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)

Pack 2 – Final Report

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

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Disclaimer

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

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1.0 Background and Objectives

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

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

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

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

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

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

- The reliability of a substitute is not ensured, meaning that the probability that EEE using the substitute will perform the required function without failure for a period of time comparable to that of the application in which the original substance is included, is lower than for the application itself;
- The negative environmental, health and consumer safety impacts of substitution outweigh the benefits thereof.

- Once one of these conditions is fulfilled, the evaluation of exemptions, including an assessment of the duration needed, now has to consider the availability of substitutes and the socio-economic impact of substitution, as well as adverse impacts on innovation, and life cycle analysis concerning the overall impacts of the exemption; and
- A new aspect is that all exemptions now need to have an expiry date and that they can only be renewed upon submission of a new application.

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

The Report includes the following Sections:

Section 2.0 Project Set-up

Section 3.0 Scope

Section 4.0 Overview of the Evaluation Results

Section 5.0 Links from the Directive to the REACH Regulation

Sections 6.0 through 9.0 – Evaluation of the requested exemptions handled in the course of this project.

2.0 Project Set-up

Assignment of project tasks to Öko-Institut and Fraunhofer IZM started 18 June 2012. The overall project has been led by Carl-Otto Gensch. At Fraunhofer IZM the contact person is Otmar Deubzer. The project team at Öko-Institut consists of the technical experts Yifaat Baron and Markus Blepp. Eunomia, represented by Dominic Hogg, have the role of ensuring quality management.

3.0 Scope

Five new RoHS exemption requests have been evaluated – exemption request 11 was handled with along with the requests of the previous project (service contract No. ENV/2012/620308/ETU/C2, Pack 1); exemption requests 12-15 were handled subsequently and their evaluations are included in this report. An overview of the exemption requests is given in Table 4-1 below.

In the course of the project, a stakeholder consultation was conducted. The stakeholder consultation was launched on 09 November 2012 and ran until 01 February 2013, covering the four requests.

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

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

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

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

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

[2] Cf. under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Project_Description_II_Pack2.pdf

4.0 Overview of the Evaluation Results

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

The – not legally binding – recommendations for exemption request no. 12 through 15 were submitted to the EU Commission by Öko-Institut and Fraunhofer IZM and will published on the EU CIRCA website on 02.10.2013. So far, the Commission has not adopted any revision of the Annex to Directive 2011/65/EU based on these recommendations.

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

No.	Wording	Applicant	Recommendation	Expiry date
12	Leaded solder utilized in stacked, area array electronics packaging within ionizing radiation detectors including CT and Xray	General Electric Healthcare	"Lead in solder in one interface of large area stacked die elements with more than 500 interconnects per interface which are used in x-ray detectors of CT and X-ray systems"	Expires 1 January 2020
13	Lead in platinized platinum electrodes for measurement instruments	The Japanese Business Council in Europe	"Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies: a. Wide Range Measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0.1mS/m and 5 mS/m) in laboratory applications for unknown concentrations b. Measurements of solutions where an accuracy of +/- 1% of the sample range and where high corrosion resistance of the electrode are required for: I. Solutions with an acidity < pH 1; or II. Solutions with an alkalinity >pH 13; or III. Corrosive solutions containing halogen gas c. Measurements of conductivities above 100 mS/m that must be performed with portable instruments" Or; Lead in platinized platinum electrodes for measurement instruments	Expires 31.12.2018 (5 years after exemption is granted)
14	Lead in solders for the ignition module and other electronic engine controls mounted directly on or close to the cylinder of hand-held engines (classes SH: 1, SH: 2, SH: 3 of 2002/88/EC)	ANDREAS STIHL AG & Co. KG	Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons, must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH: 1, SH: 2, SH: 3 of 2002/88/EC)	Expires 31.12.2018 (5 years after exemption is granted)
15	Hand crafted luminous discharge tubes (HLDT) used for signs, decorative or general lighting and light-artwork.	The European Signs Federation	Mercury in hand crafted luminous discharge tubes (HLDT) used for signs, decorative or architectural and specialist lighting and light-artwork, where *EP* represents electrode pairs and *L* is tube length in cm the mercury content shall be limited as follows:	Inconclusive

No.	Wording	Applicant	Recommendation	Expiry date
			$$Mercury\ Content\ (mg) \leq \left\{ \frac{(\alpha \times EP) + \left(\frac{\beta \times L}{50}\right)}{80} \right\}$$ a) For Indoor applications exposed to temperatures continuously above 20°C $\alpha = 15$ $\beta = 12$ b) For all other applications: $\alpha = 20$ $\beta = 15$	

5.0 Links from the Directive to the REACH Regulation

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

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

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

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

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

The approach adopted in this report is that once a substance has been included into the regulation related to authorization or restriction of substances and articles under REACH, the environmental and health protection afforded by REACH may be weakened in cases where, an exemption would be granted for these uses under the provisions of RoHS. This is essentially the same approach as has already been adopted for the re-evaluation of some existing RoHS exemptions 7(c)-IV, 30, 31 and 40,[3] as well as for the evaluation of a range of requests assessed through 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, then with regard to REACH compliance, we have checked whether the substance / or its substitutes are:

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

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

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

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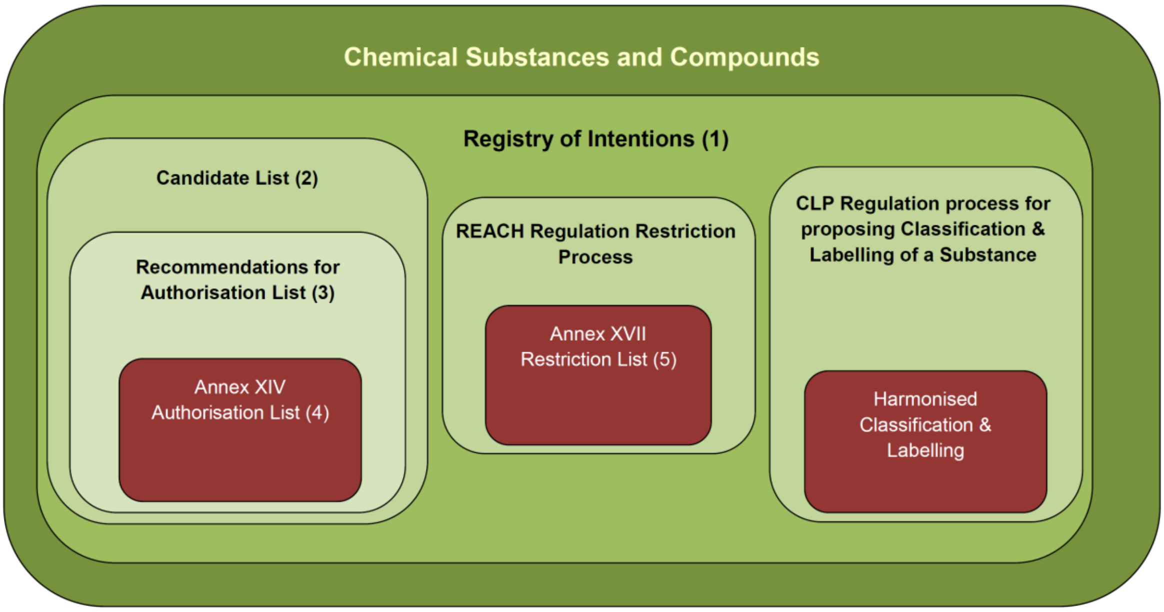
[3] See Zangl, S.; Blepp, M.; Deubzer, O. (2012) Adaptation to Scientific and Technical Progress under Directive 2011/65/EU - Transferability of previously reviewed exemptions to Annex III of Directive 2011/65/EU, Final Report, Öko-Institut e.V. und Fraunhofer IZM, Freiburg, February 17, 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Re-eval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

[4] Gensch, C., Baron, Y., Blepp, M., Deubzer, O., Manhart, A. & Moch, K. (2012) Assistance to the Commission on technological, socio-economic and cost-benefit assessment related to exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive), Final Report, Öko-Institut e. V. und Fraunhofer IZM,Freiburg, 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;

- Once a decision is made, substances may be added to the Authorisation List available under Annex XIV of the REACH Regulation. The use of substances appearing on this list is prohibited unless an Authorisation for use in a specific application has been approved. The Annex can be found in the consolidated version of the REACH Legal Text (see below);
- In parallel, if a decision is made concerning the Restriction on the use of a substance in a specific article, or concerning the restriction of its provision on the European market, then a restriction is formulated to address the specific terms, and this shall be added to Annex XVII of the REACH Regulation. The Annex can be found in the consolidated version of the REACH Legal Text (see below); and
- As of the 22 of February, 2013, the last amendment of the REACH Legal Text was dated from 19 September 2012 (Commission Regulation (EU) No 494/2011) and so the updated consolidated version of the REACH Legal Text, dated 9 October 2012, was used to check Annex XIV and XVII: The consolidated version is presented at the ECHA website: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20120601:EN:PDF.

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

Table 5-1: Relevant Entries from Annex XIV: The List of Substances Subject to Authorization

Designation of the substance, of the group of substances or of the mixture	Transitional arrangements		Exempted (categories of) uses
	Latest application date (1)	Sunset date (2)	
10. **Lead chromate** EC No: 231-846-0 CAS No: 7758-97-6	21 November 2013	21 May 2015	-
11. **Lead sulfochromate yellow** (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2	21 November 2013	21 May 2015	-
12. **Lead chromate molybdate sulphate red** (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8	21 November 2013	21 May 2015	-

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

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

Designation of 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, undergarments and linen, intended to come into contact with the skin. 2. Articles not complying with paragraph 1 shall not be placed on the market.
16. **Lead carbonates:** (a) Neutral anhydrous carbonate ($PbCO_3$) CAS No 598-63-0 EC No 209-943-4 (b) Trilead-bis(carbonate)-dihydroxide $2PbCO_3$-$Pb(OH)_2$ CAS No 1319-46-6 EC No 215-290-6	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organisation (ILO) Convention 13 on the use of white lead and sulphates of lead in paint, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors.
17. **Lead sulphates:** (a) $PbSO_4$ CAS No 7446-14-2 EC No 231-198-9 (b) Pb_xSO_4 CAS No 15739-80-7 EC No 239-831-0	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of ILO Convention 13 on the use of white lead and sulphates of lead in paint, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors.
18. **Mercury compounds**	Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use: (a) to prevent the fouling by micro-organisms, plants or animals of: — the hulls of boats, — cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, — any totally or partly submerged appliances or equipment; (b) in the preservation of wood; (c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture; (d) in the treatment of industrial waters, irrespective of their use.
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).

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	2. The restriction in paragraph 1 shall not apply to measuring devices that were in use in the Community before 3 April 2009. However Member States may restrict or prohibit the placing on the market of such measuring devices. 3. The restriction in paragraph 1(b) shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007; (b) barometers (except barometers within point (a)) until 3 October 2009. 4. By 3 October 2009 the Commission shall carry out a review of the availability of reliable safer alternatives that are technically and economically feasible for mercury containing sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses. On the basis of this review or as soon as new information on reliable safer alternatives for sphygmomanometers and other measuring devices containing mercury becomes available, the Commission shall, if appropriate, present a legislative proposal to extend the restrictions in paragraph 1 to sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses, so that mercury in measuring devices is phased out whenever technically and economically feasible.
23. **Cadmium** and its compounds CAS No 7440-43-9 EC No 231-152-8	For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87 (*). 1. Shall not be used in mixtures and articles produced from synthetic organic polymers (hereafter referred to as plastic material) such as: — polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21] — polyurethane (PUR) [3909 50] — low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] — cellulose acetate (CA) [3912 11] — cellulose acetate butyrate (CAB) [3912 11] — epoxy resins [3907 30] — melamine-formaldehyde (MF) resins [3909 20] — urea-formaldehyde (UF) resins [3909 10] — unsaturated polyesters (UP) [3907 91] — 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 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

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	apply to articles placed on the market before 10 December 2011. The first and second subparagraphs apply without prejudice to Council Directive 94/62/EC (**) and acts adopted on its basis. 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 of newly produced PVC in compliance with paragraph 1 above. Suppliers shall ensure, before the placing on the market of mixtures and articles containing recovered PVC for the first time, that these are visibly, legibly and indelibly marked as follows: ‘*Contains recovered PVC*’ or with the following pictogram:  In accordance with Article 69 of this Regulation, the derogation granted in paragraph 4 will be reviewed, in particular with a view to reducing the limit value for cadmium and to reassess the derogation for the applications listed in points (a) to (e), by 31 December 2017. 5. For the purpose of this entry, ‘cadmium plating’ means any deposit or coating of metallic cadmium on a metallic surface. Shall not be used for cadmium plating metallic articles or components of the articles used in the following

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	sectors/applications: (a) equipment and machinery for: — — food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] — agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] — cooling and freezing [8418] — printing and book-binding [8440] [8442] [8443] (b) equipment and machinery for the production of: — household goods [7321] [8421 12] [8450] [8509] [8516] — furniture [8465] [8466] [9401] [9402] [9403] [9404] — sanitary ware [7324] — central heating and air conditioning plant [7322] [8403] [8404] [8415] In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited. 6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below: (a) equipment and machinery for the production of: — paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] (b) equipment and machinery for the production of: — industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431] — road and agricultural vehicles [chapter 87] — rolling stock [chapter 86] — vessels [chapter 89] 7. However, the restrictions in paragraphs 5 and 6 shall not apply to: — articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. 8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01% by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01% by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and under- taken at temperatures above 450 °C. 9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons.

