate octahydroxide	256-418-0	49663-84-5	19 Dec 2011	Carcinogenic (article 57 a)
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9	19 Dec 2011	Carcinogenic (article 57 a)
Lead styphnate	239-290-0	15245-44-0	19 Dec 2011	Toxic for reproduction (article 57 c)
Trilead diarsenate	222-979-5	3687-31-8	19 Dec 2011	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Strontium chromate	232-142-6	7789-06-2	20 Jun 2011	Carcinogenic (article 57a)
Acids generated from chromium trioxide and their oligomers. Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid.	231-801-5, 236-881-5	7738-94-5, 13530-68-2	15 Dec 2010	Carcinogenic (article 57a)
Chromium trioxide	215-607-8	1333-82-0	15 Dec 2010	Carcinogenic and mutagenic (articles 57 a and 57 b)
Potassium dichromate	231-906-6	7778-50-9	18 Jun 2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)

Substance name	EC No.	CAS No.	Date of inclusion	Reason for inclusion
Ammonium dichromate	232-143-1	7789-09-5	18 Jun 2010	Carcinogenic, mutagenic and toxic for reproduce-tion (articles 57 a, 57 b and 57 c)
Sodium chromate	231-889-5	7775-11-3	18 Jun 2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Potassium chromate	232-140-5	7789-00-6	18 Jun 2010	Carcinogenic and mutagenic (articles 57 a and 57 b).
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2	13 Jan 2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c))
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8	13 Jan 2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Lead chromate	231-846-0	7758-97-6	13 Jan 2010	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Lead hydrogen arsenate	232-064-2	7784-40-9	28 Oct 2008	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Sodium dichromate	234-190-3	7789-12-0, 10588-01-9	28 Oct 2008	Carcinogenic, mutagenic and toxic for reproduction (articles 57a, 57b and 57c)

Additionally, Member States can register intentions to propose restrictions or to classify substances as SVHC. The first step is to announce such an intention. Once the respective dossier is submitted, it is reviewed and it is decided if the restriction or authorisation process should be further pursued or if the intention should be withdrawn.

As at the time of writing (Summer 2014), it cannot yet be foreseen how these procedures will conclude. It is thus not yet possible to determine if the protection afforded by REACH Regulation would in these cases consequently be weakened by approving the exemption requests dealt with in this report. For this reason, the implications of these decisions have not been considered in the review of the exemption requests dealt with in this report. However, for the sake of future reviews, the latest authorisation or restriction process results shall be followed and carefully considered where relevant.[6]

[6] 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 01.07.2014)

As for registries of intentions to identify substances as SVHC, as of 1 July 2014, Sweden has submitted intentions regarding the classification of cadmium fluoride and cadmium sulphate as CMR, intending to submit dossiers in August 2014.None of the current registries of intentions to propose restrictions apply to RoHS regulated substances.[7]

As for prior registrations of intention, dossiers have been submitted for the substances listed in Table 5-5.

Table 5-5: Summary of substances for which a dossier has been submitted, following the initial registration of intention

Restriction / SVHC classification	Substance name	Submission date	Submitted by	Comments
Restriction	Cadmium and its compounds	17 Jan 2014	Sweden	Artist paints
	Cadmium and its compounds	17 Oct 2013	ECHA	Amendment of the current restriction (entry 23) on use of paints with TARIC codes [3208] & [3209] containing cadmium and cadmium compounds to include placing on the market of such paints and a concentration limit.
	Lead and lead compounds	18 Jan 2013	Sweden	Placing on the market of consumer articles containing Lead and its compounds
	Chromium VI	20 Jan 2012	Denmark	Placing on the market of leather articles containing Chromium VI
	Phenylmercuric octanoate; Phenylmercury propionate; Phenylmercury 2-ethylhexanoate; Phenylmercury acetate; Phenylmercury	15 Jun 2010	Norway	Mercury compounds
	Mercury in measuring devices	15 Jun 2010	ECHA	Mercury compounds
	Lead and its compounds in jewellery	15 Apr 2010	France	Substances containing lead

[7] Ibid.

Restriction / SVHC classification	Substance name	Submission date	Submitted by	Comments
SVHC Classification	Cadmium chloride	03 Feb 2014	Sweden	CMR; other;
	Cadmium sulphide	05 Aug 2013	Sweden	CMR; other;
	Lead di(acetate)	05 Aug 2013	Netherlands	CMR
	Cadmium	04 Feb 2013	Sweden	CMR; other; Substances containing Cd
	Cadmium oxide	04 Feb 2013	Sweden	CMR; other; Substances containing Cd
	Trilead dioxide Phosphonate; Lead Monoxide (Lead Oxide); Trilead bis(carbonate)di-hydroxide; Lead Dinitrate; Lead Oxide Sulphate; Acetic acid, lead salt, basic; Dioxobis(stearato)trilead; Lead bis(tetrafluoroborate); Tetraethyllead; Pentalead tetraoxide sulphate; Lead cyanamidate; Lead titanium trioxide; Silicic acid ($H_2Si_2O_5$), barium salt (1:1), lead-doped; Silicic acid, lead salt; Sulfurous acid, lead salt, dibasic; Tetralead trioxide sulphate; [Phthalato(2-)]dioxotrilead; Orange lead (lead tetroxide); Fatty acids, C16-18, lead salts; Lead titanium zirconium oxide	30 Aug 2012	ECHA	CMR; substances containing Lead
	Lead(II) bis(methanesulfonate)	30 Jan 2012	Netherlands	CMR; Amides
	Lead styphnate; Lead diazide; Lead azide; Lead dipicrate	01 Aug 2011	ECHA	CMR; Substances containing lead
	Trilead diarsenate			CMR; Arsenic compounds
	Strontium Chromate	24 Jan 2011	France	CMR; Substances containing chromate
	Acids generated from chromium trioxide and their oligomers: Chromic acid; Dichromic acid; Oligomers of chromic acid and dichromic acid	27 Aug 2010	Germany	CMR; Substances containing chromate

Restriction / SVHC classification	Substance name	Submission date	Submitted by	Comments
	Chromium Trioxide	02 Aug 2010	Germany	CMR; Substances containing chromate
	Sodium chromate; Potassium chromate; Potassium Dichromate	10 Feb 2010	France	CMR; Substances containing chromate
	Lead chromate molybdate sulfate red (C.I. Pigment Red 104); Lead sulfochromate yellow (C.I. Pigment Yellow 34)	03 Aug 2009	France	CMR; substances Containing Lead
	Lead Chromate	03 Aug 2009	France	CMR; Substances containing chromate
	Lead hydrogen arsenate	27 Jun 2008	Norway	CMR; Arsenic compounds
	Sodium dichromate	26 Jun 2008	France	CMR; Substances containing chromate

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

Table 5-6 shows the check of substitutes and alternative materials of relevance to the exemption requests evaluated in the course of this project for specific provisions under REACH, e.g. conditions of restriction in REACH Annex XVII and Annex XIV. The evaluation and recommendations of each exemption request that are presented in the following chapters will only briefly refer to the relationship to the REACH Regulation, indicating the results of the REACH check described below.

Table 5-6: In Progress: Check of conditions of restriction and authorisation in REACH Annex XVII and Annex XIV, for possible substitutes

Request No.	Substance or compounds	Specific provisions etc. under REACH
2013-6	No relevant substitutes named	

6.0 Exemption request No. 2013-6:

Abbreviations

Cat. 8	RoHS 2, Annex I, Category 8: Medical devices, as defined in RoHS Article 3(22): 'medical device' means a medical device within the meaning of point (a) of Article 1(2) of Directive 93/42/EEC and which is also EEE
Cat. 9	RoH2 Annex I, Category 9: Monitoring and control instruments including industrial monitoring and control instruments
CE marking	As defined under Regulation (EC) No 765/2008a, Article 2(20): "marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing"
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
Cr VI	Hexavalent chromium
FEI	FEI Company
KEMI	The Swedish Chemicals Agency
Pb	Lead
Sub-Cat. 8 in vitro	As defined in RoHS Article 3(22): 'in vitro diagnostic medical device' means an in vitro diagnostic medical device within the meaning of point (b) of Article 1(2) of Directive 98/79/EC
Sub Cat. 9 industrial	As defined in RoHS Article 3(24): industrial monitoring and control instruments' means monitoring and control instruments designed for exclusively industrial or professional use

6.1 Background

FEI[8] Company (FEI) explains that manufacturers of electron microscopes regularly reuse parts that are removed from used equipment and these parts are refurbished and then used to repair other microscopes. This practice is explained to be performed through a closed loop system, meaning that microscope manufacturers take back equipment for repair and refurbishment, also "harvesting" parts from equipment, which can then be used for the repair of similar devices. At present, parts recovered from microscopes contain leaded solders and a few contain hexavalent chromium (CrVI). These may be reused as parts for the repair of equipment that will be placed

[8] FEI (2013a) Original exemption request submitted by FEI on 25.6.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/Request_2013-6/20130625_Oko_Exemption_Request_Form_FEI.pdf

on the market before 22 July 2017, but without an exemption, could not be reused in equipment that will be placed on the market after this date. FEI claims that such reuse of parts will have a significantly smaller environmental impact than the alternative of scrapping old parts and replacing them with new ones. Against this background, FEI requested the following exemption:

> *"Lead and hexavalent chromium in reused spare parts, recovered from industrial monitoring and control instruments placed on the global market before 22 July 2017 and used in category 9 equipment placed on the market before July 22 2024, provided that use and reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer*."

In a later communication, FEI[9] explained that, following discussions with the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), it was clarified that some changes were needed to this formulation. The following changes were thus requested:

> *"1. All 6 substances exempted: despite we know that some of the RoHS substances are not used in our old products, providing proof in the technical documentation is quite impossible, as suppliers (if still existing) have no clue about substance contents of components they sold many years ago when RoHS was not an issue. Testing is unfeasible as well.*
>
> *2. "Initially recovered" added: it should be possible to reuse parts, which have been already reused.*
>
> *3. "Spare parts" changed with "parts": there is no clear difference between parts and spare parts. We would like to be allowed to reuse all parts not just a subset that is not even well defined.*"

COCIR[10], who submitted a contribution during the Stakeholder Consultation (see Section 6.5) of this request, explained that though it had applied for and was granted a similar exemption in the past, it had become clear that a reformulation of the exemption wording was necessary. COCIR explains that the wording of the granted exemption, recommended by the consultants and agreed by COCIR, was based on RoHS Article 4(5). However, it has since been realised that this wording creates insurmountable difficulties for medical equipment refurbish, reuse and repair operations, as identification of whether parts arise from within the EU or outside of the EU is not possible with 100% certainty. COCIR thus proposes that this issue

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[9] FEI (2014a), Request to change formulation of requested exemption 2013-6, submitted by FEI per Email on 27.2.2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/Request_2013-6/20140227_FEI_Request_Adjustments_geschwaerzt.pdf

[10] COCIR (2014a), Contribution to RoHS Stakehlder Consultation of Ex. Request 2013-6, submitted by COCIR on 5.2.2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/Request_2013-6/20140205_COCIR_Contribution_to_RoHS_stakeholder_consultation_5Feb2014.pdf

should be resolved by changing the wording of the current RoHS 2 Annex IV Exemption 31 (see Section 6.3 for further details) to the following:

> "*Lead and hexavalent chromium in reused parts, initially* recovered from industrial monitoring and control instruments placed on the global market before 22 July 2017 and used in category 9 equipment placed on the market before July 22 2024, lead, cadmium, hexavalent chromium, mercury, PBB and PBDE in reused parts initially* recovered from medical devices placed on the global market before 22 July 2014 and used in category 8 equipment placed on the market before July 22 2021 and lead, cadmium, hexavalent chromium, mercury, PBB and PBDE in reused parts initially* recovered from in-vitro medical devices placed on the global market before 22 July 2016 and used in category 8 equipment placed on the market before July 22 2023; provided that use and reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts are notified to the consumer. "Placed on the global market" means making available for the first time globally*".