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	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** **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;**	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, - as substances, - as constituents of other substances, or, - in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: - either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, - the relevant concentration specified in Directive 1999/45/EC. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: - motor fuels which are covered by Directive 98/70/EC, - mineral oil products intended for use as fuel in mobile or fixed combustion plants, - fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC. (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**	

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
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 Sodium chromate Nickel dichromate Lead acetate Lead alkyls Lead azide Lead Chromate Lead di(acetate) Lead hydrogen arsenate Lead(II) methane- sulphonate Trilead bis- (orthophosphate) Lead hexa-fluorosilicate Lead nickel salt Lead 2,4,6-trinitroresorcinoxide, lead styphnate Mercury	
43. Azocolourants and Azodyes Not allocated Component 1: CAS-No: 118685-33-9 C 39 H 23 ClCrN 7 O 12 S.2Na A mixture of: disodium (6-(4-anisidino)-3- sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1- naphtholato)(1-(5-chloro-2-oxidophenylazo)-2- naphtholato)chromate(1-); Component 2: C 46 H 30 CrN 10 O 20 S 2 .3Na trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-)	1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 mg/kg (0,003% by weight) in the articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used, in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as: — clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags, — footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck, — textile or leather toys and toys which include textile or leather garments, — yarn and fabrics intended for use by the final consumer. 2. Furthermore, the textile and leather articles referred to in paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph. 3. Azodyes, which are contained in Appendix 9, 'List of azodyes' shall not be placed on the market, or used, as substances, or in mixtures in concentrations greater than 0,1% by weight, where the substance or the mixture is intended for colouring textile and leather articles.
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

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

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

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction	Amended Annex	Amendment date
Mercury	(1) paragraph 4 is deleted; (2) the following paragraphs 5 to 8 are added: 5. The following mercury-containing measuring devices intended for industrial and professional uses shall not be placed on the market after 10 April 2014: (a) barometers; (b) hygrometers; (c) manometers; (d) sphygmomanometers; (e) strain gauges to be used with plethysmographs; (f) tensiometers; (g) thermometers and other non-electrical thermometric applications. The restriction shall also apply to measuring devices under points (a) to (g) which are placed on the market empty if intended to be filled with mercury. 6. The restriction in 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.'	Annex XVII, entry 18a	20.09.2012
Addition of **Entry 62** concerning: (a) **Phenylmercury acetate** EC No: 200-532-5 CAS No: 62-38-4 (b) **Phenylmercury propionate**	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	20.09.2012

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction	Amended Annex	Amendment date
EC No: 203-094-3 CAS No: 103-27-5 (c) Phenylmercury 2-ethylhexanoate EC No: 236-326-7 CAS No: 13302-00-6 (d) Phenylmercury octanoate EC No: - CAS No: 13864-38-5 (e) Phenylmercury neodecanoate EC No: 247-783-7 CAS No: 26545-49-3			

As of the 01.3.2013, the Candidate list includes the following substances relevant for RoHS (i.e., 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 Candidate List

Substance Name	EC Number	CAS Number	Date of Inclusion	Reason for inclusion
Pyrochlore, antimony lead yellow	232-382-1	8012-00-8	2012/12/19	Toxic for reproduction (Article 57 c)
Lead bis(tetrafluoroborate)	237-486-0	13814-96-5	2012/12/19	Toxic for reproduction (Article 57 c)
Lead dinitrate	233-245-9	10099-74-8	2012/12/19	Toxic for reproduction (Article 57 c)
Silicic acid, lead salt	234-363-3	11120-22-2	2012/12/19	Toxic for reproduction (Article 57 c)
Lead titanium zirconium oxide	235-727-4	12626-81-2	2012/12/19	Toxic for reproduction (Article 57 c)
Lead monoxide (lead oxide)	215-267-0	1317-36-8	2012/12/19	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	2012/12/19	Toxic for reproduction (Article 57 c)
Trilead bis(carbonate)dihydroxide	215-290-6	1319-46-6	2012/12/19	Toxic for reproduction (Article 57 c)
Lead oxide sulfate	234-853-7	12036-76-9	2012/12/19	Toxic for reproduction (Article 57 c)
Lead titanium trioxide	235-038-9	12060-00-3	2012/12/19	Toxic for reproduction (Article 57 c)
Acetic acid, lead salt, basic	257-175-3	51404-69-4	2012/12/19	Toxic for reproduction (Article 57 c)
[Phthalato(2-)]dioxotrilead	273-688-5	69011-06-9	2012/12/19	Toxic for reproduction (Article 57 c)
Tetralead trioxide sulphate	235-380-9	12202-17-4	2012/12/19	Toxic for reproduction (Article 57 c)
Dioxobis(stearato)trilead	235-702-8	12578-12-0	2012/12/19	Toxic for reproduction (Article 57 c)
Tetraethyllead	201-075-4	78-00-2	2012/12/19	Toxic for reproduction (Article 57 c)
Pentalead tetraoxide sulphate	235-067-7	12065-90-6	2012/12/19	Toxic for reproduction (Article 57 c)
Trilead dioxide phosphonate	235-252-2	12141-20-7	2012/12/19	Toxic for reproduction (Article 57 c)
Orange lead (lead tetroxide)	215-235-6	1314-41-6	2012/12/19	Toxic for reproduction (Article 57 c)
Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7	2012/12/19	Toxic for reproduction (Article 57 c)
Lead cyanamidate	244-073-9	20837-86-9	2012/12/19	Toxic for reproduction (Article 57 c)
Lead(II) bis(methanesulfonate)	401-750-5	17570-76-2	2012/06/18	Toxic for reproduction (Article 57 c)
Lead diazide, Lead azide	236-542-1	13424-46-9	2011/12/19	Toxic for reproduction (article 57 c),
Lead dipicrate	229-335-2	6477-64-1	2011/12/19	Toxic for reproduction (article 57 c)
Dichromium tris(chromate)	246-356-2	24613-89-6	2011/12/19	Carcinogenic (article 57 a)
Pentazinc chromate octahydroxide	256-418-0	49663-84-5	2011/12/19	Carcinogenic (article 57 a)
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9	2011/12/19	Carcinogenic (article 57 a)
Lead styphnate	239-290-0	15245-44-0	2011/12/19	Toxic for reproduction (article 57 c)
Trilead diarsenate	222-979-5	3687-31-8	2011/12/19	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Strontium chromate	232-142-6	7789-06-2	2011/06/20	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	2010/12/15	Carcinogenic (article 57a)

Substance Name	EC Number	CAS Number	Date of Inclusion	Reason for inclusion
Chromium trioxide	215-607-8	1333-82-0	2010/12/15	Carcinogenic and mutagenic (articles 57 a and 57 b)
Potassium dichromate	231-906-6	7778-50-9	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Ammonium dichromate	232-143-1	7789-09-5	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Sodium chromate	231-889-5	7775-11-3	2010/06/18	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Potassium chromate	232-140-5	7789-00-6	2010/06/18	Carcinogenic and mutagenic (articles 57 a and 57 b).
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2	2010/01/13	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	2010/01/13	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Lead chromate	231-846-0	7758-97-6	2010/01/13	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Lead hydrogen arsenate	232-064-2	7784-40-9	2008/10/28	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Sodium dichromate	234-190-3	7789-12-0, 10588-01-9	2008/10/28	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 (Spring 2013), 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, process results shall be followed and carefully considered where relevant.[6]

Concerning registrations of intentions to propose substances for classification as SVHC, Sweden has registered an intention concerning *cadmium sulphide* as a CMR substance (Carcinogenic, Mutagenic or Reproduction toxic chemicals) on the 18th of April 2012 and intends to submit a dossier by August 2013.[7]

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[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 22 August 2012)

[7] ECHA website, accesses 04.03.2013: http://echa.europa.eu/web/guest/registry-of-current-svhc-intentions

As for registries of intentions to propose restrictions, on the 18th of January 2013 the COM requested that an Annex XV restriction dossier be prepared concerning *cadmium and its compounds in plastics and paints*, to investigate whether entry 23 should cover additional plastic materials, and whether the existing restriction on the use of cadmium and cadmium compounds in paints with TARIC codes [3208] & [3209] should be extended to also cover the placing on the market of such paints containing cadmium.[8]

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

Concerning Restriction/ SVHC Classification	Substance Name	Submission Date	Submitted by	Comments
Restriction	Lead and lead compounds in articles intended for consumer use	18.01.2013	Sweden	Substances containing lead
	Phenylmercuric octanoate; Phenylmercury propionate; Phenylmercury 2-ethylhexanoate; Phenylmercury acetate; Phenylmercury	15.06.2010	Norway	Mercury compounds
	Mercury in measuring devices	15.06.2010	ECHA	Mercury compounds
	Lead and its compounds in jewellery	15.04.2010	France	Substances containing lead
SVHC Classification	Cadmium	04.02.2013	Sweden	CMR; other; Substances Containing Cd
	Cadmium oxide	04.02.2013	Sweden	CMR; other; Substances Containing Cd

[8] ECHA website, accesses 04.03.2013: http://echa.europa.eu/registry-of-current-restriction-proposal-intentions/-/substance/3101/search/+/term

Concerning Restriction/ SVHC Classification	Substance Name	Submission Date	Submitted by	Comments
	Trilead dioxide Phosphonate; Lead Monoxide (Lead Oxide); Trilead bis(carbonate)dihydroxide; 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;	30.08.2012	ECHA	CMR; substances Containing Lead
	Lead(II) bis(methanesulfonate)	30.01.2012	Netherlands	CMR; Amides
	Lead styphnate; Lead diazide; Lead azide; Lead dipicrate;	01.08.2011	ECHA	CMR; Substances containing lead
	Trilead diarsenate;			CMR; Arsenic compounds
	Strontium Chromate	24.01.2011	France	CMR; Substances containing chromate
	Acids generated from chromium trioxide and their oligomers: Chromic acid; Dichromic acid; Oligomers of chromic acid and dichromic acid;	27.08.2010	Germany	CMR; Substances containing chromate
	Chromium Trioxide	02.08.2010	Germany	CMR; Substances containing chromate
	Sodium chromate; Potassium chromate; Potassium Dichromate;	10.02.2010	France	CMR; Substances containing chromate
	Lead chromate molybdate sulfate red (C.I. Pigment Red 104); Lead sulfochromate yellow (C.I. Pigment Yellow 34);	03.08.2009	France	CMR; substances Containing Lead

Concerning Restriction/ SVHC Classification	Substance Name	Submission Date	Submitted by	Comments
Lead Chromate;	Lead Chromate;	03.08.2009	France	CMR; Substances containing chromate
Lead hydrogen arsenate	Lead hydrogen arsenate	27.06.2008	Norway	CMR; Arsenic compounds
Sodium dichromate	Sodium dichromate	26.06.2008	France	CMR; Substances containing chromate

Additionally, on 19 April 2012, Sweden registered the intention at ECHA[9] to propose the restriction (Annex XVII) of “Lead and lead compounds in articles intended for consumer use”. The proposal for restriction must be submitted by 19 April 2013. This proposal stems from the recent findings deeming lead to be a toxic substance with no threshold below which it has no neurotoxic effects, particularly for children. As earlier decisions concerning restrictions on the use of lead were based on the belief that there is a threshold below which no effect occurs, Sweden considers there is a rationale for imposing restrictions on the use of lead in additional applications.

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

On the 3rd of September, ECHA launched a consultation for contributions concerning the proposal of 54 substances for the candidate list for Substances of Very High Concern (SVHC). This list refers among others to 21 lead compounds. Decisions concerning these substances were anticipated to be reached towards the end of 2012. Based on the date of inclusion, it is understood that some of the substances appearing in Table 5-4 have been added to the candidate list as a result of this process. In any case, the process of inclusion of a substance in the candidate list is only one of the first steps in regulating the use of a substance through restriction or authorisation. As at the time of writing (August 2013), it cannot yet be foreseen how if the further investigation of these substances will result in a restriction of use, it is not possible at this time to determine if the protection afforded by REACH Regulation would consequently be weakened by approving the exemption requests dealt with in this report. For this reason, the implications of these decisions have not been considered in the review of the exemption requests dealt with in this report. However for the sake of future reviews, process results shall be followed and carefully considered where relevant.

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

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
12		
13	Lead Acetate - Substance	Mentioned in entries 28 and 30. However, exemption would not weaken the protection afforded by REACH
	Thalium, Copper, Gold (Mercury not cross checked n light of comparable RoHS status) – potential substitutes	Copper mention in article 28, however an exemption would not weaken the protection afforded by REACH. Thallium not mentioned though considered very toxic. Gold not metioned. For these substances the REACH threshold criteria is at present fulfilled.

6.0 Exemption Request No. 12: "Lead in Stacked Area Array Electronics in Ionizing Radiation Detectors for CT and X-ray Systems"

Abbreviations

CT	Computer Tomography
GE	GE Healthcare
SAC	tin-silver-copper alloy
SDE	stacked die elements
TCE	thermal coefficient of expansion

GE Healthcare[10] has applied for the following exemption:

"Leaded solder used to create stacked, area array electronics within ionizing radiation detectors used in CT and X-ray systems until 31 December 2019 and in spare parts for CT and X-ray systems placed on the EU market before 1 Jan 2020".

GE[11] proposed to narrow the scope of the exemption to large stacked area array electronics where the Stacked Die Elements contain over 500 interconnections in a single interface. According to GE[12], this would take into account the existing capabilities to manufacture large stacked area array electronic modules. GE[13] proposes the following altered exemption scope and wording:

"Leaded solder used to create stacked, area array electronics containing over 500 interconnects in a single interface within ionizing radiation detectors used in CT and X-ray systems until 31 December 2019 and in spare parts for CT and X-ray systems placed on the EU market before 1 Jan 2020"

GE[14] summarizes that a new digital X-ray detector architecture is being developed that will allow patients to be exposed to lower X-ray doses, but this design requires the use of a solder alloy containing lead. This exemption is required because the

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[10] GE (2012a) General Electric Healthcare original exemption request no. 12, document "Exemption_Leaded_solder_utilized_in_Stacked_Area_Array_REV_0_-_Public_Version.pdf", GE Healthcare 2012, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_12/Exemption_Leaded_solder_utilized_in_Stacked_Area_Array_REV_0_-_Public_Version.pdf, last accessed 4 February 2013

[11] GE (2013a) General Electric Healthcare, stakeholder document "2nd-Questionnaire-Exe-req 12_ - public" submitted to the consultants via e-mail on 20 June 2013 by James Vetro, GE Health Care

[12] Ibid.

[13] Ibid.

[14] Op. cit. GE (2012a)

interconnects within these architectures require a lower temperature solder with superior wetting and reflow that is compatible with the stacked assembly requirements. The only viable solution found has been eutectic Pb/Sn solder. Research has been carried out with a SAC solder but this gives unsatisfactory performance. No other lead –free solder has all of the essential requirements. All alternative designs of digital silicon X-ray detectors expose patients to higher X-ray doses, which have been shown to increase the risk of side-effects such as cancer.

6.1 Description of Requested Exemption

Sections 6.1 through 6.2.4 are heavily based on information provided by the applicant and other stakeholders and do not necessarily reflect the view of the consultants.

6.1.1 Technical Background

GE[15] describes that detectors have evolved from a distributed or remote assembly technique where flex circuits were used to transport low level analogue signals to remote electronics found on the perimeter of the system. This architecture was sufficient when performance, coverage and total number of pixels were lower than is required today.

GE[16] explains that current state of the art detectors are increasing in dose efficiency, requiring lower electronic noise levels, and that the detectors' total size increases as well. Larger detectors allow imaging of organs such as the liver or heart in a single exposure and for single tomographic rotation, providing better temporal resolution and a reduced overall patient dose. Being able to see a larger area gives superior diagnostic capability which will improve human health. Imaging the whole liver or heart in one image has several advantages which assist with diagnosis. It is often necessary to view a large area simultaneously such as the head/neck, which requires quite large detector areas that are difficult to achieve with silicon detectors. Therefore limiting detector size to smaller areas could result in a negative impact on human health.

GE[17] puts forward that the detector design for which GE requests the exemption reduces the electronic noise in order to improve image quality in low dose examinations. For improved temporal resolution, less detector sensor elements can share the same analogue-digital conversion channel. By locating electronics closer to the X-ray scintillator and photo diode assembly, the analogue path is as short as possible. This assembly method significantly increases the system's signal-to-noise ratio so that the minimum signal required for good images can be achieved using a lower radiation dose.

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[15] Op. cit. GE (2012a)

[16] Op. cit. GE (2012a)

[17] Op. cit. GE (2012a)

GE[18] states that reducing the analogue path in order to improve the signal-to-noise ratio requires stacking electronics on a large area array, which includes the scintillator and diode assembly. Such stacked large area arrays with over 500 interconnects can only be manufactured in multiple assembly soldering process steps, where the solder reflow temperatures of each subsequent solder process must be lower than in the previous one to avoid remelting of the previously applied solder on the assembly.

According to GE[19], the first soldering step for the manufacturing of the stacked area array uses tin-silver-copper (SAC) solder that melts at ~220 °C followed by soldering with eutectic tin/lead (SnPb) solder that melts at 183°C. The use of a leaded solder interconnect step is a requirement that has been demonstrated to be necessary for successful manufacture and design robustness.[20]

The number of area arrays used for one detector varies depending on the detector size and shape, but can have over 100,000 solder bump connections. One defective bond can appear as a feature in images causing possible misdiagnosis. Being able to achieve 100 % perfect bonding and extremely high reliability are essential to avoid such problems. Currently, this can only be achieved with leaded solders.[21]

6.1.2 Amount of Lead Used under the Requested Exemption

GE[22] expects the total amount of lead (Pb) shipped to the EU in ionizing radiation detectors to reach 1.2 kg annually. The amount used globally is predicted to reach 4.5 to 5 kg per year.

6.2 Applicant's Justification for Exemption

GE[23] requests the exemption for the use of lead in stacked die elements (SDE), a schematic of which is shown in Figure 6-1.

[18] Op. cit. GE (2012a)

[19] Op. cit. GE (2012a)

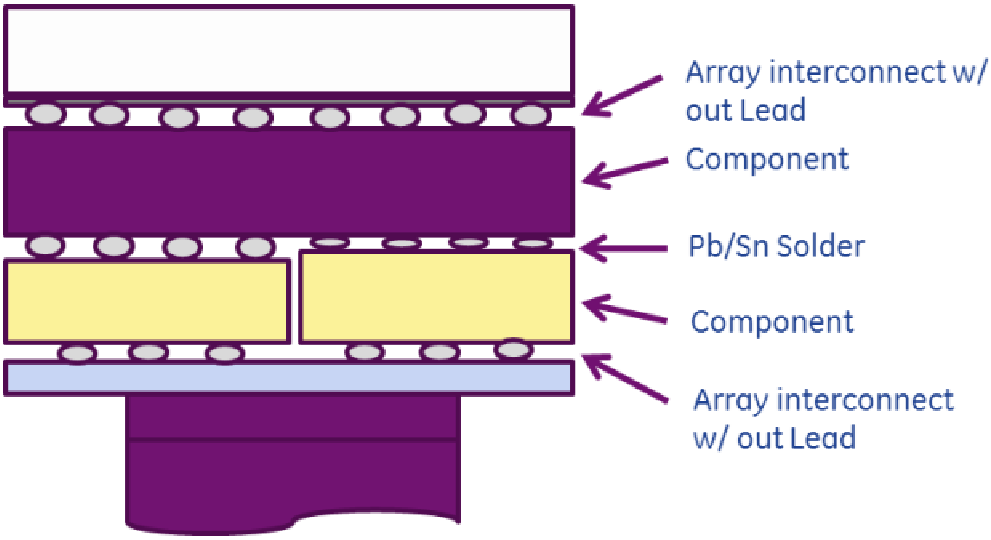
[20] Op. cit. GE (2012a)

[21] Op. cit. GE (2012a)

[22] Op. cit. GE (2012a)

[23] Op. cit. GE (2012a)

Figure 6-1: Outline of a stacked die element



Source: GE (2012c)[24]

GE[25] explains that the interfaces mentioned in the proposed exemption wording are where the SDE layers are electrically joined together. In the above figure, there are three interfaces, from which only the middle interface requires the tin-lead solder.

According to GE[26], the interconnects within the stacked large area array detectors require lower temperature solder with superior wetting and reflow and good ductility that is compatible with the stacked assembly requirements. The lower melting point eutectic, ductile nature of leaded solder (SnPb) is needed to achieve an assembled product that can be manufactured with high yield and is a reliable product. Therefore, GE[27] considers this exemption to be justified as no scientific or technical substitute without lead is available.

6.2.1 Substitution of Lead

6.2.1.1 Solder Trials with SAC305 Lead-free Solder

GE[28] says that the complex array of parts and materials used in principle only allow lead-free solders as potential substitutes. The most common lead-free solder used for electrical equipment are various SAC (tin-silver-copper) alloys, and so GE selected

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[24] GE (2012c) General Electric Healthcare, stakeholder document “Wording Confirmation.pdf” submitted to the consultants via e-mail on 5 July 2013 by James Vetro, GE Health Care

[25] GE (2013d) General Electric Healthcare, stakeholder document “CZT-detectors.pdf” submitted to the consultants via e-mail on 23 July 2013 by James Vetro, GE Health Care

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

[27] Op. cit. GE (2012a)

[28] Op. cit. GE (2012a)

SAC 305 (SAC alloy with 3% silver and 0.5 % copper, the rest being tin) for comparison with SnPb solder.

During the development of the assembly process, GE[29] completed many manufacturing lots with more than 100 parts constructed with SAC 305 solder using 6-Sigma methods known as DOEs (design of experiments). Careful adjustments to solder printing stencil aperture size, solder volume, reflow thermal profiles (ramp up and down) etc. were tried to determine the quality and performance of the solder bonds. GE[30], however, discovered numerous solder interconnect failures through careful failure analysis techniques such as "dye and pry[31]" and detailed solder joint and pad micro sections. After extensive trials during an ~18 month time frame and significant resource investment, where all variables were investigated, GE could not produce an analogue interconnect array with a quality equivalent to the lead-soldered one. GE[32]

By contrast, GE[33] constructed stacked die elements (SDEs), in which the analogue interconnect array was created using eutectic Sn-Pb solder. The same Dye & Pry analysis was performed, which showed excellent connections.

GE[34] puts forward another difficulty in this type of stack die assembly, which is the variation in adjacent solder joint height that may be required. Again, eutectic tin-lead solders were found to provide the best overall solder quality including column geometry when challenged with this type of adjacent solder joint height variation. GE attempted the assembly of SDEs using SAC305 solder throughout, but the results were extremely poor. Cracks in the solder bonds of the analogue array interconnects and defects within a single element were found. Therefore accelerated stress testing has not been performed because the lead-free analogue interconnect array baseline units could not be produced without defects. GE[35] explains that detector imaging system assemblies require as many as 400 or more of these SDE's, but a single interconnect failure may result in image artefacts and overall system malfunction resulting in inacceptable image integrity. A concern is that if defect free assemblies could be produced with SAC, the rigidity of the solder and the large mismatch in the thermal coefficient of expansion (TCE) is more likely to cause fatigue failures than SnPb solders.

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

[30] Op. cit. GE (2012a)

[31] Dye & pry": A highly penetrative dye solution is injected around the solder bonds and allowed to penetrate into any cracks that are present. The dye is then dried before the solder bonds are broken. The presence of red dye on the fracture surface confirms that cracks were present.