The consultants understand that both FEI and various medical manufacturers (represented by COCIR) would benefit from the provision of the requested exemption/reformulation of Ex. 31. The evaluation of this request shall therefore discuss the various requests of both FEI (also referred to as the applicant) and of COCIR.

6.2 Description of requested exemption

Sections 6.2 through 6.5 are heavily based on information provided by the applicant and other stakeholders and do not necessarily reflect the view of the consultants.

Scanning electron microscopes (SEM) and transmission electron microscopes (TEM) are instruments that are used for research and development and for investigating defects and failures. They are used to obtain images, of items and materials, which can have good depth of field, three-dimensional and can be very high magnification. They are also capable of obtaining chemical composition information, and TEM can also provide crystal structure information of materials. Small Dual Beam (SDB) and Large Dual Beam (LDB) equipment consist of an electron beam as well as a Focussed Ion Beam (FIB). The latter can be used for material manipulation[11] like adding or removing atoms from a surface.[12]

[11] In FEI (2014b), it is clarified that despite the possibility of interpreting material manipulation as a manufacturing activity (not necessary Cat. 9) it is not the sole use of such equipment. To this end, FEI states: „*Material manipulation is just one aspect of this type of equipment; other aspects include observing, measuring and monitoring of dimensions and behaviour. The primary functions are observing, measuring and monitoring, we believe that this equipment would be classified as IMCI.*

[12] Op. cit. FEI (2013a)

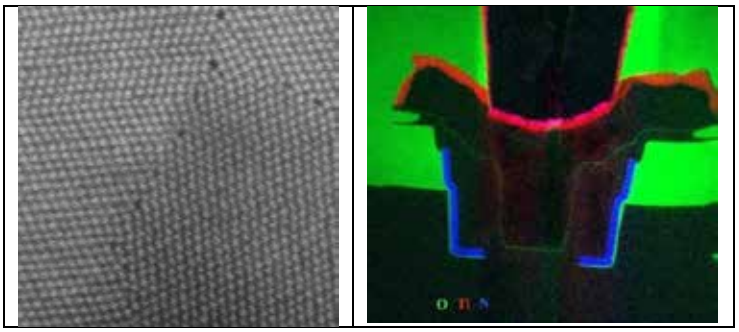
Pictures of a few of the above mentioned equipment are provided in Figure 6-1. Examples of images that can be obtained through their operation are provided in Figure 6-2.

Figure 6-1: SEM/SDB, TEM and LDB equipment

Source: FEI (2013a)

Objects are most commonly examined by visible light, as the human eye is sensitive to these wavelengths range. There are however two limitations of visible light which are the maximum magnification and the depth of field at high magnification. Objects and features that have a size that is similar to and smaller than the wavelength of light are invisible and so cannot be seen with visible light microscopes. As magnification increases, focusing becomes more critical and so the images are clear only within a very small distance range (the depth of field) and they appear to be two-dimensional. Magnification of 1000 times is about the maximum that is achievable with visible light microscopes, which is good enough to see human blood cells of ~1 micron diameter, whereas imaging of micro-organisms such as viruses and bacteria and features on modern integrated circuits, etc. need much higher magnification. These limitations are overcome by replacing visible light with a beam of electrons, which has extremely short wavelengths, and so, much higher magnification is possible. Features as small as one tenth of a nanometre is the size of individual atoms that can be seen with TEM. [13]

Figure 6-2:TEM image of an atom structure (l) and SEM image of a wafer cross section (r)



Source: FEI (2013a)

[13] Op. cit. FEI (2013a)

FEI[14] seeks an exemption for the refurbishment and repair practice it has developed for its devices. These are explained to fall under sub-category 9 industrial (i.e. IMCI) as the primary functions are measurements and monitoring. Devices are expected to be RoHS compliant in time with their coming into the scope of ROHS:

> "*We strive to have all our products, build in all our factories and shipped to all parts of the world RoHS compliant. This is part of our Product Roadmap and we are monitoring and reviewing on weekly basis our progress on RoHS compliancy. At this moment we are on track with our implementation roadmap and have no reason to believe that any of our products sold globally will not be RoHS compliant after 22.7.2017.*"

However, as products are designed to have a long service life, components are often robust and it is explained that a practice of recovering and refurbishing of parts from faulty devices has been developed. Used parts are collected from FEI equipment [possibly also from other manufacturers equipment] in use world-wide and most is shipped to its EU warehouse for refurbishment and then reused globally. Segregation of parts from EU equipment from parts from non-EU equipment is impractical, since parts used in the EU and outside the EU are identical and the refurbishment processes used for both are the same. Although some parts collected from non-EU equipment are reused as parts in EU equipment, an equal quantity of parts collected from EU equipment will be reused as parts in non-EU equipment. Hence, there will be no overall increase in the amounts of RoHS substances placed on the EU market.[15]

A closed loop return system already exists and is in operation for FEI's electron microscopes and their component parts. The electron microscopes are highly complex instruments that must be repaired and maintained by highly trained and qualified engineers who are approved by FEI. When an electron microscope is repaired and a part needs to be replaced, the engineer will return the used parts to FEI and will use refurbished parts from FEI to replace the parts that they remove. In this way, FEI can ensure that their parts are under their control from manufacture to end of life in a closed loop. This allows preventing uncontrolled use or disposal of FEI's parts – parts are sent to environmentally safe disposal by professional recyclers if the parts cannot be reused.[16]

It is usually possible to use refurbished parts and components in both old (non-compliant) and new (compliant) equipment. FEI explains that new designs typically ensure backwards compatibility and often this also means that the old parts perform well in new products.[17]

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[14] Op. cit. FEI (2014b)

[15] Op. cit. FEI (2013a)

[16] Op. cit. FEI (2013a)

[17] FEI (2013c), Answers to 1st Round of Clarification Questions, submitted by FEI on 28.11.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/Request_2013-6/20131128_Answers_to_Questionnaire-1_Req-6_final_reply_FEI_v0.pdf;

FEI provides additional detail as to components and applications where RoHS substances are present and which would be recovered as spare parts in the refurbishment practice. Details can be found in Appendix A.1.0.

Though FEI states that the exemption may be relevant for other microscopes falling under the general Cat. 9 scope, their information only specifies details relevant for their products explained to fall under Cat. 9 industrial.[18]

FEI[19] explains that parts are removed from used and defective electron microscopes, are refurbished and are then reused to repair other electron microscopes. As IMCI have high requirements concerning precision and stability, all electron microscope parts need to be very reliable and robust and as a result have very long useful lifetimes. This is explained to result in each part capable of being reused several times. FEI explains that parts harvested from older equipment may contain:

- Ø Lead could be present in solders for printed circuit boards, to make connections to connectors and in some types of components; and/or
- Ø Hexavalent Chromium, which may have been used in passivation layers of metal sheet parts to prevent corrosion of steel parts;

FEI[20] provides the following examples for types of parts that are reused:

- Ø Parts containing lead:
  - Many types of printed circuit boards;
  - High voltage power supply units;
  - Microscope stages;
  - Microscope column parts;
  - Vacuum pumps and other vacuum components;
  - Camera heads;
  - Laser assemblies; and
  - Detectors;
- Ø Parts containing hexavalent chromium:
  - Present in CrVI passivation coatings of sheet steel;

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[18] Confirmed in both:

Op. cit. FEI (2013c); and

FEI (2014b) Answers to 2nd Round of Clarification Questions, submitted by FEI on 2.7.2014 per Email.

[19] Op. cit. FEI (2013a)

[20] Op. cit. FEI (2013a)

FEI[21] estimate that where lead is used in solders, it accounts for ~37% and where Cr VI is used in passivation coatings, it accounts for less than 10% CrVI of the layer. Calculations are provided, and can be viewed in Appendix A.1.3 to show that the annual amounts expected to be placed on the market are estimated at:

- 44 kg of Pb used in PCBs (a third is relevant for EU sales, i.e., 14.7 kg);
- an additional 6.4 kg Pb for electric bonds in columns and stages used for equipment (so 2.1 kg Pb in the EU); and
- 0.5 grams of Cr VI in passivation coatings (this is a worst case estimate as coatings are probably <500nm thickness) [the consultants understand this to be the global amount].

6.3 Earlier evaluations

In 2011, COCIR[22] submitted a request for a very similar exemption. COCIR explained that many medical equipment parts were refurbished and used for the repair of medical equipment. COCIR argued that parts (containing RoHS substances) would become waste prematurely, if they could not be used to repair medical devices placed on the EU market after 22 July 2014. It claimed that the reuse of parts from used assemblies will have a smaller negative impact on the environment than if there was no re-use of parts.

In the evaluation of this request, the consultants could follow that the information, comparing the environmental impacts of using refurbished parts to that of substituting refurbished parts with new non-compliant ones, demonstrated that the total negative environmental, health and consumer safety impacts of substitution, would outweigh the total benefits thereof. It was thus concluded that an exemption would be justified according to Article 5(1)(a) of the RoHS 2 Directive.

It was thus recommended to grant an exemption available for category 8 (medical devices). The Commission Delegated Directive 2014/15/EU of 18 October 2013 approved the recommendation, and Ex. 31 was added to Annex IV of RoHS 2 (Published in the Official Journal on 9 January 2014) with the following formulation:

"*Lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before 22 July 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer. Expires on 21 July 2021*."

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[21] Op. cit. FEI (2013a)

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

6.4 Applicant's justification for exemption

FEI[23] explain:

> *"As lead-free versions will not be available until a short time before July 2017, FEI and other microscope manufacturers will in consequence build up a stock of refurbished used parts that contain lead-based solders The number of parts containing lead that will be needed will gradually decline, without an exemption, as the number of post-2017 microscopes placed on the market increase and old microscopes are replaced. There are no technical reasons why parts made with leaded solders cannot be used after 2017, but without an exemption, many will have to be disposed of as waste and replaced by new parts that comply with the RoHS substance restrictions. Reuse of parts within a closed loop system by FEI will have a significantly smaller environmental impact than from the creation of waste and replacement by new parts and so this exemption is requested because the alternative (reuse of parts) has a less negative impact on the environment as is demonstrated by a comparative life cycle assessment..."*

Furthermore, FEI asks to bear in mind that the reuse of parts should be considered preferable to recycling and to materials recovery, as it creates less waste and consumes less raw materials and energy in comparison to the latter practices. It was also explained to be encouraged by the EU WEEE Directive (recital 20) and by RoHS 2 in Article 4.5, though this article is only beneficial for equipment that was in scope of RoHS 1 (Directive 2002/95/EC) and not suitable for Cat. 9 equipment, to enter scope July 22 2017.