[32] Op. cit. GE (2012a)

[33] Op. cit. GE (2012a)

[34] Op. cit. GE (2012a)

[35] Op. cit. GE (2012a)

6.2.1.2 Other Lead-free Solders

Even though there are many other lead-free solders available, GE[36] has not tested them. GE does not expect that any of these lead-free solders will give the same performance as eutectic SnPb solder because none of these lead-free solders has the required combination of properties as summarised below:

Table 6-1: Characteristics of lead-free solders compared to lead solders

Solder alloy	Melting temperature	Characteristics[37]
SnPb	183 °C	Ductile, melting point ~35 °C lower than SAC
SnCu	227°C	Higher melting point than SAC, not ductile
SnAg	221°C (3.5%Ag)	Slightly higher melting point than SAC. Not ductile
Sn3.5Ag0.5Cu	217 °C	All SAC alloys are much harder than SnPb: SAC Vickers hardness = ~21 whereas SnPb hardness = 12.9
Sn-3.5Ag-3Bi	206 – 213°C	Fully melts at only 4°C below SAC 305's melting point Bismuth addition increases hardness and so reduces ductility
Sn3Ag3Zn	Not available	Vickers hardness about double that of SnPb (21.9). Alloys with zinc suffer from corrosion so are unsuitable for products with long lifetimes.
Sn3Ag3In	Not available	Vickers hardness about double that of SnPb (21.3)
Sn9Zn, Sn8Zn3Bi	189 - 199	The zinc content makes this alloy very susceptible to corrosion. Sn8Zn3Bi is not ductile due to bismuth content (Vickers hardness = at least 23)[38].
Sn20In2.8Ag	175 - 187	Availability of indium is an issue. This alloy is expensive due to the high indium content and so is rarely used and very little reliability data published. It is also susceptible to corrosion

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[36] Op. cit. GE (2012a)

[37] Note from (GE 2012 a): Some solder hardness data is from table 2.2.15 of http://swp.fr/metaconcept-v1/telechargement/notes/Liste_dalliages_sans_plomb_ANG.pdf

[38] Source as cited in (GE 2012 a): http://www.jim.or.jp/journal/e/pdf3/43/08/1797.pdf

		under high humidity conditions. A low melting temperature phase with m.pt of 118°C[39] has been detected which will limit operating temperature which must be well below this temperature. No hardness data published.
58Bi42Sn	138	Very hard alloy due to high bismuth content. Research also shows that this is more susceptible to thermal fatigue than SnPb[40]

Source: GE (2012a)

According to GE[41], there are a few lead-free solder alloys with melting points that are sufficiently lower than SAC 305 to prevent the SAC305 bonds from melting when the PTC[42] - 2SP bonds are formed. These alloys include Sn9Zn, Sn8Zn3Bi and Sn20In2.8Ag. These alloys however have a ~10°C melting range, as they are not eutectic alloys, which, as explained above, is a requirement. The SnZn alloys are also harder and less ductile than SnPb. Contrary to SnPb, the SnZn as well as the Sn20In2.8Ag[43] alloys are susceptible to corrosion and so would not be suitable in medical devices that have long service lives.

GE[44] explains that the BiSn solder is not sufficiently ductile for this application either. Another potential substitution option would be to use SAC305 instead of SnPb and a higher melting point solder to make the first solder bonds. GE[45] puts forward two reasons why this would not be possible:

- SAC305 is much less ductile than SnPb so the PTC-2SP bonds are likely to fracture during assembly.
- Lead-free solders, with melting points that are ~30 °C higher than SAC305, need to melt at 247 °C or higher. There are very few choices, of which Sn5Sb[46] with a melting point of 232 – 240 °C has too small a difference to SAC305 (only 12 °C). All other choices, such as AuSn melt at around 280 °C.

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39 See page 20 of http://www.colorado.edu/engineering/MCEN/MCEN5166/Homeworks/chapter_solder_opkg.PDF

40 HP tested 58%BiSn with 63%SnPb for cyclic thermal fatigue resistance and found that SnBi bonds failed much sooner than SnPb with all of the package types tested. "Low-Temperature Solders", Z. Mei, H. Holder and H A. Vander Plas. H. P Journal, August 1996 (GE 2012 a)

41 Op. cit. GE (2012a)

42 PTC: "Pass Through Ceramic", a ceramic substrate circuit

43 Tin-indium-silver alloy with 20 % indium and 2.8% silver, the rest being tin

44 Op. cit. GE (2012a)

45 Op. cit. GE (2012a)

46 Tin-antimony alloy with 5 % of antimony, the rest being tin

This is too high as this temperature will destroy some of the materials used for the assembly such as the flex circuit.

As the size of the detector is a crucial factor influencing the possibilities to use lead-free solders, GE[47] proposed to restrict the requested exemption to SDEs with more than 500 interconnects in a single interface, as this would reflect the current status of the lead-free manufacturing capabilities.

6.2.2 Elimination of Lead by Alternative Designs

GE[48] explains that the detector design, for which it requests the exemption, was newly developed. This detector design shall replace older designs of silicon X-ray detectors to enable larger area examinations and lower radiation doses. The benefits of larger detectors are described in section 6.1. GE[49] claims that these properties cannot be achieved with any other detector design that might possibly allow eliminating the use of lead and thus achieve RoHS compliance.

GE[50] reports that research has shown a linear relationship between radiation dose and risk of cancer. The International Commission on Radiological Protection (ICRP)[51] has determined that the risk coefficient is 5 % at 1 Sievert although this is a very high dose and low milli-Sievert doses are more typical of medical imaging. One of the highest X-ray doses used for imaging is used for cardiology where continuous irradiation is needed to view blood vessels during surgical procedures. Huda[52] has established that typical computer tomography (CT) doses, which are similar to cardiology doses, cause about 1 person in 1,000 (0.12 %) to have cancer. In this case, a 10 % increase in radiation dose will cause statistically one additional person in 10,000 to have cancer. Clearly, it is important to minimise radiation doses. The "Directive 97/43/Euratom – Medical Exposures Directive" requires that all patient exposures are optimised.

GE[53] concludes that it would conflict with Euratom – Medical Exposures Directive, if RoHS were to result in doses that were higher than could be technically achieved.

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[47] Op. cit. GE (2013a)

[48] Op. cit. GE (2012a)

[49] Op. cit. GE (2012a)

[50] Op. cit. GE (2012a)

[51] Source as referenced in (GE 2012 a) ICRP publication 103 "The 2007 Recommendations of the International Commission on Radiological Protection.

[52] Source referenced in (GE 2012 a): W. Huda, W. T. Rowlett and U. J. Schoef "Radiation dose at cardiac computed tomography: facts and fiction" J. Thorac. Imaging, 2010 Aug; 25(3) p 2014; Source referenced in (GE 2012 a)

[53] Op. cit. GE (2012a)

6.2.3 Environmental Arguments

6.2.3.1 Low Amounts of Lead

GE[54] says that only solders can be used for the interconnects. According to GE[55], the lead in the solder has extremely low environmental, health and safety concerns with only 1.2 kg of lead placed on the market annually into systems that have robust take back and recycling programs.

6.2.3.2 The US-EPA Solder Study

The US Environmental Protection Agency (EPA)[56] has carried out full life cycle assessments comparing SnPb with SAC as well as other solder compositions. According to GE[57], the study concluded that for the majority of environmental impacts, lead-free solders had greater negative impacts than the tin-lead solder they replace.

6.2.3.2.1 Extraction, Refining and Production

GE[58] reports that in the US EPA study the SAC solder paste consumes slightly more energy than all of the other solders mainly because of the energy consumption for the extraction and refining of silver and the higher melting temperature than SnPb. GE[59] references the environmental impact scores for energy use for the paste solders in the US-EPA study.

Table 6-2: Environmental impact scores of different solders

Alloy	10^4 MJ energy / dm^3 solder
SnPb	1.25
SAC (Sn3.9Ag0.6Cu)	1.36
SABC (Sn2.5Ag1Bi0.5Cu)	1.31

Source: GE (2012a)

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54 Op. cit. GE (2012a)

55 Op. cit. GE (2013a)

56 Source as referenced in (GE 2012 a): http://www.epa.gov/dfe/pubs/solder/lca/index.htm

57 Op. cit. GE (2012a)

58 Op. cit. GE (2012a)

59 Op. cit. GE (2012a)

GE[60] interprets from the US-EPA study that the extraction and refining of silver creates significantly more waste than lead and so SAC and SABC have significantly larger environmental impacts

Table 6-3: Waste created for extraction, mining and refining of metals for solder pastes

Alloy	dm^3 waste created / dm^3 solder
SnPb	2.75
SAC	16.2
SABC	11.3

Comment: SABC: tin-silver-bismuth-copper alloy

Source: GE (2012a)

GE[61] explains that in the US-EPA study, SnPb solder had a greater impact than SAC and SABC for occupational health and public health –non cancer, but SAC had the largest public health-cancer impact. Overall, SnPb had the largest impact for six impact categories whereas SAC had the largest impact for 10 categories. The US EPA stated that different environmental impacts cannot be compared but since the LCA was published, research has been carried out to determine how they can be compared (e.g. by assessing weighting factors for each impact), but this work is not yet complete.[62]

6.2.3.2.2 Use Phase and End-of-Life Phase

GE[63] explains that the choice of solder alloy has no impact on the use phase as long as it does not affect reliability. If an alloy were to be less reliable causing unexpected early failures, this would potentially have a serious impact on patient health and would create additional waste.

GE[64] puts forward that, when X-Ray and CT Detectors reach end of life, the parts are separated and recycled or may be re-used in refurbished units. The separated parts are mostly aluminium which is recycled as metal with very high yields. The mass of output of Lead (Pb) expected in the SDE is extremely small and is safely treated as hazardous waste.

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[60] Op. cit. GE (2012a)

[61] Op. cit. GE (2012a)

[62] Op. cit. GE (2012a)

[63] Op. cit. GE (2012a)

[64] Op. cit. GE (2012a)

6.2.4 Roadmap to Substitution or Elimination of Lead

GE[65] is assessing the use of various ASIC (*application-specific integrated circuit*) packaging techniques to better match TCE of the Diode. GE expects this to be accomplished within five years by 2017.

GE[66] says that the first phase of development will require the identification of a lead-free solder that is relatively ductile, is a eutectic alloy and has a melting point at least 20 °C lower than the lead-free solder used for the previous soldering step. If this proves to be impossible, the only remaining option is an alternative design, and at present no such designs are known. GE[67] presents the following plan:

1) Research Phase: already started, expected to take until ~2014
This will include testing of solders and investigation of alternative interconnection architectures involving various area array technologies.
2) Development Phase: during 2015-2017
Specific component design, mass production process designs and robust reliability testing including G-force and thermal cycle stress testing.
3) Construction and reliability testing of imaging equipment: takes ~ 2 years, from 2017 - 2019
4) Approval by Medical Devices Directive: can take up to 1 year, therefore to 2020

GE[68] states that the above schedule is viable only if a suitable alloy can be found or if alternative detector architecture can be developed.

6.2.5 Stakeholders Contributions

No contributions were made during the stakeholder consultation, concerning this request for exemption. It was also not possible to obtain further information from other stakeholders in the course of the evaluation.

6.3 Critical Review

6.3.1 REACH Compliance - Relation to the REACH Regulation

This exemption request concerns lead used in solders applied in a detector for CRT and other X-ray medical devices. Section 5.0 of this report lists entry 30 in Annex XVII of the REACH Regulation, stipulating that lead and its compounds shall not be placed

[65] Op. cit. GE (2012a)

[66] Op. cit. GE (2012a)

[67] Op. cit. GE (2012a)

[68] Op. cit. GE (2013a)

on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public. A prerequisite to granting the requested exemption would therefore be to establish whether the intended use of lead in this exemption request might weaken the environmental and health protection afforded by the REACH Regulation.

In the consultants' understanding, the restriction for substances under entry 30 of Annex XVII does not apply to the use of lead in this application. Putting lead in solder in a detector used in a CRT or other X-ray medical device on the market, in the consultants' point of view is not a supply of lead and its compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, entry 30 of Annex XVII would not apply. Additionally, such medical devices are products that are not provided to the general public, but to other than private users, e.g. to hospitals.

No other entries relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status September 2013).

The review of related restriction and authorization processes, revealed one process underway concerning lead and lead compounds. This concerns the use of lead and lead compounds in articles intended for consumer use, for which Sweden proposes a restriction. The articles in the focus of this exemption request are, however, not intended for consumer use, in case the consultants' understanding of "consumer use" is correct in that it does not refer to commercial users of products. In the current proposed wording, this intended restriction proposal would not affect the exemption for the use of lead under this requested exemption.

Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

6.3.2 Summary of the Exemption Request

As the exemption request is technically complex, the main facts are summed up. The detector consists of multiple stacked die elements (SDE). Each single SDE is a complex assembly with several layers of different substrates and components arranged in three dimensions, resembling a small tower with several levels. The SDEs are manufactured in more than one soldering process. This requires that the solder used for the first solder bonds has a higher melting point than the solders used in subsequent soldering processes. Otherwise, the first solder bonds would remelt in the subsequent soldering processes affecting the reliability of the SDEs. GE therefore uses tin-silver-copper-(SAC) solder with 217 °C melting point for the first solder bonds, and tin-lead solder with a melting point of 183 °C for the next soldering process.

Next to the mechanical and electrical function to connect components to a substrate like a printed wiring board, solder bonds also must relieve the mechanical stress on the solder bonds resulting from the differences in the coefficient of thermal expansion between the components and the substrate. Otherwise either the solder bonds, the components or the substrate may break. This compensating function requires a certain ductility of the solder joints, which is best achieved with lead-containing solders. In the SDE, the lead solder, according to GE, is the only viable option to connect two levels of the SDE with a higher difference in thermal expansion. Lead-free solders are more brittle than lead solders and therefore are not a viable option. Further on, there is, according to GE, no lead-free solder that offers a melting point as low as to establish sufficient distance to the melting point of the SAC solder.

Exchanging substrates or components in the SDE assembly to approximate the TCEs is impossible, according to GE. Approximating the TCEs between two levels would increase the TCE to and between materials in other levels below or above. So the TCEs of the various substrates and components in the assembly are already optimized.

6.3.3 Substitution of Lead

The consultants consider the applicants' arguments as plausible to explain why lead-free solders cannot be used and the use of lead-solders is required in large SDE detectors with more than 500 interconnects in a single interface. The problems described are generally known to be related to lead-free solders, and in particular the brittleness and lower ductility of the lead-free solders compared to lead-solders creates problems in larger components. Similar problems have been assessed for flip chip packages, for which exemption 15 in RoHS Annex III allows the continued use of lead as well.

6.3.4 Elimination of Lead through Alternative Interconnection and Detector Technologies

The applicant plausibly explained that the GE SDE architecture requires the use of lead solders.

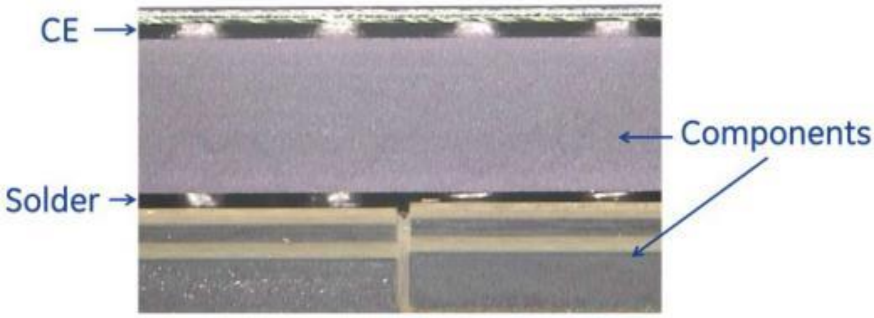
The elimination aspect of RoHS Art. 5(1)(a) allows the justification of exemptions only if a certain functionality or property cannot be achieved with an alternative technology that does not depend on the use of a RoHS-restricted substance. GE was therefore asked to explain in more detail the technical and medical advantages or other advantages of the SDE technology, and whether these properties cannot be achieved with alternative interconnection technologies or alternative detectors that do not require the use of restricted substances.

6.3.4.1 Elimination of Lead by Conductive Adhesives

Conductive adhesives are a technology which in principle allows eliminating the use of lead. They are based on an organic glue, for example an epoxy resin, filled with silver flakes for the conductivity. They do not require the use of lead.

GE was therefore asked to explain why such conductive adhesives cannot be used to eliminate the use of lead solder, the more as a conductive adhesive is already applied in the stacked die element to connect the photodiode array with the pass-through-ceramic as illustrated in Figure 6-2.

Figure 6-2: Section of the SDE detector



Comment: CE: conductive epoxy

Source: GE (2012b)[69]

GE[70] says that there are many challenges to overcome to use conductive adhesives successfully at other "levels" of the microelectronic assembly. For the "level" with lead solder there are several reasons why conductive epoxy could not be used.

The first is a large variation in the surface topology of the components. The components vary in thickness from part to part and lot to lot and they have a natural non-flatness (curvature) that adds to the mechanical gap variation between the components as displayed in the above Figure 6-2. Proper conductive epoxy area array interconnects require uniform deposits of material that are nearly equally displaced (compressed) during assembly so as to not create a short (over compression) or an electrical open (under compression).

Another challenge with high and low gaps is the resultant electrical resistivity variations from one interconnect to another which is attributed to the intrinsic high electrical volumetric resistivity in conductive epoxies. Large variations in electrical resistances make it very difficult to calibrate the device and could compromise the performance.

Additionally interconnects at the "levels" below the components are not suited for conductive epoxy because they include power and ground with significantly higher current requirements. Again the intrinsic high resistivity of conductive epoxies won't work for the milli-amps of current required for these interconnects. The voltage drop would greatly compromise the module performance.

[69] GE (2012b) General Electric Healthcare document "Request_No_12_1st_Clarification_Questions_final_GE_response_2_public_version.pdf" submitted by GE Healthcare on exemption request no. 12 in 2012 for the consultation, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_12/Request_No_12_1st_Clarification_Questions_final_GE_response_2_public_version.pdf; last accessed 4 February 2013

[70] Ibid.

6.3.4.2 Elimination of Lead Through Alternative Detector Designs

GE[71] explains that the detector design, for which it requests the exemption, shall replace older designs of silicon X-ray detectors to enable larger area examinations and lower radiation doses as explained in section 6.1.

GE[72] lists the following interconnection technologies currently used in CT and X-ray systems:

a) "Wire Bond" technology
This technology uses a wire to connect the diode from the diode substrate to the circuit board where signal processing begins. The limitations of the wire bond technology are with density (how close together the diodes can be placed) and added capacitance of the wires.

b) "Flex Interconnect" technology
This technology uses a flex circuit to attach the diode and route signals to the signal processing electronics. The flex interconnect technology also suffers from limitations in density and electrical interface capacitance.

According to GE[73], when developing a detector with large area array electronics containing over 500 interconnects in a single interface, the use of either of these technologies is not practical due to reliability and complexity. The electrical interface capacitance of these technologies also affects the signal to noise ratio. These technology limitations drove the exploration of a new interconnect method which GE calls the Stack Die Element (SDE).

GE[74] claims that SDE detectors achieve properties that cannot be achieved with any other detector design that might possibly allow eliminating the use of lead and thus achieve RoHS compliance. GE[75] claims that the technology and architecture of SDE detectors is in particular superior to the other interconnection technologies listed above in the following parameters:

- Reliability improvements:
    - Smaller area array electronics need many more Stacked Die Elements to build the final detector assembly;
    - More modules increase the probability of disconnects proportionately; and

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[71] Op. cit. GE (2012a)

[72] GE (2013b) General Electric Healthcare, stakeholder document "3rd-Questionnaire-Exe-req 12 – final.pdf" submitted to the consultants via e-mail on 27 June 2013 by James Vetro, GE Health Care

[73] GE (2013d) General Electric Healthcare, stakeholder document "CZT-detectors.pdf" submitted to the consultants via e-mail on 23 July 2013 by James Vetro, GE Health Care

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

[75] Op. cit. GE (2013a)

- Previous modules with less than half the number of photodiodes per Stacked Die Elements have more than 2 times the probability of a discontinuity.

- Image quality benefits:
  - GE's goal of improved image quality drives continued reduction in image element size. A smaller imaging element results in better imaging spatial quality. Higher density architecture results in higher resolution images. New architectures for future CT applications require both larger field of view and higher spatial resolutions. To attain these characteristics the current wire bond manufacturing methods are not capable of meeting these sizes and density requirements. Only the newer Large Stacked Die Elements are able to achieve these characteristics. The new architecture results in densities of greater than 75 connections per cm^2, which, according to GE[76] is around 10 % more interconnects compared to other detector architectures.
- Reduction of the noise floor by approximately 30 %:
  - Large stacked array architecture has lower inherent capacitance than bond wire connections. Lower capacitance reduces the noise floor;
  - Vertical component integration (stacking) was required for this bond wire free density;
  - According to GE[77], an increase in the signal-to-noise ratio by 30 % allows around 20 % to 25 % reduction of the X-ray dose for the patient required for good images, in particular when examining large patients; and
  - The lower X-ray dose reduces the risk of contracting cancer.[78]

6.3.4.3 Elimination of Lead by Alternative Detector Systems

Even though GE claims that no alternative detectors can provide the combination of advantageous properties like SDE detectors, the properties of alternative detectors had been addressed already in the course of reviews of previous exemption requests. It was learned during these reviews that CZT (cadmium-zinc-telluride) detectors are more sensitive to x-rays than silicon detectors[79]. As one of the applicant's main justifications is that with the SDE detector patients are exposed to lower x-ray doses than with other silicon detectors, GE was asked how the dosage reduction of the SDE detectors compares to that of CZT detectors. GE[80] explained that the new SDE

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76 Op. cit. GE (2013d)

77 Op. cit. GE (2012a)

78 Cf. section 6.2.2 on page 7

79 For details about CZT detectors see Gensch et al, page 44

80 Op. cit. GE (2013d)

architecture has similar benefits in dose reductions as CZT detectors, but without the use of cadmium (Cd). The two architectures, however, are independently beneficial to their own imaging applications. The "direct conversion" CZT detectors are typically used in very low energy (photon starved) systems like Nuclear medicine or astronomical imaging equipment whereas the SDE detectors are used in higher energy computer tomography (CT) scanners that have a very wide dynamic range of signal input. [81]

According to GE[82], CT detection systems, among other properties, rely on extremely stable, linear responses over a wide dynamic range of ~ 1:1,000,000, as otherwise they are subject to creation of image artefacts that increase the risk of misdiagnosis. The current capability of CZT/CdTe detection cannot match the stable linearity of scintillator – photodiode based systems like the SDE detector, for which the exemption is requested.

GE explained that CZT detectors and the SDE X-ray detectors thus both facilitate reducing the X-ray dosage, but their properties and their application fields are different, even though they may overlap to a certain degree. Possibly, CZT-detectors therefore might be a replacement for the SDE detectors in certain cases. This was, however, not further investigated because CZT detectors contain cadmium so that their use is only RoHS compliant due to exemption 1 in Annex IV of the RoHS Directive, which allows cadmium and lead in detectors for ionising radiation.

Another alternative to silicon x-ray detectors are image intensifier systems, which might be a replacement for SDE detectors in some cases as well. Image intensifier systems, however, contain lead as well, and an exemption has been recommended for the use of lead in this application.[83]

The information submitted to the consultants suggests that there are no alternatives to SDE detectors that do not require the use of substances restricted under the RoHS Directive and provide comparable features and performance. The elimination of restricted substances by use of alternative detectors thus is deemed to be technically impracticable.

6.3.5 Environmental Arguments

The applicant says that the environmental impact of the requested exemption is low due to the small amount of just 1.2 kg of lead involved. The RoHS Directive does not specify a minimum amount of a restricted substance that would justify an exemption.

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[81] For example uses of CZT detectors see "GE Healthcare: White Paper CZT Technology: Fundamentals and Applications", retrievable from http://www3.gehealthcare.com/~/media/Downloads/us/Product/Product-Categories/Nuclear-Medicine/Cardiac%20Scanners/Discovery-NM570c/GEHealthcare-Whitepaper_CZT-Technology-20111201.pdf?Parent={638AE305-3FFC-431C-8F3D-24250A2598EE}

[82] Op. cit. GE (2013d)

[83] For details see Gensch et al, page 39 ff

The referenced US-EPA-study[84] actually shows that lead-free as well as lead-solders have negative impacts on the environment. Lead-free solders perform better than the lead-solders in some environmental categories, in others worse. This study does, however, not allow the conclusion that the use of lead-free solders may have higher impacts on the environment and on human health than the use of lead solders, and the authors of the study actually refrain from such a conclusion.

6.3.6 Rewording of the Requested Exemption

The applicant had proposed the following wording:

"Leaded solder used to create stacked, area array electronics within ionizing radiation detectors used in CT and X-ray systems

The exemption expires on 1 January 2020 and after that date may be used in spare parts for CT and X-ray systems placed on the EU market before 1 Jan 2020".

This wording would allow the use of lead solders in all SDE interfaces with more than 500 interconnects, while it is only required in one interface, in this case in the middle interface.[85] Restricting the exemption to the use of lead solder in the middle interface might, however, confine the exemption to the SDE technology used by the applicant and prevent the design of alternative SDE detectors and manufacturing methods.

The consultants and GE[86] hence agreed upon the following alternative wording:

Lead in solder in one interface of large area stacked die elements with more than 500 interconnects per interface which are used in x-ray detectors of CT and X-ray systems.

The exemption expires on 1 January 2020 and after that date may be used in spare parts for CT and X-ray systems placed on the EU market before 1 Jan 2020".

6.4 Recommendation Exemption Request 12

Based on the available evidence and in the absence of contrary information, the consultants recommend granting the exemption. Compared to other detector architectures, the SDE detector technology offers advantages, in particular, according to the applicant, an up to 30 % increase in the signal-to-noise ratio, which enables reducing the X-ray dose patients are exposed to in order to achieve a good image. Lower X-ray doses reduce the patient's risk of contracting cancer. SDE detectors offer a combination of technological advantages, which other detectors currently cannot provide.

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[84] Cf. section 6.2.3 on page 35

[85] Cf. Figure 6-1 on page 30

[86] GE (2013c) General Electric Healthcare, stakeholder document "Wording Confirmation.pdf" submitted to the consultants via e-mail on 5 July 2013 by James Vetro, GE Health Care

Large area stacked die elements (SDE) in detectors cannot yet be produced with lead-free solders. Alternative detectors that do not depend on the use of lead or other substances restricted under the RoHS Directive are currently not available.