6.4.1 Possible alternatives for substituting RoHS substances

According to FEIs[24], substitute (i.e. replacement) parts must be equally reliable to those currently in use. FEI are currently developing equipment which will be manufactured with lead-free solders, and expects to be able to produce equipment with these solders before July 2017. FEI further state that Cr VI passivation coatings have been phased out of the manufacture of FEIs devices and supplied components.

6.4.2 Environmental arguments

FEI's main argumentation for justifying the exemption is based on fulfilment of the third Article 5(1)(a) criteria concerning environmental, health and consumer safety impacts tied to the use of alternatives.

FEI[25] states that the use of possible substitutes (replacement parts) for the repair of devices (both old and new) requires that new components and parts have to be manufactured in the first place, using more new materials and consuming more

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[23] Op. cit. FEI (2013a)

[24] Op. cit. FEI (2013a)

[25] Op. cit. FEI (2013a)

energy than would generally be needed for repair with refurbished parts, recovered from faulty equipment. In this sense, though alternatives exist, according to FEI, from an environmental perspective, the current practice of refurbishing and reusing parts recovered from faulty devices, will have a less negative impact on the environment.

To further substantiate this argument, FEI[26] provide a quantified comparison of the waste created and energy consumed for the case that an exemption is granted and for the case of no exemption. FEI explains that there are two alternative scenarios:

- "***With exemption***: *Parts removed from electron microscopes will be refurbished and then reused to repair other electron microscopes including those placed on the market after 22 July 2017*
- ***Without exemption***: *Parts that contain RoHS substances cannot be reused in electron microscope placed on the market from 22 July 2017 and so as the number of pre-2017 SEM and TEM in use gradually decline, so an increasing number of parts cannot be used and so will become waste. The number of pre-2017 parts will be stable until this date, so an increasing proportion will become waste earlier than if an exemption was in force and these will have to be replaced by new "compliant" parts. Construction of new replacement parts will consume energy and raw materials. Since most of the parts are very heavy in weight (>100kg for columns and stages), shipping of these spare parts to other global warehouses should be avoided due to high shipping costs and transport GHG emissions and the risk of mixing old and new items."*

An estimation, prepared for the period between 2014 and 2027, is provided in Figure 6-3. The data presented shows the development of the stock of components available for reuse, in comparison with the number of replacement articles that shall need to be manufactured, along with an estimation of waste and energy consumption relevant for the manufacture of replacement components.

The consultants understand stock spare parts accumulating in the no exemption scenario after the 2017 deadline, to represent the phase in of compliant refurbished spare parts to be recovered from compliant devices as they replace non-compliant ones.

[26] Op. cit. FEI (2013a)

Figure 6-3: Estimated Quantities of Waste with and without an Exemption, between 2014 and 2027

Future year quantities of waste	2014	2015	2016	Compliance deadline 2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
With exemption														
PCBs available for reuse	5500	5500	5500	**5500**	5500	5500	5500	5500	5500	5500	5500	5500	5500	5500
Stages / columns, etc available for reuse	4238	4238	4238	**4238**	4238	4238	4238	4238	4238	4238	4238	4238	4238	4238
Mass of PCB reused [kg]	550	550	550	550	550	550	550	550	550	550	550	550	550	550
Mass of stage / column reused [tonnes]	580	580	580	580	580	580	580	580	580	580	580	580	580	580
Without exemption														
PCBs available for reuse	5500	5500	5500	**2644**	0	825	2090	2915	3520	3905	4235	4455	4620	4785
Stages / columns, etc available for reuse	4238	4238	4238	**2119**	0	636	1610	2246	2712	3009	3263	3433	3560	3687
Number of new replacement PCBs	0	0	0	**2856**	**5500**	**4675**	**3410**	**2585**	**1980**	**1595**	**1265**	**1045**	**880**	**715**
Number of replacement stages, columns, etc	0	0	0	**2119**	**4238**	**3602**	**2628**	**1992**	**1526**	**1229**	**975**	**805**	**678**	**551**
Mass of PCB waste	0	0	0	**285,6**	**550,0**	**467,5**	**341,0**	**258,5**	**198,0**	**159,5**	**126,5**	**104,5**	**88,0**	**71,5**
Mass of additional waste stage / column waste (tonnes)	0	0	0	**278**	550	467,5	341	258,5	198	159,5	126,5	104,5	88	71,5
Energy consumption for replacement parts (GJ)	0	0	0	30.766	61.070	51.998	35.257	22.905	15.246	21.282	12.741	8.047	15.776	14.506
Accumulated additional energy consumed (GJ)	0	0	0	30.766	91.836	143.834	179.091	201.995	217.241	238.523	251.263	259.310	275.086	289.591

Source: FEI (2013b)[27]

[27] FEI (2013b), Additional Information Submitted with Original Request for Ex. 2013-6, on 25.6.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/Request_2013-6/20130625_Exemption_calculations_FEI.pdf

According to FEI[28], this calculation shows that, if the exemption is not granted, "*we cannot use the parts coming from the field and we have to throw this away, thus creating waste (PCB=550kg, solder=110kg, components=580 tonnes) and the accumulated extra energy needed would be around 290GJ over 10 years.*"

Further details are provided by FEI in its original application document, concerning the comparison of the two scenarios for certain components. For further details, please refer to Appendix A.1.4.

6.4.3 Socio-economic impact of substitution

FEI[29] explain that "*not having this exemption could detrimentally affect electron microscope manufacturers based in the EU if they have to dispose of many millions of euros worth of parts, whereas their non-EU competitors who sell mainly to customers outside the EU do not need to do this. EU microscope manufacturers will be at a competitive disadvantage and job losses could occur. There are about 5 EU-based electron microscope manufacturers and 7 that are located in the USA and Asia. Two thirds of electron microscopes are sold outside of the EU and so some non-EU manufacturers could focus on non-EU markets and so may not need to dispose of non-compliant parts"*. FEI mention possible economic effects that could occur if an exemption is denied:

- Increase in direct production costs - Cost of provision of new replacement parts;
- Increase in fixed costs;
- Increase in overhead;
- Possible social impacts within the EU;
- Possible social impacts external to the EU;

6.5 COCIR's (stakeholder) contribution

COCIR submitted a contribution to the stakeholder consultation, supporting the request and further asking its scope be changed to also cover medical devices (for further details, see Section 6.1). In its contribution[30], COCIR raises similar arguments to those presented by FEI. To avoid repetition, only additional aspects are specified below.

COCIR[31] support the extension of the exemption scope to **all RoHS substances**, referring to the difficulties of determining whether used parts contain RoHS restricted substances. They provide detail for the example of reuse of used MRI magnets, to

[28] Op. cit. FEI (2013c)

[29] Op. cit. FEI (2013a)

[30] Op. cit. COCIR (2014a)

[31] Op. cit. COCIR (2014a)

show how, based on the unavailability of original component suppliers, piece part inventory and the invalidation of the magnet Pressure Vessel Certification - MRI Magnet RoHS Compliance assessment is not possible:

- "*Complete Bills of Materials (BOM) are available for MRI magnet types. However, a significant percentage of original piece part suppliers no longer exist to obtain RoHS compliance certification.*
- *The original piece part components for the MRI magnet types are no longer available for Laboratory Testing/Analysis to determine RoHS compliance. Components have been obsoleted by supplier and are not carried in inventory.*
- *Magnet tear down for each of the magnet types could be performed to retrieve suspect piece part components for Laboratory Testing/Analysis. But magnet tear downs will violate the ASME/PED/AD2000 Pressure Vessel certification and essentially mean that the magnets will become unusable scrap suitable only for waste disposal. Also, a significant sample of each magnet type will often have to be torn down to accurately verify full compliance*."

In this regard, COCIR provide[32] explanations for the various RoHS substances, to clarify why there are uncertainties as to their presence, in refurbished parts, and why a RoHS compliance assessment would not be practical.

COCIR[33] provide a number of reasons to explain why the exemption should apply to parts recovered from products placed on the global market, the main points being as follows: Most professional category 8 equipment and its constituent parts are the same, irrespective of where they are sold globally. *Such parts and systems are manufactured at one factory, which is usually also the refurbishing facility. "Parts that are collected globally and refurbished parts should be permitted to be used globally, including in the EU, because of the insurmountable difficulties of segregating parts that were used parts from equipment that was placed on the EU market before the compliance deadline and to use these after refurbishment only in the EU. [...] Segregation of parts by where the equipment was first sold will at best create an extremely difficult logistics problem and in reality is impossible to manage and guarantee that mistakes do not occur. [...] This could eventually result in reduced access to healthcare because new equipment and parts are more expensive than refurbished*".

COCIR[34] further explain that finished equipment has a serial number and this can be used to indicate when and where it was first sold. However, used parts are removed from equipment by service engineers or by end users, and then shipped to the refurbishment centre. These parts will not be marked to identify them in any way. For this reason, it is not usually possible to determine from which EEE items have been

[32] Op. cit. COCIR (2014a)

[33] Op. cit. COCIR (2014a)

[34] Op. cit. COCIR (2014a)

removed, nor where that EEE was first placed on the market. It is further explained why introducing such labelling would not be practical.

COCIR[35] explains that the current RoHS exemption wording is closely based on Article 4(5), which refers to equipment "placed on the market". Based on the definition of "placed on the market" in Article 3(12), this exemption would only be relevant for recovery and reuse of products placed on the EU market (i.e. "the Union market").

COCIR also provide a comparison of possible scenarios, with the additional aspect of an exemption applicable for the EU market in comparison to one applicable to the global market. The comparison is presented in Appendix A.1.5.

COCIR[36] explains that their original parts reuse exemption request did not take into account the different compliance dates for In-Vitro-Diagnostic (IVD) medical devices, which enter scope two years after medical devices, despite the relevance of this practice to the IVD sector. The quantities of RoHS substances in reused IVD parts are claimed to cover a small proportion of all medical devices. However, the weight of refurbished parts is many tonnes so not being able to reuse these would have a significant negative environmental impact. One factory in the EU, for example, refurbishes about 130 tonnes of IVD equipment each year and another 22 tonnes of used parts per year, and these refurbished units contain a significant proportion of reused parts that are removed from different equipment. Therefore, COCIR request that the new wording takes account of the compliance dates for IVD equipment.