Neither the substitution nor the elimination of restricted substances is therefore scientifically and technically practicable, and an exemption would be justified in line with Art. 5(1)(a)(i) of the RoHS Directive.

The applicant's proposal for the expiry date in 2020 is plausible. The following wording was therefore agreed upon with the applicant:

Lead in solder in one interface of large area stacked die elements with more than 500 interconnects per interface which are used in x-ray detectors of CT and X-ray systems.

The exemption expires on 1 January 2020 and after that date may be used in spare parts for CT and X-ray systems placed on the market before 1 Jan 2020.

6.5 References

GE 2012a	General Electric Healthcare original exemption request no. 12, document "Exemption_Leaded_solder_utilized_in_Stacked_Area_Array_REV_0_-_Public_Version.pdf", GE Healthcare 2012, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_12/Exemption_Leaded_solder_utilized_in_Stacked_Area_Array_REV_0_-_Public_Version.pdf, last accessed 4 February 2013
GE 2012b	General Electric Healthcare document "Request_No_12_1st_Clarification_Questions_final_GE_response_2_public_version.pdf" submitted by GE Healthcare on exemption request no. 12 in 2012 for the consultation, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_12/Request_No_12_1st_Clarification_Questions_final_GE_response_2_public_version.pdf; last accessed 4 February 2013
GE 2013a	General Electric Healthcare, stakeholder document "2nd-Questionnaire-Exe-req 12_ - public" submitted to the consultants via e-mail on 20 June 2013 by James Vetro, GE Health Care
GE 2013b	General Electric Healthcare, stakeholder document "3rd-Questionnaire-Exe-req 12 – final.pdf" submitted to the consultants via e-mail on 27 June 2013 by James Vetro, GE Health Care
GE 2013c	General Electric Healthcare, stakeholder document "Wording Confirmation.pdf" submitted to the consultants via e-mail on 5 July 2013 by James Vetro, GE Health Care
GE 2013d	General Electric Healthcare, stakeholder document "CZT-detectors.pdf" submitted to the consultants via e-mail on 23 July 2013 by James Vetro, GE Health Care
Gensch et al. 2013	Carl-Otto Gensch, Yifaat Baron, Markus Blepp, Andreas Manhart, Katja Moch, Öko-Institut; Otmar Deubzer, Fraunhofer Institute for Reliability and Microintegration – IZM: 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); retrievable from https://circabc.europa.eu/sd/d/42ccb088-4c26-4e3a-8a0c-218ea738964c/RoHS_V_Final_report_12_Dec_2012_Final.pdf; last accessed 24 September 2013

7.0 Exemption Request No. 13 "Lead in Platinized Platinum Electrodes for Measurement Instruments"

Abbreviations

mg	milligram
Pb	lead
PPE	Platinized Platinum electrode

7.1 Platinized Platinum Electrode Technology

Sections 7.1 and 7.4 are heavily based on information provided by the applicant and other stakeholders and do not necessarily reflect the view of the consultants.

According to the Japanese Business Council in Europe (JBCE), the applicant, the platinized platinum electrode is a platinum electrode covered with a thin layer of platinum black.[87] These electrodes are used when wide-range conductivity measurements are required or for measuring conductivity under strongly acidic or alkaline conditions. [88]

Platinum is used for these electrodes because it:[89]

- Prevents chemical reaction in the solution;
- Functions as a catalyst; and
- Efficiently stimulates the oxidation-reduction reaction of hydrogen.

The performance of electrodes as a catalyst and their electric capacitance is proportional to their surface area. In order to increase the effective surface area, platinum black is added to the surface of the electrodes, which increases the effective surface area by a factor of 1,000. This is achieved using a process of electro-deposition where the platinum powder particles, which are suspended in a solution, are deposited onto the electrode using an electric field that passes through the solution.[90]

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[87] A fine powder of platinum.

[88] JBCE, (2012a), Original application for exemption request no 13 submitted by applicant on 25.09.2012. http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/platinized_platinum_electrode_exemption_application_JBCE.pdf

[89] Op. cit. JBCE, (2012a)

[90] Op. cit. JBCE, (2012a)

Lead is used as an additive (in the form of lead acetate) in the electro-deposition process of platinum black onto the electrode, and a small amount remains in the layer of platinum black.[91] Using lead acetate as an additive has been shown to produce very good platinum black deposits.[92] The applicant states that the use of lead acetate cannot be sufficiently substituted in the production of platinized platinum electrodes.

A similar exemption (1a) exists in Annex IV of the RoHS Directive for:

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

However, this exemption is not applicable to non-ion-selective electrodes.

Therefore the Japan Business Council in Europe (JBCE) has applied for an exemption for "*Lead in platinized platinum electrodes for measurement instruments*".

7.2 Applicant's Justification for Exemption

The applicant argues for exemption on the grounds of:

- **Practicability:** There are not currently adequate alternative substances available that are known to similarly enhance platinum black deposition on electrodes; and
- **Environmental Performance:** At this time, if lead was removed from the process, more material would need to be used, both in the solution containing the platinum black, and in the electrodes themselves, being more wasteful in terms of use of resources.

The following arguments are those of the applicant and do not necessarily reflect the opinions of the consultants.

7.2.1 The Need for Platinized Platinum Electrodes

The conductivity (of water) is a measure of the ability of water to pass an electrical current. Conductivity in water is affected by the presence of inorganic dissolved solids such as chloride, nitrate, sulphate, and phosphate anions (ions that carry a negative charge) or sodium, magnesium, calcium, iron, and aluminium cations (ions that carry a positive charge). Organic compounds like oil, phenol, alcohol, and sugar do not conduct electrical current very well and therefore have a low conductivity when [these

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[91] Op. cit. JBCE, (2012a)

[92] Based on Feltham, A. M. & Spiro, M. (1970), "*Platinized Platinum Electrodes*", Chemical Reviews, 1971, Vol. 71, No. 2. No qualitative comparison is made between platinum black produced with different additives or with different amounts of lead acetate. See formulation in section 7.2.3 Possible Substitute Alternatives. Reference to the deposit quality is understood to regard the adherence of the deposit to the electrode, (surface) area of the deposit as well as it's texture (coarse or smooth) and colour (black or grey) which may vary in light of the additive and the amount in which it is used.

compounds are dissolved – consultants comment] in water. Conductivity is also affected by temperature: the warmer the water, the higher the conductivity. For this reason, conductivity is reported as such at a defined temperature, usually at 25 degrees Celsius (25°C).[93]

In electrochemistry, the standard potential of a chemical species is measured as the voltage difference between the oxidation-reduction potential of hydrogen and that of the chemical species being analysed. This is done using the standard hydrogen electrode because the oxidation-reduction potential of hydrogen is zero volts.[94]

Conductivity is measured with a probe and a meter. Voltage is applied between two electrodes in a probe immersed in the sample water. The drop in voltage caused by the resistance of the water is used to calculate the conductivity per centimetre. The meter converts the probe measurement to micro-siemens[95] per centimetre and displays the result for the user.[96]

Most conductivity measuring electrodes are suitable for measuring conductivity within a specific range, however in certain cases, a specific range cannot be assumed and so an electrode suitable for detecting a wide range of conductivities must be used. The same holds true for measurements carried out in very acidic or vary alkaline environments, for which most electrodes are insufficient as the material of the electrode may react with ions in the solution that is being measured. According to the applicant, the platinized platinum electrode is used when wide-range conductivity measurements are required or when measuring conductivity under strongly acidic or alkaline conditions.[97]

The applicant explains that the “standard hydrogen electrode” is one of the applications of the platinized platinum electrode for measurement. The standard hydrogen electrode is a thin platinum plate with platinum black electro-deposition on its surface (see Figure 7-1 below). The platinum functions as a catalyst to efficiently stimulate the oxidation-reduction reaction of hydrogen,[98] whilst the platinization of

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[93] EPA website (2012), “Water Monitoring and Assessment”, Accessed 12th November 2012, http://water.epa.gov/type/rsl/monitoring/vms59.cfm

[94] Op. cit. JBCE, (2012a)

[95] Originally „in micromhos per centimetre (µmhos/cm)“ in text, however the 1/Ω unit is nowadays addressed as Siemens.

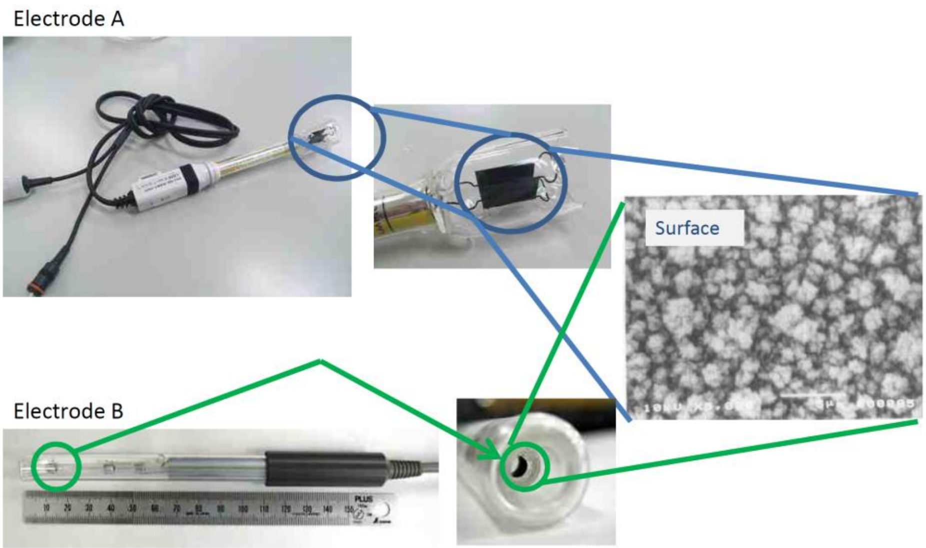
[96] Op. cit. EPA (2012)

[97] Op. cit. JBCE, (2012a)

[98] As explained above, the standard potential of a chemical species is measured as the voltage difference between the oxidation-reduction potential of hydrogen and that of the chemical species being analysed. Platinum electrodes catalyse the proton reduction and thus facilitate the measurement of conductivity based on the difference in potentials. Stable oxidation-reduction potential improves reaction kinetics and the maximum possible current, thus increasing the accuracy of the measurement.

the electrode is necessary to create larger surface area of the electrode so as to generate stable oxidation-reduction potential. [99]

Figure 7-1: The Platinum Platinized Electrode



Source: JBCE (2012a-1), Example pictures provided by the applicant with original application for exemption request 13, submitted on 25.09.2012; *http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/Picture_platinized_platinum_electrodes.pdf*

The importance of surface area can be understood from how the electrode functions and how conductivity values are deduced from measurements. A detailed explanation is given in Appendix A.1.0. In short, JBCE explain that the accuracy of measurements depends on the polarisation impedance of capacitance[100] at the surface boundary between the electrode and the solution. If both the accelerated frequency and the "capacitance created" between the electrodes are high, the inaccuracy will be negligible. This can be achieved by using an electrode with a larger surface area. [101]

To enlarge the surface area, either a small sized electrode can undergo platinization, in which case the platinum black deposited provides a larger electrode surface area, or a larger sized electrode must be used. Platinization enables a surface area approximately 1000 times larger than that of the area of the flat electrode.

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[99] Op. cit. JBCE, (2012a)

[100] Literally how much charge leaks away from the capacitor plate – the more charge that leaks, the less accurate the reading – consultants comment.

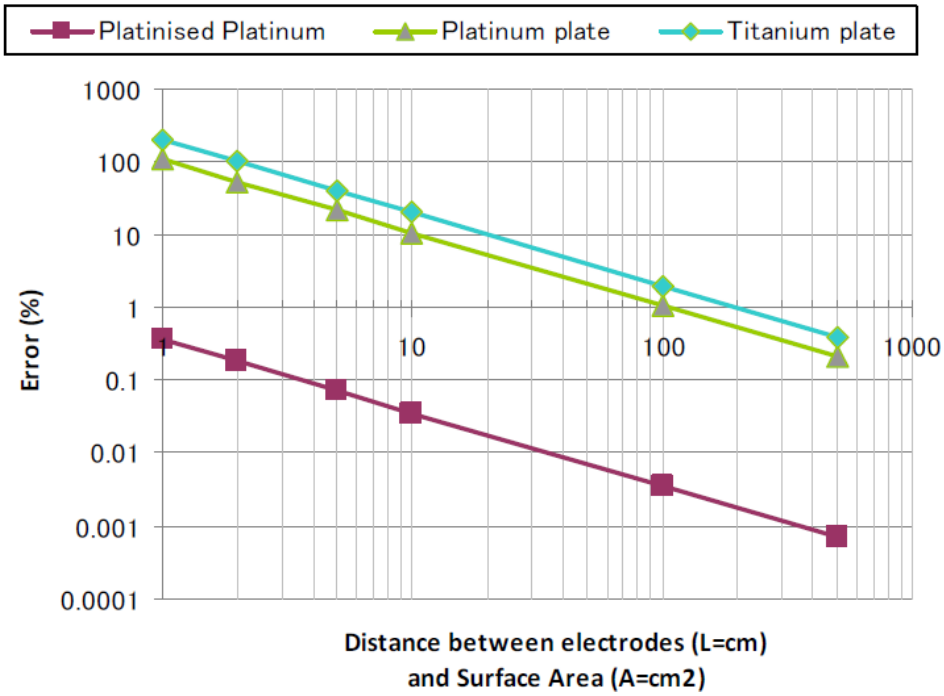
[101] JBCE (2013a) Further Information Provided by the Applicant Concenring Exemption Request No. 13 during the Stakeholder Consultation, on 01.02.2013; *http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/20130201_Further_Information_JBCE_2nd_round_clarification_questions.pdf*

In this sense where the size of an electrode is not an issue for a particular application, unplatinized electrodes may be used. However JBCE argue that for practical needs the market requires an electrode size of 30 mm(φ) x 185 mm(L) at maximum for AC2 and 48 mm(φ) x 116 mm(L) for electromagnetic induction type.[102]

To demonstrate this issue, the applicant submitted Table 7-1 and Table 7-2. Table 7-1 shows that "the capacitance and polarization impedance are different between the case with lead and without lead. Figure 7-2 (based on the data from Table 7-2) indicates that for electrodes from platinum with lead, L=1.00(cm) and A=1.00(cm^2)… a 0.35% error…" is sufficient (L being the distance between electrodes and A the surface area of the electrode),"while a set of electrodes of L=500(cm)], A=500(cm^2) would be needed for platinum without lead or for titanium plate" to achieve a similar rate of error. "Thus, it is not possible to measure the conductivity of a small amount of solution with platinum plate without lead or titanium plate. The large size is, moreover, against resource saving, as well as against eco-design."

Figure 7-2: Calculated Error of Electrode per Surface area and Electrode distance

(Cell constant = 100/m = 1/cm)



Source: JBCE (2013a-3), further Information submitted by the applicant within the Stakeholder Consultation on 1.2.2013: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/20130201_Further_Information_JBCE_figure_1_rev.pdf

102 JBCE (2013a)

Table 7-1: Relation between Surface Area and Distance between Electrodes (Cell constant = 100 /m = 1 /cm)

Distance between electrodes (L=cm)	Surface Area (A=cm²)	Platinised Platinum			Platinum plate			Titanium plate		
		C *1 (μF • cm²)	PR *2 (Ω)	Error *3 (%)	C *1 (μF • cm²)	PR *2 (Ω)	Error *3 (%)	C *1 (μF • cm²)	PR *2 (Ω)	Error *3 (%)
1.00	1.00	4500	0.0354	0.3539	15	10.62	106.1571	8	19.90	199.0446
2.00	2.00	9000	0.0177	0.1769	30	5.31	53.0786	16	9.95	99.5223
5.00	5.00	22500	0.0071	0.0707	75	2.12	21.2314	40	3.98	39.8089
10.00	10.00	45000	0.0035	0.0354	150	1.06	10.6157	80	1.99	19.9045
100.00	100.00	450000	0.0004	0.0035	1500	0.11	1.0616	800	0.20	1.9904
500.00	500.00	2250000	0.0001	0.0007	7500	0.02	0.2123	4000	0.04	0.3981

Source: JBCE (2013a-2), further Information submitted by the applicant within the Stakeholder Consultation on 1.2.2013: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/20130201_Further_Information_JBCE_table_2.pdf

Table 7-2: Relation between Surface area and Distance between Electrodes for figure 1 (Cell constant = 100 /m = 1 /cm)

Distance between electrodes (L=cm) And Surface Area (A=cm²)	Platinised Platinum	Platinum plate	Titanium plate
	Error *3 (%)	Error *3 (%)	Error *3 (%)
1.00	0.3539	106.1571	199.0446
2.00	0.1769	53.0786	99.5223
5.00	0.0707	21.2314	39.8089
10.00	0.0354	10.6157	19.9045
100.00	0.0035	1.0616	1.9904
500.00	0.0007	0.2123	0.3981

*1: Capacitance according to the permittivity of the solution created between electrodes
*2: Polarization resistance
*3: Measurement error for 10 [S/m] solution
Source: Op. cit. JBCE (2013a-2)

The applicant states that due to the composition of the plating solution, a small amount of lead is present in the platinum black surface of the electrode.[103] The amount of lead imported into the EU from Japan in platinized platinum electrodes for measurement instruments, prepared using this method including the use of a plating solution of the composition described above, would be less than 1 gram per year. The applicant details that each electrode contains an average 0.6 mg of lead.[104] During 2011 around 1,500 electrodes were exported from Japan to the EU market, totalling 0.9 grams of lead per year.

7.2.2 The Platinization Method

The applicant has provided a detailed explanation as to how platinization of platinum electrodes is carried out. [105] The technical aspects are outlined below:

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

7.2.3 Possible Substitute Alternatives

According to the applicant, though research has been performed into the possibility of reducing the quantity of lead in the final product, it has not been possible to reach a level less than 1000 ppm in the homogenous material (i.e., a concentration below the 1% by weight restriction stipulated in the RoHS 2 directive).[106]

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[103] JBCE (2013a)

[104] JBCE (2012b), further information concerning exemption request no 13, submitted by applicant on 29.10.2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/JBCE_response_Request_No_13_1st_Clarification_Questions_JBCE_final.pdf

[105] Op. cit. JBCE, (2012a)

[106] Op. cit. JBCE (2012b)

The applicant additionally submitted an article reviewing the platinization technologies available in 1970 written by Feltham & Spiro.[107] Additional information includes the history of the platinization process used to produce PPEs and states that:

> *"platinum black can easily be precipitated from chloroplatinic acid by adding copper or lead, so that such chemically prepared platinum black always contains some copper or lead as well… adding a small amount of copper sulphate, to the extent of about 1% of the chloroplatinic acid present, to the plating solution… regularly produced very good platinum black deposits. Even better results were achieved by adding a small quantity of lead acetate…"*

The article further mentions that though adherent deposits of platinum black are best produced by using lead acetate,

> *"…copper and mercury were found to be acceptable substitutes for lead, and gold and thallium gave deposits of good quality. Cadmium, zinc, nickel and iron have given grey inferior deposits."*

Concerning these possible alternative additives, Feltham & Spiro write that though these have been studied, "none has been employed as extensively as lead acetate."

7.2.4 Possible Design Alternatives

From the various information submitted by the applicant, it could be understood that other electrodes and methods are also in use for performing certain conductivity measurements. The consultants therefore requested further information about where the use of alternatives could not eliminate the need for lead arising through the use of the PPE.[108] The applicant subsequently detailed four areas of application in which PPEs are essential:[109]

- A wide ranged measurement capability is required
- High reliability is required under extreme acidic/alkaline conditions
- High accuracy is required
- A small sized electrode is required in cases of low volume samples

Additionally the applicant has provided various comparisons to demonstrate why the platinized platinum electrodes are the only appropriate electrode for analysis of

[107] Op. cit. Feltham& Spiro (1970)

[108] JBCE (2012b-2), "Comparative Chart of Measurement Ranges of Sensors Used in Conductivity Meters", Additional information concerning exemption request no 13 submitted by applicant on 29.10.2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/Table1_Comparative_chart_of_measurement_range.pdf

[109] Op. cit. JBCE (2013a)

samples that are strongly acidic or basic and for wide ranged electrical conductivity measurements.

To establish under what conditions other electrodes or methods cannot be used, the applicant has provided some detail as to the limiting factors. Table 7-3 compares the conductivity range of the platinized platinum electrode with other electrodes. The comparison has been submitted to demonstrate that in the low conductivity ranges (below 100 mS/m or 1 mS/cm), PPEs are the only electrode that can be used for wide ranged conductivity measurements.[110, 111, 112]

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[110] Op. cit. JBCE (2012b-2)

[111] JBCE (2013b), Information Provided in Answer to 3rd Round of Clarification Questions, submitted by the applicant per email on 27.02.2013.

[112] JBCE (2012b-1), Corrosion Resistance Tables Second Edition, provided by JBCE as Table 2: Additional information concerning exemption request no 13 submitted by applicant on 29.10.2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/Table2_resistance_properties.pdf

Table 7-3: Comparative Chart of Measurement Range of Sensors Used in Conductivity Meters

				0.1mS/m (0.001m/cm)	1mS/m (0.01mS/cm)	10mS/m (0.1mS/cm)	100mS/m (1mS/cm)	1S/m (10mS/cm)	10S/m (0.1S/cm)	100S/m (1S/cm)	1000S/m
Classification/ Type	Cell constant (m^{-1})	Material of Sensing station	Measurement range (mS/cm)	NaCl 0.001% Solution (21.4μS/cm)	NaCl 0.05% Solution (1.03mS/cm)	NaCl 0.5% Solution (9.48mS/cm)	NaCl 5% Solution (81.0mS/cm)	NaCl 10% Solution (140mS/cm)	HNO3 30% Solution (780mS/cm)		Usage environment
AC 2 electrodes class/type	10	platinized platinum	0.0001～10								Mainly used for laboratories. A glass tube is adopted, as it is not eroded by strong acid and strong alkali in high concentration, which could be wetted material of electrodes and so on. Its great advantage is that it has very high chemical-resistance, which makes any measurement possible through wide range with high accuracy.
	100		0.001～100								
	1000		0.01～1000								
	5000		0.01～5000								
AC 2 electrodes class/type	10	SUS, titanium, graphite, etc.	0.001～0.01								Mainly used for measurement of environmental water. They have lower measurement accuracy and corrosion resistance than platinized platinum electrodes, with very narrow range for measurement. Their electrodes are large, and not suitable for laboratories.
	100		0.01～0.1								
	1000		0.1～1								
	5000		0.5～5								
AC 4 electrodes class/type	100～1000	SUS, titanium, etc.	1～1000※1								Mainly used for measurement of environmental water. They have lower measurement accuracy and corrosion resistance than platinized platinum electrodes. Their electrodes are large, and not suitable for laboratories.
electromagnetic induction class/type	100～1000	Magnet coil	20～200000								Mainly used for management of chemicals of high concentration more than 10%. The electrode size is very large. Principally used for process management, and they are not available in the market as a sensor for laboratories.

Source: Op. cit. JBCE (2012b-2);

http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/Table1_Comparative_chart_of_measurement_range.pdf

JBCE[113] provide some examples in which wide ranged measurement is necessary:

- Monitoring and measuring of the conductivity to prepare any objected solutions through adding a small amount of chemicals to purified water;
- Measurement for unknown concentrations of solutions of the volume < 100ml; and
- Titration[114] by measuring conductivity.

JBCE also submitted information comparing the corrosion resistance of various electrode materials with that of platinum. The information detailed in Table 7-4 below, was submitted to demonstrate that platinum based electrodes can be more widely utilised for the analysis of strongly acidic and alkaline solutions.[115]

Table 7-4: Resistance properties for strong acid and

Material of metal	30% Sodium chloride	20% Hydrochloric acid	10% Nitric acid	15% Sodium hydroxide	10% Sulfuric acid
SUS316	G (Good)	U (Unsatisfactory)	E (Exellence)	E (Exellence)	U (Unsatisfactory)
SUS316	<20Mils Penetration/Year at less than 100℃	>50Mils Penetration/Year at 25℃	<2Mils Penetration/Year at less than 100℃	<2Mils Penetration/Year at less than 65℃	>50Mils Penetration/Year at 25℃
Titanium	E (Exellence)	U (Unsatisfactory)	E (Exellence)	E (Exellence)	U (Unsatisfactory)
Titanium	<2Mils Penetration/Year at less than 100℃	>50Mils Penetration/Year at 25℃	<2Mils Penetration/Year at less than 100℃	<2Mils Penetration/Year at less than 100℃	>50Mils Penetration/Year at 25℃
Platinum	E (Exellence)	E (Exellence)	E (Exellence)	E (Exellence)	E (Exellence)
Platinum	Not described. Platinum is not corroded by these chemical solutions.				