6.6 Other stakeholders' contributions

The **Swedish Agency of Chemicals** (KEMI) submitted two documents during the stakeholder consultation. The first document[37] was submitted during the initial 8-week period, whereas the second document[38] was submitted towards the end of the extended consultation. The main points, raised by KEMI in the documents, are summarised below:

- KEMI does not support the wording of the originally requested exemption, nor does it consider it legally possible to extend the scope of the application under the RoHS directive during the period of the consultation. FEI has requested an

[35] Op. cit. COCIR (2014a)

[36] Op. cit. COCIR (2014a)

[37] The Swedish Agency of Chemicals (KEMI), 2014a, Contribution to the RoHS Stakeholder Consultation concerning Ex. Re. 2013-6 – first comments, submitted 28 February 2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/Request_2013-6/Keml_Comments_to_RoHS_SC_2013_6.pdf

[38] The Swedish Agency of Chemicals (KEMI), 2014b, Contribution to the RoHS Stakeholder Consultation concerning Ex. Re. 2013-6 – additional comments, submitted 10 April 2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/Request_2013-6/Keml_Comments_to_RoHS_SC_2013_6_2nd_submission.pdf

exemption for reused spare parts in all category 9 equipment. In KEMI's view, the impact assessment [the information provided by the applicant – consultants note] covers only electron microscopes and thus provides no justification for a wide-scope exemption for all category 9 equipment. KEMI proposes to limit the exemption to electron microscopes.

- KEMI proposes to limit the exemption to spare parts containing lead, recovered and used for the repair of electronic microscopes and equipment used for the operation of the electron microscopes. KEMI explains that the applicant has stated that Cr VI has been substituted by suppliers of electron microscope manufacturers over the last ten years. By the time the equipment is to come into scope (Sub-Cat. 9 industrial), KEMI estimates a considerable amount of equipment shall have been set on the market that is free of Cr VI.
- KEMI agree that reuse of spare parts, in many cases, may be beneficial for the environment. However, KEMI also explain that an exemption can only be adopted if the criteria in article 5(1)(a) are fulfilled for the specific uses. The consultants regard this as a reference to the necessity of the information provided in the request application, to sufficiently clarify why the requested exemption would be justified for the equipment for which it is requested.
- KEMI question whether the purpose of the exemption system is to provide the kind of wide and general exemptions that the FEI and COCIR are requesting.
- KEMI raise concern to the applicants request to allow the "harvesting" of parts from all equipment placed on the global market. This concern is understood to be associated with the potential of such practice to allow the use of parts harvested from non-compliant equipment placed on the market beyond the EU, after such equipment is required to comply with the substance restrictions within the EU.
- KEMI do not support FEIs request to replace the term "spare parts" with the term "parts" in lack of a definition of the latter term in the RoHS Directive (Article 3(27) provides a definition for Spare parts).
- Even if "consumer" is not defined in the RoHS directive, it is implicitly used as a description of private individuals; KEMI suggest that the word "consumer" be replaced by "recipient" in the wording of the exemption, as this term is already used in REACH in the corresponding context. [37]
- KEMI raise concern that electron microscopes are also used for medical purposes, and that the dates referred to in the context of a possible exemption should be in line with the dates of the current Ex. 31, which is available to medical devices, i.e., 21.7.2021.
- In KEMI's view, it must be absolutely clear, that refurbished spare parts containing Pb or Cr VI can never be used in new equipment set on the market for the first time after 22 July 2017.

6.7 Critical review

6.7.1 REACH compliance – relation to the REACH regulation

In refurbishment operations, it is understood that for the most part no new RoHS substances are to be used (aside from some cases where lead solders may need to be used in the repair of PCBs). In this sense, as new materials are not used for the most part, in the case of recovery of parts and their reuse when practiced within the EU, this would not be considered to require that new materials enter the market. Thus REACH restrictions would not apply. However, once parts are recovered from devices from non-EU markets, if they are to be used for repair of devices on the EU level, even if they are to replace equivalent recovered parts that would be exported, this could provide a violation of the protection afforded by the REACH Regulation. In such cases, the REACH Authorisations or Restrictions might apply.

The various entries of Annex XIV (Authorisation) and Annex XVII (Restrictions) have thus been screened, and the table below presents a short analysis. For the full formulation of the mentioned items, please refer to Section 5.0, which cites the various articles of relevance.

Substance mentioned	REACH Annex and Item	Analysis of relevance
Lead chromate	Annex XIV, Item 10	Substances on the Authorisation list cannot be manufactured or used in EU manufacture. Thus, in the case of EU refurbishment, no new material could be used, whereas import of articles containing these substances is not restricted. As for non-EU manufacture, the lead substances mentioned are all used for manufacturing paints and pigments, whereas only lead soldering has been mentioned as an area where refurbishment may require addition of small amounts of new solders. Thus these authorisations are assumed to be irrelevant. As for the Cr based substances, both FEI and COCIR have explained that refurbishment would not include use of new CrVI plated metal and so the limitation would also not apply.
Lead sulfochromate yellow	Annex XIV, Item 11	
Lead chromate molybdate sulphate red	Annex XIV, Item 12	
Chrom based substances mentioned in the various items.	Annex XIV, Item 16, 17, 16, 19, 20, 21, 22	
Polybromobiphenyls; Polybrominatedbiphenyls (PBB)	Annex XVII, Item 8	Use is restricted in textiles intended to come into contact with the skin. It is assumed that such articles are not used in Cat. 8 devices nor in electron microscope.
Lead carbonates	Annex XVII, Item 16	Restriction concerns use in paints, which is understood to be irrelevant for this request.
Mercury compounds	Annex XVII, Item 18	Restrictions concern use in anti-fouling agents and substances used for wood preservation, none of which are understood to be relevant.
Mercury	Annex XVII, Item 18a	Restrictions concern among others use of Hg in mercury-containing measuring devices intended for industrial and professional uses (a list of relevant devices is specified in the REACH Annex XVII and can also be viewed in Table 5-2 above.). Placing on the market of such items is restricted.

Substance mentioned	REACH Annex and Item	Analysis of relevance
		In this sense, if refurbishment activities would involve the reintroduction of such items, it could not be exempted in RoHS as this would conflict with the protection afforded by REACH. As mercury has only been mentioned as a substance for which manufacturers are not aware of its relevance to use in refurbished items, it is assumed that the applicability of this restriction would be limited if at all relevant.
Cadmium	Annex XVII, Item 23	The use of Cd is restricted in a number of synthetic organic polymers (otherwise referred to as plastic materials). Such mixtures and articles manufactured from such plastics cannot be placed on the market if they contain more than 0.01% weight Cd. Here too, manufacturers are said not to anticipate presence of Cd, though, according to COCIR, producing documentation would not be feasible in some cases.
Various compounds containing some of the RoHS compounds	Annex XVII, Items 28, 29, 30	These items restrict the placing on the public market of substances, mixtures containing substances and constituents thereof. The restricted substances are specified in adjunct appendices. If a compound appears on one of the appendices, it cannot be provided to the public in substance form or as a mixture or a constituent of a mixture. However, use of these substances in articles to be placed on the market is not prohibited and thus the protection afforded by these items would not be weakened if the exemption were granted.
Chromium VI compounds	Annex XVII, Item 47	Restrictions concern use in cement, which are understood to have no relevance here.
Phenylmercury acetate and Phenylmercury propionate	Annex XVII, Item 62	Use of substances is restricted in use as well as when placed on the market. Here too, manufacturers are said not to anticipate presence of Cd, though producing documentation as COCIR explain would not be feasible in some cases.
Lead and its compounds	Annex XVII, Item 63	Restriction regards use in jewellery and thus assumed to have no relevance here.

To summarise the analysis, it seems that the only cases of concern are tied to the possible use of mercury and cadmium, which are both not anticipated by manufacturers to be present in articles recovered and used in the refurbishment practice. Thus it is assumed that the protection of REACH should not be weakened where this could be proved to be true by device safety sheets and other documentations of RoHS substance presence. However, providing such documentation has been mentioned as problematic in cases of older equipment where the original manufacturer may not be active anymore, or where documentation was not saved. This may provide a limitation to the applicability of an exemption in

some cases. This aspect is reflected in the recommended formulation for an exemption in Section 6.8 (i.e. exemption for reused spare parts *"[…] provided that spare parts comply with Regulation (EC) No 1907/2006"*); any modification to this wording of the exemption ought to consider obliging compliance with REACH.

6.7.2 Scientific and technical practicability of substitution

Both FEI and COCIR provide information concerning the practicability of substitution of parts recovered from faulty devices, refurbished and reused in the repair of other devices. Though it can be understood that substitutes in the form of newly manufactured parts would be available, it is also understood that their use would result in a higher negative impact in terms of environmental and health aspects:

This is associated with the consumption of resources and energy required for the manufacture of such parts. One could argue that newly manufactured parts may be compliant with RoHS. However, at least for the repair of devices placed on the market before the deadline for compliance with RoHS, Article 4(4) provides an exemption for the use of RoHS substances in such articles:

> "*Paragraph 1 shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:*
>
> *(b) medical devices placed on the market before 22 July 2014;*
>
> *(c) in vitro diagnostic medical devices placed on the market before 22 July 2016;*
>
> *(d) monitoring and control instruments placed on the market before 22 July 2014;*
>
> *(e) industrial monitoring and control instruments placed on the market before 22 July 2017;*

In this sense, the manufacture of new parts for repair of equipment is understood to result in additional use of resources, including RoHS substances, and is thus not seen as beneficial in comparison with the use of refurbished parts. This is further supported by the general intention of the Directive apparent in Recital 20: "*As product reuse, refurbishment and extension of lifetime are beneficial*…" as well as in an exclusion provided in Article 4(5):

> "*Paragraph 1 shall not apply to reused spare parts, recovered from EEE placed on the market before 1 July 2006 and used in equipment placed on the market before 1 July 2016, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer*…".

Furthermore, the approval of Exemption 31 of Annex IV, as a result of an exemption request evaluation finalised in 2013[39] in 2012, further clarifies that the Member

[39] See report under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/20130412_RoHS2_Evaluation_Proj2_Pack1_Ex_Requests_1-11_Final.pdf.

State representatives have agreed that extending this approach to other EEE newly coming into scope was deemed to be beneficial.

In the case of refurbishment practices in the medical sector, as mentioned by COCIR, it can also be followed that a temporal discontinuation or limitation of such practices would result in a lower supply of second-hand (refurbished) devices. In this case, some medical facilities would be faced with higher costs for acquisitions of devices, possibly delaying the range of medical services to be supplied to patients.

6.7.2.1 The scope of the exemption – RoHS substances

Both the 2012-2013 request submitted by COCIR (resulting in Ex. 31 of Annex IV of ROHS) and the original application submitted by FEI, requested an exemption for a limited number of RoHS substances. However, FEI and COCIR later requested that the exemption be considered for **all RoHS substances**, mainly on the basis that providing documentation that substances were not contained in older refurbished parts still in circulation could prove challenging, in some cases resulting in destruction of parts, i.e. early end-of-life for parts that could otherwise remain in use.

Therefrom, the consultants can follow that refurbishing practices such as those mentioned by COCIR and FEI are beneficial to the environment in light of the extended use of products and parts. If to assume that in the practice of refurbishment, no additional RoHS substances are brought onto the market (or at least less then when compared to the alternative of a newly manufactured part), such practices would be beneficial regardless of the RoHS substance of concern. In this sense, where the Article 5(1)(a) criteria are concerned, an exemption would be justified on grounds of environmental, health and consumer safety impacts.

However, a few areas of concern need to be addressed in this regard.

To begin with, as the exemption has been requested for recovery of parts from devices placed on **the global market**, a question was raised as to the potential of additional RoHS substances to enter the EU market through the recovery of parts from non-compliant devices placed on non-EU markets after the deadlines for compliance with the RoHS substances. FEI have stated in their submitted information that all devices to be manufactured and sold by FEI after the relevant compliance date (22.07.2017) are expected to be compliant with the RoHS substance restrictions, regardless of whether they are to be sold in the EU or elsewhere. COCIR were also asked to clarify how they can guarantee that the exemption shall not result in additional RoHS substances entering the EU market in this way, and explained:

> *"the exemption is linked to the concept of an auditable closed loop take back system. Only parts taken from products from the manufacturer and taken back by the same manufacturer for re-use operation (refurbishment) can benefit from the exemption. The auditability of the system ensures that market surveillance authorities or third party auditors can determine that the*

take-back system is closed and that only permitted parts are being reused in equipment that is in scope of the RoHS directive..."[40]

Furthermore:

> *"all medical devices placed on the market after July 2014 are CE marked and therefore they comply with all possible restrictions and legislations, in particular RoHS 2. After July 22, 2014 it is not possible (as clearly expressed by Notified Bodies who are required to approve medical devices under the Medical Device Directive) to CE mark a medical device if it does not comply with RoHS 2, even if it destined to be sold on extra-EU markets*."

A second point is that it is beyond the consultants mandate to determine what is expected of manufacturers in terms of providing documentation of the content of RoHS substances. Article 16 of the Directive states among others that:

> "*Materials, components and EEE on which tests and measurements demonstrating compliance with the requirements of Article 4 have been performed, or which have been assessed, in accordance with harmonised standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to comply with the requirements of this Directive*."

Even if an exemption is to be approved, which would suffice for manufacturers to be able to claim compliance, in the consultants understanding, manufacturers may still have obligations of providing technical documentation as to contents of RoHS substances. Such obligations are understood to be relevant for affixing the CE marking to a product, without which the product cannot be placed on the market. In this sense, in cases where the CE marking is already affixed, it could be that documentation would be assumed sufficient. However, it should be noted that the consultants are not aware whether granting an exemption to allow for compliance would alleviate manufacturers from requirements of providing such documentation.

Finally, though it can be followed that refurbishment practices as described by FEI and COCIR fulfil one of the criteria for justifying an exemption, it is unclear whether the threshold criteria concerning the protection afforded by REACH shall be met in all cases. This point shall be elaborated in Section 6.7.6 below.

6.7.3 Scope of the requested exemption – product categories and sub-groups

FEI produces mainly Electron Microscopes, but there are also other devices related to electron microscopy, which are produced as FEI products. FEI[41] see these other devices as also falling under Category 9 products and request not to limit the proposed exemption only to Electron Microscopes, suggesting that the exemption could be limited to parts that are collected within closed-loop systems, which will be predominantly B2B equipment. FEI have furthermore mentioned Zeiss, JEOL and

[40] Op. cit. COCIR (2014b)

[41] Op. cit. FEI (2013c)

Hitachi as some of the other major suppliers of electron microscopes. Though FEI originally requested an exemption for all Cat. 9 equipment, information provided in the application only concerned electron microscopes and other devices related to their use. In this sense, if additional Cat. 9 manufacturers have similar refurbishment practices in place for other devices, they would have been required to clarify this directly through the stakeholder consultation. As other Cat. 9 manufacturers did not provide further input, the consultants need to assume that such practices are either non-existent or are similar to those presented by FEI.

In contrast, COCIR have requested the exemption for all medical equipment, clarifying that similar practices exist for a wide range of products of both Cat. 8 and sub-Cat. 8 in-vitro.

6.7.4 Discussion of wording formulation

The applicants have provided a number of wording formulations. Furthermore, some additional aspects have been raised, through the evaluation that, in the consultants' opinion, would need to be integrated into an exemption, should one be granted.

A first aspect regards the limitation of the scope of an exemption to articles for which refurbishment practices exist. The consultants can follow that the exemption is relevant to a wide range of medical products, making a limitation to specific products non-practical. However, in light of the available information, this cannot be followed for the full range of Cat. 9 products, let alone for sub-Cat. 9 industrial. The consultants would thus suggest limiting the exemption to electron microscopes, and according to FEIs request, to other devices related to electron microscopy. This term is considered to be very broad, as it can be interpreted that any equipment, including consumer equipment that needs to be RoHS compliant, could benefit from a possible exemption. FEI[42] were thus contacted and provided an alternative formulation to limit the scope to the relevant articles: "*instruments used as accessory and/or part of Electron Microscopes which is part of the Electron Microscopy workflow*". It should be noted in this regard, that the exemption, should it be granted, shall only enable the refurbishment and reuse of spare parts recovered from such "accessories" and will not allow manufacture of new non-compliant articles. In this respect, the risk of a broad interpretation, having negative environmental impacts, is understood to be reduced, as reuse is generally understood to be associated with environmental benefits in comparison with manufacture of new products to replace malfunctioned ones.

It was additionally requested to replace the word "spare parts" with the word "parts", in light of the unclear definition of spare parts. In the consultants' opinion, as "spare parts" is defined under RoHS 2 (Article 2(4)(27)), it can be understood that there is a difference between "spare parts" and "parts" and/or "components". As "parts" is not defined at present in the Directive, it is not recommended to add additional terms which, in the consultants' opinion, would not provide more clarity in comparison with the current term.

[42] Op. cit. FEI (2014b)

In their contribution, KEMI[43] recommended replacing the word “consumer” with the word “recipient” (in use in the REACH Regulation), as the term “consumer” usually describes private individuals. The consultants generally agree that alignment of terminology with that of other EU legislation, such as REACH, is beneficial. However, the term “consumer” has been preferred in this case as it is aligned with Article 4(5), which regards the use of RoHS Annex II substances in recovered spare parts from equipment placed on the market before 2006. As this article is understood to cover similar aspects, it has been used as a basis for the formulation of a possible exemption.

It is further understood that adding reference to the CE marking would ensure that only articles that were compliant with RoHS at the time placed on the market for the first time, could enter into global closed-loop refurbishment programs. The consultants thus proposed the following wording, to incorporate the various aspects of relevance:

Exemption	Duration
The use of substances listed in Annex II of the Directive, in reused spare parts, recovered from CE marked EEE, initially placed on the global market, and used in equipment to be placed on the market: a. provided that reuse takes place in auditable closed-loop business-to-business return systems; and b. that the reuse of parts is notified to the consumer, where “placed on the global market” means making available for the first time globally; and where spare parts are recovered from EEE placed on the global market before the dates stipulated in Article 4(3) of the Directive and are to be used in:	
i. Annex I Category 8: Medical devices	22.07.2021
ii. Annex I Sub-Category 8: In-vitro diagnostic medical devices	22.7.2023
iii. Electron microscopes and instruments used as accessories and/or as parts of electron microscopes which fall under Annex I Sub-Category 9: Industrial monitoring and control devices	22.7.2024

This formulation was sent to FEI and COCIR to clarify whether the exemption would cover the refurbishment practices described by the various actors.

In their response, COCIR[44] raised a number of points, which have led to a further reformulation:

[43] Op. cit. KEMI (2014a)

[44] COCIR (2014c), Answers to Clarification Questions regarding Possible Formulation of an Exemption, submitted per E-mail on 12.08.2014.

- COCIR[45] raises concern regarding the use of the word initially. It explains that the formulation "*reused spare parts, recovered from CE marked EEE, initially placed on the global market*" could be understood to mean that spare parts could only be recovered from the equipment, in which they are initially brought onto the market. However, the purpose of the exemption is also to allow reuse of such parts once recovered from the equipment, in which they are later installed, to allow parts to be refurbished and reused a number of times.
- COCIR[46] refer again to the difference between spare parts and parts, explaining that from the logistic perspective, the same component may be manufactured both:
  - as a spare part for replacing an identical component in the repair of articles; or
  - as a part for use in the assembly of new EEE or in the assembly of refurbished EEE.

  Despite the component being identical from a technical perspective, spare parts and parts would have different catalogue numbers and would be distributed to different users (i.e. to repair facilities or to manufacturing facilities/ refurbishment facilities, respectively). In this sense, the use of the term "spare parts" could create an unintentional limitation of this practice to repair operations, which, according to COCIR, are not always logistically connected with refurbishment practices. [47]

  In a later communication, COCIR[48] mentioned that "as long as refurbishment activities are explicitly mentioned in the report [here] as one of the possible destinations of recovered parts", the term" spare parts" would be acceptable. COCIR[49] use the term business-to-business **take back** system instead of **return** system, referred to in article 4(5). When asked about this difference, COCIR[50] agreed that the term used in Article 4(5) was also sufficient. Nonetheless, the consultants' note that differences may exist which could require that the terminology be clarified in the future.

In a phone call held with COCIR[51] regarding the issues raised, it was further discussed if it were still relevant to refer to spare parts recovered from equipment placed on the

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[45] Op. cit. COCIR (2014c)

[46] Ibid.

[47] Interview with Riccardo Corridori held on 19.08.2014.

[48] COCIR (2014d), Email titled „COCIR exemption for parts/spare parts" concerning differentiation between the terms spare parts, components and parts, submitted per email on 20.08.2014.

[49] Op. cit. COCIR (2014c)

[50] Interview with Riccardo Corridori held on 19.08.2014.

[51] Ibid.

market before a certain date, once reference is made to the CE marking. In the consultants' opinion, the reuse of parts from equipment which has been placed on the market in the past is generally considered beneficial. The main risk of misuse of such an exemption concerns the possible risk of additional amounts of EEE containing RoHS-Substances entering the EU. This could happen in cases where EEE not compliant with the valid RoHS restrictions is placed on external markets, and later used for recovering parts to be used in refurbishment of products to be placed on the EU market. This risk would be relevant in cases where non-compliant equipment placed on external markets after the Article 4(3) compliance deadlines is later to be used for recovering parts for refurbishing EEE to be placed on the EEE in the future.

In the consultants' view, from a logistic perspective, if parts can only enter the refurbishment system if they are to be recovered from CE marked equipment, this risk would be handled sufficiently. Regardless of where the equipment is placed on the market, it is equivalent to equipment that could be placed on the EU market at the same time and in compliance with the RoHS requirements of relevance. This change would also allow including EEE placed on the market after the Article 4(3) compliance deadlines, in which RoHS substances have been used based on an exemption, and which was thus compliant when placed on the market and CE marked.

As for the possible differing definitions between "spare parts" and "parts", the consultants can follow that the use of differing definitions will influence how a possible exemption is to be interpreted by various users, and in this sense possibly also its applicability. However, at present there exists no clear distinction between "parts" and "spare parts". In order not to introduce a new term into the RoHS Annexes, at present the term "spare part", defined in Article 3(27) and used in Article 4(5) is thus understood to be preferable. That said, the consultants urge the EU COM to further look into the differing definitions in the future, in order to provide more clarity and certainty for the various stakeholders in the future.

In light of these aspects, a new formulation was drafted as proposed in Table 6-1 below, and FEI and COCIR were asked to clarify if this formulation would cover the applications for which the exemption was required.

Table 6-1: Exemption Formulation Proposal

Exemption	Duration
The use of substances listed in Annex II of the Directive, in reused spare parts, recovered from CE marked EEE, placed on the global market, and used in equipment to be placed on the market: a. provided that reuse takes place in auditable closed-loop business-to-business return systems; and b. that the reuse of parts is notified to the consumer; and c. provided that spare parts comply with Regulation (EC) No 1907/2006. Where "placed on the global market" means making available for the first time globally; and where spare parts are to be used in repair and or refurbishment activities of EEE falling under:	

Exemption	Duration
i. Annex I Category 8: Medical devices	22 Jul 2021
ii. Annex I Sub-Category 8: In-vitro diagnostic medical devices	22 Jul 2023
iii. Electron microscopes and instruments used as accessories and/or as parts of electron microscopes which fall under Annex I Sub-Category 9: Industrial monitoring and control devices	22 Jul 2024

*Note: *In the formulation sent to stakeholders, a second version with the following sentence was also included: "Where spare parts are initially recovered from EEE, placed on the global market before the dates stipulated in Article 4(3) of the Directive;". In light of the CE marking already addressed in the proposed formulation, it was later decided that adding this sentence was not necessary.*

FEI[52] approved the formulation, clarifying that it was understood that under the term "instruments used as accessories" they classified the items "*which are used in the workflow of sample preparation and sample management*." Though the consultants agree that the term "instruments" used as "accessories" is not well defined, examples have been provided by FEI and are specified in this report to clarify what accessories could benefit from the exemption.

FEI[53] also asked if the addition of item "*c. provided that spare parts comply with Regulation (EC) No 1907/2006*" would have added value to the exemption, in light of the need of EEE, falling under the exemption, to comply with this regulation already.

COCIR[54] also raise concerns in this regard, explaining:

"...*REACH... applicable obligations to products....*

- *Article 33 is about declaration of the content of SVHC... not relevant...*
- *Annex XIV is about ban of the production and use of substances. But it does not apply to import of articles in EU. So it is not relevant here.*
- *Annex XVII is about restriction to the use of substances. It applies to substances, but also requires, sometimes, that such articles are not "placed on the market". We see no applications which may apply to medical devices but in the future something can be added.*

Said that, we see two big problems:

- *Parts can be recovered by products placed on the EU market, therefore they do not have to comply with Annex XVII restrictions, if any is applicable now or in the future. In fact, the Annex applied to the full medical device at the time it*

[52] FEI (2014c), e-mail communication submitted 11.09.2014

[53] FEI (2014d), e-mail communication submitted 11.09.2014

[54] COCIR (2014e), e-mail communication submitted 12.09.2014

was placed on the market and the device was compliant. Recovered parts are "made available".

- *Parts imported for reuse (or the full equipment) are not meant to be placed on the market, therefore there is no obligation according to REACH, RoHS or any other legislation at the moment of importation. The parts are then incorporated into a refurbished/repaired product, which is not "placed on the market" but simply "made available". The obligation for the "original" product to be CE marked ensures the parts are compliant with EU legislation at the time they were originally "placed on the market" incorporated in the medical device.*

I would like to note we are asking an exemption from RoHS to ensure that used parts can be reused. Such exemption is not necessary in REACH. If we extend REACH far beyond its scope, then we would find ourselves in the same situation of having a RoHS without exemption: used parts cannot be reused (right now it is not an issue, considering Annex XVII content, but it may be in the future if new restrictions are added)… Therefore in conclusion, the new proposed point c) while not adding any particular issue or problem to medical companies in the context of this exemption seems to be "legally" wrong in principle, as it extends REACH obligations far beyond their scope and intentions. While this kind of provision may be acceptable in the context of Green public Procurement green criteria, it is not acceptable in the legal text of an official Directive."

The REACH aspect has been discussed in part in Section 6.7.1. In Article 5(1)(a), the RoHS Directive stipulates a threshold criteria for granting and adapting exemptions, in the sense that exemptions cannot be granted if the protection afforded by the REACH Regulation is weakened. Typically, an exemption shall refer to a specific substance used in a specific application, making it possible to clarify if any of the REACH restrictions would limit an exemptions' applicability in this sense. However, in this request, the scope of applicability has been broadly defined (particularly where medical devices are concerned). It has also been requested that the exemption be available for all RoHS substances, despite the understanding that some substances are not expected to be present in parts that are recovered and used in refurbishment operations. The logic presented for these requests can be followed, in the context of RoHS. However, based on the available information, it is beyond the consultants' mandate to clarify, if and how this would be interpreted, where the REACH Regulation is concerned, i.e., to establish that the exemption shall not weaken the protection afforded by REACH. Though this aspect at present mainly refers to the presumably low risk of Cd or Hg to be present in articles relevant to Items 18a, 23 and 62 of REACH, the fact that this exemption is generally sought for a long duration could mean that in the future other restrictions would become apparent. In the past, in the evaluation of RoHS exemptions addressing a specific application of a specific substance, future restrictions were not taken into consideration in this respect. However, given the broad scope of the exemption and the long duration for which it is requested, it seems that this aspect must be considered to avoid inconsistencies between the Directives that would hinder the use of the exemption. As the consultants understand this question to be of legal merit, it has been integrated into the proposed formulation, allowing the EU COM to decide if REACH compliance needs to be reasserted in the formulation of a possible exemption.

The fact that the REACH Regulation applies to imported[55] articles as well as to articles supplied or made available free of charge, is of further concern, where the protection afforded by REACH is addressed. It is understood that parts recovered and used in refurbishment operations on a global basis may in certain instances be considered to be "imported into the EU":

- Either when a part is recovered outside the EU and shipped to an EU refurbishment facility; or
- When the part is used in products sent from a non-EU refurbishment facility to the EU;

Once defined as import, it is understood that the REACH restrictions would apply, and therefore use of RoHS substances (those listed in Annex II at present or in the future) would only be allowed so long as this was not forbidden under REACH. One may argue that in such cases manufacturers/importers shall have the legal obligation of REACH compliance regardless of a possible RoHS exemption. However, addressing this aspect in the formulation of an exemption should clarify that this aspect was in the mind of the legislator at the time of formulation and that the exemption is not to be interpreted as an exemption from possible REACH obligations.

Concerning the term "refurbishment", COCIR mention "This part is very useful as it specifies that "spare parts" may be used for refurbishment activities." However, COCIR also raises concern in light of a lack of a legal definition for refurbishment, which could result in misinterpretations. They suggest that "*the idea of refurbishment… be mentioned in the report as the report is not a legally binding text. As refurbishment has a clear meaning for EU Companies, this would be enough to solve possible discussions with national authorities*."[56]

The consultants can follow that introducing a new term without its definition may create uncertainties; however, this argument does not refer to the exemption at hand but to a general discussion on how or to which extent refurbishment contributes to environmental benefits. Such a discussion is beyond the scope of this evaluation.

A last aspect raised by COCIR[57] concerns the use of the term "to be placed on the market", said to suggest that refurbished parts may only be used in articles to be placed on the market for the first time. COCIR recommended omitting the words "to be" in the proposed formulation. In the consultants' opinion, the term "placed on the market" is well defined in the RoHS Directive, and this change would not necessarily solve the problem. As it is apparent that refurbished parts may be used in repair of articles placed on the market in the past as well as in the assembly of new articles etc., the consultants recommend using the formulation "to be made available on the

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[55] Article 3(12) defines: "placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market";

[56] Op. cit. COCIR (2014e)

[57] COCIR (2014f), e-mail communication submitted 17.09.2014

market", understood to cover both the first sale as well as secondary market operations.

6.7.5 Stakeholder contributions

Concerning the contribution made by KEMI[58], the consultants would like to respond to a point raised, not discussed elsewhere, in Section 6.7.

The extension of the duration of the stakeholder consultation, in light of the requested scope changes of the exemption formulation, was coordinated with the Commission. The consultants interpret the European Commission's approval of the extension of the stakeholder consultation as a signal that the change in the scope of the originally requested exemption is acceptable. In this regard, available information (either from the consultation, from follow-up correspondence with the applicant and other stakeholders, or from other publicly available sources) could be used in the evaluation of the need for an exemption, both as requested in the original request and as requested in later correspondence by the applicant or by other stakeholders.

6.7.6 Conclusions

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

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

In the consultants' opinion, it can be followed that that recovery of parts from faulty equipment and their refurbishment and reuse in the repair or refurbishment of other devices is generally a beneficial practice. The alternative of using substitution, in the form of using newly manufactured parts, is understood to result in negative environmental, health and consumer safety impacts to be higher than the benefits thereof, at least in the cases of electron microscopes and medical devices, as observed from the information provided by FEI and COCIR. In this respect, one of the criteria mentioned above is fulfilled, meaning that where the REACH threshold criterion is also fulfilled, an exemption could be justified.

However, it is unclear whether this is the case, and whether the threshold criteria concerning the protection afforded by REACH shall be met in all cases. Under the current state of the REACH annexes, the consultants can follow that the use of spare parts in which Pb or Cr are present would not weaken the protection afforded by REACH. As for other RoHS substances, their presence in spare parts recovered from

[58] See KEMI (2014a) and KEMI (2014b)

all devices, particularly from older equipment which has already been reused and which lacks sufficient documentation of the use of RoHS substances is unclear. In light of the current status of the REACH annexes, special concern regards:

- Ø Parts which may contain Cd in plastic materials as listed in Annex XVII, Item 23;
- Ø The use of Hg in measuring devices intended for industrial and professional uses as listed in Annex XVII, Item 18a; and
- Ø The use of Hg compounds as detailed in Annex XVII, Item 62.

In this regard, the consultants would recommend limiting a possible exemption to parts, which are in compliance with the REACH Regulation.

6.8 Recommendation

The consultants recommend granting an exemption as follows:

Exemption	Duration
The use of substances listed in Annex II of the Directive, in reused spare parts, recovered from CE marked EEE, placed on the global market, and used in equipment to be made available on the market: a. provided that reuse takes place in auditable closed-loop business-to-business return systems; and b. that the reuse of parts is notified to the consumer; and c. provided that spare parts comply with Regulation (EC) No 1907/2006. Where "placed on the global market" means making available for the first time globally; and where spare parts are to be used in repair and or refurbishment activities of EEE falling under:	
i. Annex I Category 8: Medical devices	22 Jul 2021
ii. Annex I Sub-Category 8: In-vitro diagnostic medical devices	22 Jul 2023
iii. Electron microscopes and instruments used as accessories and/or as parts of electron microscopes which fall under Annex I Sub-Category 9: Industrial monitoring and control devices	22 Jul 2024

If an exemption is to be granted, it should be added to Annex IV of the RoHS Directive.

If the European Commission considers that the risk, of old spare parts containing RoHS substances entering the EU market for the first time, does not result in a possible weakening of the protection afforded by REACH, then item c. could be omitted.

6.9 References exemption request 2013-6

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

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Interviews:

Interview with Riccardo Corridori, Environmental Affairs Manager of COCIR, held on 19.08.2014.

A.1.0 Appendices

A.1.1 Appendix 1: Applications in which RoHS substances are present in electron microscope parts

The following information has been provided by FEI (2013a).

"Component parts of electron microscopes include a very wide variety of printed circuit boards (PCBs), some of which are very complex. The interior of the microscope is at high vacuum[59] and so thick steel parts are used to withstand the pressure. "Column" parts and also parts attached to the vacuum chamber such as the stage, cameras, detectors, etc. all need to withstand the vacuum pressure and so are very heavy (examples are given of columns weighing 100 Kg and stages as much as 200 Kg). Samples are examined on special stages that move using electric motors in three axes and these form part of the vacuum chamber and so also have thick metal sections. Other parts that are reused that also need to withstand the high vacuum are electron beam accelerators, wafer handlers (for examination of silicon wafers), special high voltage power supplies that power the electron gun and vacuum pumps.

Concerning the complex printed circuit boards used in SEM and TEM, FEI explain that currently, these are made using lead-based solders as lead-free versions will not be mandatory in professional SEM and TEM until 22 July 2017 (although simpler easier to use SEM that may be used by university students would need to comply by 2014). The SEM and TEM manufactured by FEI are designed to be used exclusively by professionals. FEI is carrying out research to build PCBs with lead-free solders but this is expected to take several more years due to the specific design requirements of advanced SEM and TEM PCBs. These circuits must be extremely stable and not affected by environmental conditions such as temperature or electromagnetic interference and the signals generated to control electron optics must not drift over time. Achieving the level of electrical stability required is very challenging and so FEI expect to have lead-free PCBs for all of its products only a short time before the 2017 deadline. At this time, FEI will have in stock a large number of PCBs and other electron microscope parts that will have been refurbished and can be used in future years, but which will contain lead-based solders.

Electron microscopes are long-lived products and so steel parts need to be protected from corrosion. In the past, coatings containing hexavalent chromium were used, but hexavalent chromium-free coatings are now used by FEI. However, older parts with hexavalent chromium coatings will continue to be reused as spare parts in future years."

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[59] FEI (2013a) clarify that examination is carried out under high vacuum conditions, aside from "Environmental SEM, designed for imaging of specimens that would be damaged by high vacuum, in which examples are examined in air or in low vacuum.

A.1.2 Appendix 2: List of devices relevant for practice of closed-loop refurbishment practice

The following information has been provided by FEI, regarding devices from which parts are recovered and devices in which refurbished parts are used for repair. Information was provided in FEI's answers to the second round of clarification questions[60] (FEI (2014b)).

The devices from which parts are to be recovered from:	The devices in which such parts are to be used in:
Devices: Ø *TEM (Transmission Electron Microscopes)* Ø *SEM (Scanning Electron Microscopes)* Ø *SDB (Small Dual Beam)* Ø *LDB (Large Dual Beam);* *Dual Beam equipment consists of Electron Beam Column (identical to SEM) as well as an Ion Beam Column.* *Instruments used as accessory and/or part of Electron Microscopes, which are part of the Electron Microscopy workflow, like:* Ø *Special designed cryo freezers;* Ø *Plasma cleaners;* Ø *Microtomes;* Ø *Sample preparators;* Ø *Correlative sample imagers* Ø *Chemical sample optimizers;* Ø *Sample fixators etc.;*	*Devices:* Ø *TEM (Transmission Electron Microscopes)* Ø *SEM (Scanning Electron Microscopes)* Ø *SDB (Small Dual Beam)* Ø *LDB (Large Dual Beam);* *Dual Beam equipment consist of Electron Beam Column (identical to SEM) as well as an Ion Beam Column.* *Instruments used as accessory and/or part of Electron Microscopes, which are part of the Electron Microscopy workflow, like:* Ø *Special designed cryo freezers;* Ø *Plasma cleaners;* Ø *Microtomes;* Ø *Sample preparators;* Ø *Correlative sample imagers;* Ø *Chemical sample optimizers;* Ø *Sample fixators etc.*

[60] Op. cit. FEI (2014b)

A.1.3 Appendix 3: Calculations for annual quantities of Pb and Cr VI placed on the market through refurbishment practice

The following information has been provided by FEI (2013a).

"FEI estimate that where lead is used in solders, it accounts for ~37% and where Cr VI is used in passivation coatings, it accounts for less than 10% CrVI of the layer.

To this end, they calculate the following amounts of substances placed on the EU per annum:

- *Calculations are based on data relevant for FEIs products (i.e., electron microscopes). FEI estimates its EU market share to be above 50%.*
- *The quantity of lead that will be present in reused PCBs is estimated based on the quantity of lead in a single solder joint: One solder joint has about 0.02 grams of solder. On average FEI assume 1000 joints per board (PCB), leading to 20 grams of solder per board. Database analysis shows FEI has about 5500 boards in Service Stocks being used yearly, and they thus calculate about 100 kg of solder in total, with about 40% of this being lead (eutectic solder is 37% Lead). The amount of lead in PCBs that are reused globally per year is estimated at 44kg (a third is relevant for EU sales, i.e., 14.7 kg). If this continues for a 5 year period after July 2017, the amount of lead is 220kg but this is not new lead entering the EU market.*
- *Column and stage components primarily consist of steel and aluminium but also include a small number of electrical connections (up to 200 bonds per device), which are made with leaded solder. This accounts for an additional 6.4 kg lead per annum globally (so 2.1kg Pb in the EU)*
- *The quantity, of hexavalent chromium present in reused parts, is calculated as follows: Typically 10 pieces of sheet steel with CrVI passivation coatings are present in reused parts per annum in the EU. Passivation coating typical thickness is up to 500nm (typical maximum thickness for yellow passivate) and density is 5g/cm3. Average sheet area = 20 x 50cm - two sides so 2 x 10 x 20 x 50 = 100,000cm2. Mass of coating is calculated from: 0.00005 cm (thickness) x 100,000 (area) x 5.0 (density) = 5 grams . As the CrVI content is expected to be less than 10% , the quantity of CrVI in reused parts per year is 0.5 grams (this is a worst case estimate as coatings are probably <500nm thickness)."*

A.1.4 Appendix 4: Summary of environmental assessment provided for ex. request 2013-6

The information below has been provided as part of FEI's original exemption application (FEI (2013a)).

"…

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to

1) Environmental impacts: *YES, explained below:*

2) Health impacts: *See below*

3) Consumer safety impacts: *None*

- Do impacts of substitution outweigh benefits thereof? *Yes,*

There are two options:

1. *Reuse parts containing lead and CrVI with exemption*
2. *Without exemption, discard parts that contain lead solder and CrVI and replace by new parts*

There is a larger negative environmental impact for option 2 than for option 1 as shown below:

Reuse of printed circuit boards made with lead solder (PCBs):

PCBs used in electron microscopes have already been produced and should have very long lifetimes, in excess of 25 years. More PCBs will be made with lead until lead-free versions are developed prior to the 2017 deadline and so by the time when industrial category 9 equipment enters the scope of RoHS, there will be a large number of these PCBs in use and in store ready for reuse and these could continue to be used for at least 25 years.

- *With an exemption, these can be removed from used equipment, refurbished then reused. Refurbishment involves very little energy or raw materials and almost no waste is generated.*
- *Without the exemption, these PCBs would become waste and have to be replaced by new PCBs with the corresponding consumption of raw materials and energy for fabrication.*
    - *Quantity of waste – 5500 PCBs p.a. are refurbished and reused annually on global scale (and 1500 PCBs in the EU). Their total mass is about 550 kg.*
    - *Energy consumed making replacements, Average reflow ovens consume about 100,000 kWh per year and typically produce about 50 PCBs per hour. If these operate 1,920 hours per year (5 days / week, 8 hours / day and 48 weeks per year), then production of 5500 replacement PCBs will consume 5.7MWh/year. Energy will also be consumed to manufacture the replacement materials (solder,*

laminate, components) but it is impossible to calculate the total amount with any precision. The US EPA has calculated that the energy consumed mining, refining and processing of the metals used for soldering PCBs with SAC solder paste will consume 1,863MJ/kg of solder, so 110kg of SAC solder will consume 20.5GJ (57MWh)[61].

- *Mass of raw materials as replacements (PCB=550kg, solder=110kg (mostly tin), components= 550 tonnes)*

Reuse of stages and columns made with lead solders:

Columns and stages consist of large pieces of steel and aluminium but relatively small amounts of electrical components including soldered connectors. If these are removed from an electron microscope, they can be refurbished and reused in other microscopes of the same design. Without an exemption, used parts that contain lead-based solder bonds cannot be refurbished and re-used in the EU in post July 2017 microscopes so these will become waste and have to be replaced by new parts. As they consist mainly of steel and aluminium, they will have a scrap metal value and so will be recycled by melting, followed by fabrication into other parts. Replacement columns and stages need to be fabricated from steel and aluminium. In a typical year, components containing the following masses of these metals could be reused in electron microscopes:

- *Steel 580 tonnes*
- *Aluminium 10 tonnes*

There are various published values for the energy required for the production of steel and aluminium. This is due to the variations in the energy efficiency of production plant across the world and also because there is a big difference between primary metal manufacture and scrap reuse energy consumption. . Typical published values for primary metals manufacture are 30MJ/kg (steel) and 155MJ/kg (aluminium) respectively[62] and based on these values, the additional energy consumption from not being able to reuse these columns and stages would be 7850GJ per year (2.2 GWh / year). Some amount of waste would also be created as the connectors and cables could not be reused. Refinery chemicals will also be consumed (for both primary and secondary processes) and produce the associated process emissions. Best available technology guidance published for the industrial emissions directive (IED BREF guides) include the energy consumption of the best EU processes which are:

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61 http://www.epa.gov/dfe/pubs/solder/lca/lca-summ2.pdf (see table 4.1 and SAC density from table 2.1)

62 http://www.agentschapnl.nl/sites/default/files/GER-waarden_oktober_2012.xls

Metal	*Primary energy consumption*	*Secondary metal production*
Steel	*17 – 23 MJ/tonne (average = 21MJ/tonne)*	*3.5 – 4.5 MJ/tonne (about 40% of EU consumption)*
Aluminium	*137 – 158 MJ/tonne*	*Depends on feedstock, can be up to 20% of primary*

In practice, if steel or aluminium need to be used to manufacture replacement electron microscope components, the proportion of primary and secondary metals that will be used will be the same as the EU's overall consumption. Secondary only could not be used without reducing its availability for other products which would then need to be made with more primary metal.

Reuse of steel panels with CrVI coatings

The impact of reuse of these is relatively small as less than ten panels are likely to be reused each year. However, the composition of coatings on older panels is usually unknown and so many more panels would not be used without this exemption as the surface coating composition is not known and chemical analysis could cause damage. Therefore many more than 10 per year would be discarded and have to be replaced by replacement steel panels. This would require more energy for steel recycling and new panel fabrication but also some energy consumption and emissions for passivation coating; these would not be necessary if these panels could be reused.

There will be different environmental impacts from printed circuit boards, stages, columns and other parts during their life cycle depending on whether this exemption is granted. The differences are shown below.

Life cycle phase	*1. With exemption*	*2. Without exemption*
Production of materials and manufacture of parts	*Parts already produced so there will be a much smaller impact as new parts will be needed only to replace those that cannot be refurbished*	*New materials would have to be produced and parts constructed to replace all unusable parts. The environmental impact is quantified below*
Use phase	*There is no evidence that lead in solders or CrVI coatings poses a risk to users of electron microscopes. Lead and CrVI are not volatile so there are no gaseous emissions. All lead solder is internal and users and service engineers will not normally touch solder. There is no evidence that infrequent skin contact with CrVI passivation coatings is harmful*	*New parts will be similar in design and must have the same function, although lead-free solders will be used in new parts*
End of life	*Parts are re-used at least once, some several times, but all will eventually be recycled, but this is delayed by reuse of parts*	*Parts made with lead solders will become waste sooner if they cannot be reused. Recycling of large metal parts will have significant energy consumption to recycle metals.*

Risk from continued use of lead in solders of reused parts within closed-loop.

Once lead is in solder bonds within equipment it poses no risk during the use phase as there are no hazardous emissions. Users and service engineers would not normally touch solder bonds, in fact this is strongly discouraged as electrostatic damage may occur. However, brief skin contact with lead does not pose a risk as no lead will be transferred into the human body from solder in the form of solder bonds attached to equipment. Lead solder is no friable or dusty and its air formed oxide is very resilient so transfer of lead compounds to the skin is not likely to occur and there is no evidence that users of electrical equipment are at risk from lead in solders. In a closed-loop return, refurbishment and reuse system, only FEI approved engineers will handle these parts. Removal from used equipment and re-installation will involve either no physical contact or only very infrequent contact with solder bonds. However, as described above, transfer of lead compounds to workers is not likely due to the nature of solder alloys. Refurbishment may require some soldering processes. This will involve melting solder, removal of components ort connections and re-attaching new components and connections with fresh solder. The soldering process involves melting the lead-based solder at about 200 - 250˚C with a suitable flux. At this temperature, no lead compounds are emitted as any oxide that is formed is a solid at this temperature, so not volatile and is trapped within the flux. Fumes will be observed but these are only from the flux. These can be hazardous so fume extraction is used where soldering processes are carried out to prevent workers inhaling these fumes. Similar fumes are also produced when soldering with lead-free solders (i.e. to make replacement parts) so reuse of parts reduces the quantity of flux fumes that are produced. By ensuring that parts are reused within a closed-loop system, no parts containing lead will be sent to recyclers who carry out uncontrolled dangerous recycling processes.

Risk from continued use of CrVI coatings on reused parts within closed-loop.

Passivation coatings on steel parts are relatively stable and resilient so that material does not flake off and there is no transfer of CrVI to human skin when handled. There is no published evidence that frequent handling by workers of parts with CrVI passivation coatings is harmful. One reason for using these coatings is their resilience in that they do not rub off or create dust. Therefore workers who handle these parts will not be exposed to a risk from the very small amounts of CrVI within the coatings.

Risk from early recycling of parts without this exemption

Without this exemption, PCBs with lead solder that are removed could not be refurbished and so will become waste. Currently, a small proportion of WEEE generated in the EU is exported illegally to countries where unsafe recycling occurs and lead poses a risk where this occurs, although there is no evidence that electron microscope PCBs are illegally exported. Therefore extending the life of these PCBs from electron microscopes will delay the time when illegal export might occur. This delay should be beneficial as the EU is making efforts to end illegal exports and the governments of destination countries should also act to prevent these dangerous practices. Other parts that contain lead solders such as column parts are not recycled in the same way due to their valuable metal content. These tend to be recycled by melting but without removal and recycling of the small number of

electrical components and the solder bonds. The lead is therefore vaporised by the melting process but in well controlled EU processes that are regulated by the Industrial Emissions Directive, this lead should be recovered and disposed of safely. However some metal parts may be exported to countries where lead emissions could occur due to the lack of local regulation. So as with lead in PCBs, delaying end of life of these parts will allow governments more time to tighten up on enforcement of their waste shipping legislation, so that when these parts eventually reach end of life, there will be less risk of unsafe recycling processes being carried out.

Recycling steel with passivation coatings does not pose a risk as during melting, the steel reacts with CrVI to form CrIII.

Quantitative comparison of environmental impacts for two options:

The waste created and energy consumed for the two options; i) with exemption and ii) without exemption are quantified below for the years until 2027.

Future year quantities of waste				Compliance deadline										
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
With exemption														
PCBs available for reuse	5500	5500	5500	5500	5500	5500	5500	5500	5500	5500	5500	5500	5500	5500
Stages / columns, etc available for reuse	4238	4238	4238	4238	4238	4238	4238	4238	4238	4238	4238	4238	4238	4238
Mass of PCB waste [kg]	550	550	550	550	550	550	550	550	550	550	550	550	550	550
Mass of stage / column waste [tonnes]	580	580	580	580	580	580	580	580	580	580	580	580	580	580
Without exemption														
PCBs available for reuse	5500	5500	5500	2644	0	825	2090	2915	3520	3905	4235	4455	4620	4785
Stages / columns, etc available for reuse	4238	4238	4238	2119	0	636	1610	2246	2712	3009	3263	3433	3560	3687
Number of new replacement PCBs	0	0	0	2856	5500	4675	3410	2585	1980	1595	1265	1045	880	715
Number of replacement stages, columns, etc	0	0	0	2119	4238	3602	2628	1992	1526	1229	975	805	678	551
Mass of PCB waste	0	0	0	285.6	550.0	467.5	341.0	258.5	198.0	159.5	126.5	104.5	88.0	71.5
Mass of additional waste stage / column waste (tonnes)	0	0	0	278	550	467.5	341	258.5	198	159.5	126.5	104.5	88	71.5
Energy consumption for replacement parts (GJ)	0	0	0	30,766	61,070	51,998	35,257	22,905	15,246	21,282	12,741	8,047	15,776	14,506
Accumulated additional energy consumed (GJ)	0	0	0	30,766	91,836	143,834	179,091	201,995	217,241	238,523	251,263	259,310	275,086	289,591

Please provide third-party verified assessment on this: *See ERA's accompanying assessment.*[63]"

[63] Document was submitted, but is confidential.

A.1.5 Appendix 5: COCIR comparison of possible exemption scenarios

The following text was part of COCIR's contribution to the stakeholder consultation (COCIR, 2013a).

"...an option exists where refurbished parts can be reused without a more negative impact on the environment or increasing the amounts of RoHS substances in the EU. Two example scenarios; (1) and (2) are compared below to explain this;

Option 1. The reuse of parts from EEE placed on the global market;

Will have a less negative impact on the environment than on either of the following alternatives;

Option 2a. Having no exemption or;

Option 2b. Having an exemption that is limited to reuse of parts from EEE placed on the EU market before 22 July 2014 only.

The following illustrative example uses the actual amounts of parts collected by one COCIR member.

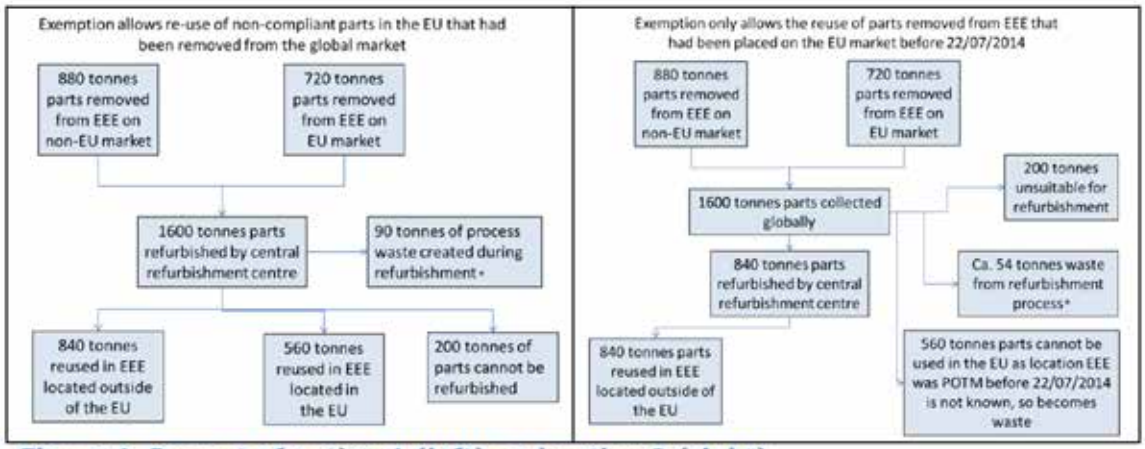

Figure 1. Impact of option 1 (left) and option 2 (right).
***Additional waste generated by materials used in the refurbishment process which adds to the mass balance.**

*In this illustrative example of a refurbishment plant located in the EU (operated by a member of COCIR), 200 tonnes of parts are too damaged to be reused and 90 tonnes of process waste (waste generated during the refurbishment of parts) is generated under option 1 making a total of **290** tonnes of waste. Under option 2 without the exemption being applicable to parts from the global market, 200 tonnes of parts are too damaged to be reused, 560 tonnes of parts could be reused but have to be discarded as it will not be known if they are from EEE that was POTM in the EU before 22 July 2014 and 54 tonnes of process waste would be generated. Under option 2, the total quantity of waste would be 200 + 560 + 54 tonnes = **814** tonnes. Also, there will be waste generated from manufacture of new replacement parts in*

*addition as well as additional energy and raw materials consumption. Therefore if the exemption applies **only** to EEE placed on the EU market before 22 July 2014 (option 2), there will be at least 814 tonnes waste (excluding estimated waste from replacement parts production) from 1600 tonnes of collected parts, whereas if global part reuse was permitted (option 1), only 290 tonnes of waste would be created...*

Figure 1 also clearly shows that the total amount of RoHS substances in the EU will not increase by allowing the reuse of parts from EEE placed on the global market before 22 July 2014, in fact as some parts are not repairable the amount will be less. There will always be a one for one replacement of parts, and replacement parts must be identical to the original parts in order to function correctly. Figure 1 also shows that the amounts of RoHS substances in non-EU countries will also not increase with this exemption being applicable to all parts from the global market.

COCIR explained in its exemption request for reuse of parts that medical device manufacturers are in the process of phasing out hexavalent chromium passivation coatings. As a result, all EEE that contains an X-ray tube that had been placed on the EU market before 22 July 2014, will include a certain proportion of X-ray tubes that contain CrVI and the rest will be CrVI free. A very similar proportion of the same type of EEE that had previously been placed on non-EU markets will have CrVI coatings. X-ray tube life is similar overall in the EU and outside of the EU and so the proportion of X-ray tubes used as replacements in the EU that contain CrVI will be the same irrespective of whether these replacement parts are only from EEE that was first placed on the EU market before 22 July 2014 or is from EEE placed on the global market before this date. As a result, the amount of CrVI in X-ray tubes in use at any time in the EU will be the same if the replacement tubes are only from EU EEE, from non-EU EEE or from EEE from the global market."