* 1Mil=0.0254mm

Source : Op. cit. JBCE (2012b-1);

http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/Table2_resistance_properties.pdf

JBCE[116] provides some examples in which high performance measurements are required:

- Measurement of low conductivity less than 1S/m for samples with organic solvent (the electromagnetic induction method cannot be applied for such samples.);

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113 Op. cit. JBCE (2013b)

114 Titration is a method of chemical analysis. For further detail see section 7.5.5 – consultants comment.

115 Op. cit. JBCE (2012b-1)

116 JBCE (2013c) Information Provided in Answer to 4th Round of Clarification Questions, submitted by the applicant per email on 8.3.2013

- High accuracy measurements with error ranges of less than +/- 1% for:
    - the strong acid samples higher than 10mol/l (31.5% and 0.7 S/cm for HCl, 48.5% and 0.6 S/cm for HNO3, 21.3% and 0.7 S/cm for H2SO4.);
    - for the strong alkaline samples higher than 1mol/l (3.8% and 0.1 S/cm for NaOH); or
    - for samples including halogen solution.
- Measurement of conductivity higher than 100S/m with portable equipment (Electromagnetic induction type is not realistic because a power source is needed.)

The applicant was further requested to comment on some assumptions that had been formulated on the basis of provided information. The following points were established through this process:[117]

- The applicant was asked whether the need for lead in PPEs can be eliminated by using magnet coils as the sensing application (classified as electromagnetic induction) for process management applications in which chemicals have concentrations above 10% (which seemed to be indicated in Table 7-3). The applicant confirmed that this was possible in many cases. However, if equipment cannot be installed in facilities, portable type products are necessary for control.
- The applicant was also asked about whether SUS, titanium and graphite electrodes can be used for determining conductivity in environmental water. Though JBCE confirmed that SUS, titanium and graphite electrodes are often used for environmental water, it expresses some reservations:

    "However, this is for samples which are periodically collected at the fixed locations only. In such cases the conductivity does not vary so much. When different kinds of environmental water are mixed due to water flow, PPE is the only electrode to cover the whole range. It is important to mention that using only one equipment minimizes uncertain instrumental errors."
- JBCE explain that though PPEs are used mainly for laboratory analysis, they are also used for portable measurement for industries [i.e. industrial monitoring] and environmental monitoring.
- Additionally the applicant emphasized the interrelations between the information provided in the various tables. Table 7-4 shows the corrosion resistance only, and it does not mean that the electrode can be used for all solutions mentioned above. For example, maximum concentration that may be measured with a titanium electrode of AC2 with 5000/m cell constant is 5 mS/cm according to Table 7-3, so that the electrode can be used for sodium

[117] Op. cit. JBCE (2013c)

chloride solutions of concentrations below 3.8%, for nitric acid solutions of concentrations less than 1% and for sodium hydroxide solutions of concentrations less than 1%. As for AC4 with 1000/m cell constant, the SUS electrode can be used to measure samples of less than 10 mS/cm, titanium electrode, likewise titanium can be used for 10 mS/cm and graphite can be used for 2000 mS/cm. In addition, the use of the titanium electrode is limited by its polarizing action due to AC acceleration causing loss of linearity and surface corrosion.

7.2.5 Environmental Arguments

Even though no technically viable substitute has been identified at present, JBCE argue that the PPE can also be considered a less environmental damaging option in some cases.[118] This is primarily related to two aspects of PPE:

- **Electrodes size** –in theory, for measurements where electrode size is not an issue, JBCE state that using a platinum (not platinized) electrode would require a bigger electrode: Therefore, "if the size of the electrode becomes larger, the size of the final products becomes larger, [and] that hinders measurements in many case" and in turn, they claim that this is "against resource saving, as well as against eco-design". Additionally, as more solution would be needed for the measurement, in some cases this would require preparing additional solution, which can also be perceived as wasteful; and
- **Measurement Range** – in areas where a wide range measurement is required, as the PPE can cover a wide range independently, using other electrodes that cannot cover the full range, would thus require a compilation of measurement data from a few alternative measurement methods. From the information provided it can be understood that this could be considered as wasteful in cases where the laboratory would not in any case be in possession of all alternative electrodes enabling a full range measurement.

7.2.6 Road Map for Substitution

Concerning the possibility of future substitution of lead in this application, or its elimination through implementation of alternative technologies, JBCE[119] list three directions for possible future research:

- Substitute of substance (no lead) or decreasing use of lead (less than 0.1%) for platinised platinum electrode;
- Substitute of material for electrode; and
- Alternative measurement methods.

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[118] Op. cit. JBCE, (2013a)

[119] Op. cit. JBCE (2012a)

The phases of developing alternatives and the time that JBCE regard for these phases, once a possible substitute is identified are detailed in Table 7-5 below, summarizing information provided by JBCE.[120]

Table 7-5: Proposed Road-Plan for Possible Substitution

Phase	Estimated time needed	Main stages
Research into substitutes or alternatives	1-2 years	Testing of substitutes on the component level; and Confirmation of performance results through theoretical calculation/simulation software
Product redesign	1-2 years for redesign of 1 product 3-4 years for redesign of full product range	finalising product specification; making proto-type; verifying prototype; and designing product for mass-production; The time needed to complete these stages depends on the quality of substitutes.
Reliability testing	1-2 years	Includes field testing. In some cases could be performed in parallel to the redesign phase.
Product approval according to standards or regulations	Not indicated by applicant	Standard EN27888:1993, equivalent to ISO7888:1985, refers to the platinised platinum electrodes and shall require revision before products can be pulled off the market

The applicant indicates that between 2 and 4 years in total are required to complete the process of substitution in one product.[121] For a broader range of products, 4- 6 years are likely to be needed to complete this process. However, for both of these scenarios, if reliability testing cannot be carried out in parallel to early stages of redesign, an additional 1- 2 years shall be required. The applicant further emphasizes that in practice, a full model change for high quality electrodes generally entails a 7-year cycle or longer. Shortening the cycle would mean that manufacturers would need to allocate resources away from other projects, having a possible effect on the development of other equipment.

7.3 Stakeholder Contributions

Though no contributions were made by stakeholders via the stakeholder consultation, an effort was made to contact further manufacturers of electrodes used for measuring conductivity. This was done in order to obtain further information as to when the need for lead in PPEs can be reduced or eliminated by using other electrodes and measuring techniques. In this regard, some additional information was provided by “Thermo Fischer Scientific” who supply electrodes for various uses.

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120 Op. cit. JBCE (2012a)

121 Op. cit. JBCE (2012a)

Though it could be understood that in some cases the use of the PPE can be avoided, it was also confirmed that PPE was ideal for tough environments such as high acidity or alkalinity:[122]

> *"Platinum cells are useful for tough sample environments due to their glass body and platinum sensing elements."*

Additionally, it was clarified that lead is also present in the glass used within the conductivity cell.

> *Generally, glass we would use for platinum conductivity cells would contain 29% lead. An estimate of the amount of glass used in one is 12-14 grams. Assuming 14 grams, which would mean about 4 grams of lead in an electrode. This is the maximum amount. Some glass would contain 19% lead*.

It should be noted that neither the applicant nor other stakeholders clarified that there is a need for the exemption to cover the lead in the glass of the device. It is understood that where measuring devices with lead containing glass are marketed in the EU-27, suppliers are aware of their responsibility to comply with the RoHS Directive stipulations concerning the allowed contents of lead in devices placed on the market. The review of the request does not address this issue, which is not covered by the proposed formulation of the exemption requested by the applicant.

7.4 Additional Information

In the context of this request for exemption, the applicant indicated that ISO standard 7888 on water quality, requires the determination of electrical conductivity. The applicant argues that PPE is required for use in such measurements, indicating the need for PPE based instruments.

Following closer inspection of the standard, it was established that this standard does not limit analysis to PPE, but rather only states that in precision analysis, if a platinum electrode is used, it must be platinized. It is additionally stated that non-platinized electrodes may only be used for field testing and for routine laboratory testing (there is no reference to clarify if this refers to platinum electrodes only, or also to other electrodes that can be platinized, such as titanium electrodes).

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[122] Thermo Fischer Scientific (2013a), Information Provided by Stakeholder Following Request, submitted per Email on 18.02.2013.

7.5 Critical Review

7.5.1 Areas of Application of a Potential Exemption

The applicant has mentioned the use of a platinized catalyser as an electrode material for fuel cells and as a hydrogen storage metal. These applications of the platinum platinized electrode are additional to the one central to this request – the use of PPE in conductivity instruments. We understand from the applicant that these applications are currently under development.[123] As these applications are under development there is no certainty regarding whether PPE will be present in the final product, and if it is, what form this will take. Furthermore, no information was contributed by other stakeholders concerning this request for exemption being relevant to other applications. It is therefore assumed that such possible applications are either excluded from the scope of RoHS or are still in development. In the latter case, as no information was submitted it was not possible to evaluate whether the exemption request was of relevance in such cases.

Additionally, the presence of lead in the glass of platinum conductivity cells has been raised. However, the proposed formulation of the exemption clearly relates only to the lead present in the electrode itself. As information was not provided to establish that lead in the glass of the cell was also relevant for this request, the consultants have no choice but to assume it to be covered by other exemptions already included in the Annexes of RoHS (for instance Exemption 7(c)-I of Annex III), otherwise stakeholders would have been expected to communicate the relevance of this issue. It is should be noted that the lead included in the glass of conductivity cells significantly exceeds the amounts present in the electrode itself as a result of the platinization process.

These additional applications and the presence of lead in the glass of the electrode are therefore not further discussed in the context of this request and would not be covered should an exemption be granted based on the proposed formulation.

7.5.2 REACH Compliance - Relation to the REACH Regulation

Section 5.0 of this report refers to various entries in Annex XIV concerning substances for which an authorisation is needed to permit for further use in a specific application. Though a few lead compounds are mentioned, the compound mentioned in the context of this request for exemption, lead acetate, is not referred to.

Annex XVII, which restricts the use of various compounds, refers to lead acetate in the context of entry 30. This entry stipulates that various compounds shall not be placed on the market, or used:

- As substances;
- As constituents of other substances; or
- In mixtures.

[123] Op. cit. JBCE (2012b)

In the case of this request for exemption, lead is used in the production process of the article, for which reason some residue is left within the end product. However, in the consultants' understanding, entry 30 of Annex XVII does not apply to the use of lead in PPEs since the compound would not be supplied directly to the public as such, as a constituent of other substances, nor in a mixture. In other words the restriction in question does not apply to the use of lead in this instance.

The consultants conclude that the use of lead in PPEs does not weaken the environmental and health protection afforded by the REACH Ordinance.

Concerning potential substitutes, a few other compounds were mentioned that have also been cross checked with the REACH Regulation, including compounds containing mercury, thallium, copper and gold.[124]

- **Mercury** is also a RoHS restricted substance, in this regard it is assumed that its use, in terms of toxicity, is comparable to that of lead and should in any case be avoided. It was therefore not further cross-checked in the context of the REACH regulation.
- Though **thallium** is also considered toxic, and thus could not necessarily be regarded as a preferable alternative, no listings were found.
- **Copper** is mentioned in the context of entries 28[125] and 30,[126] which also prohibit that mentioned substances be placed on the market, or used: as substances; as constituents of other substances; or in mixtures.
- No listings were found concerning **gold**.

In this sense, using gold and copper as well as the less preferred thallium as possible alternatives would, at present, not be understood as a use that would weaken the protection afforded by the REACH Regulation.

An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

7.5.3 Scientific and Technical Practicability of Lead Substitution

Concerning the platinized platinum electrode, substitution would require that the process of platinization be performed without lead, resulting in a platinum black deposit of similar quality to that obtainable when using lead acetate in the platinizing solution. Though the work of Feltham & Spiro[127] mentions some possible alternatives for such substitution, as the use of lead was not restricted in the past, documentation of further efforts made to clarify the relative performance of electrodes produced with other additive based platinization solutions was not available – a literature review did not reveal more current publication and so it is understood that indeed the Feltham &

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[124] Feltham and Spiro refer to using copper sulphate in the platinization process

[125] Formic acid, copper nickel salt; Trisodium-[4'-(8-acetylamino-3,6- disulfonato-2-naphthylazo)-4''-(6-benzoylamino-3-sulfonato-2-naphthylazo)biphenyl-1,3',3'',1'''-tetraolato-O, O', O'', O''']copper(II);

[126] Formic acid, copper nickel salt;

[127] Op. cit., Feltham & Spiro (1970)

Spiro study from 1970 remains the sole source of publically available evidence on the subject. Though this implies that at present, substitution with such additives could not be perceived as an immediate substitute, it does suggest that one or more of the potential alternatives could provide an adequate substitute. In this sense, one direction for further research could be focused on one of these materials. That said, mercury is also regulated by RoHS and so would probably be comparable in terms of toxicity. Thallium is also considered extremely toxic. As quantitative information is not available to allow a comparison between the performance of PPEs platinized with lead acetate and PPEs platinized with gold or copper based additives, the consultant could not verify the potential of such additives to substitute the use of lead acetate in the platinization process. Scientific and Technical Practicability of Lead Elimination

The information provided by JBCE demonstrates that possible alternatives are available and could be used in some cases to eliminate the need for lead in the applications for which this exemption has been requested. However, the information they submitted also indicates that in some application areas, such elimination is at present not possible.

This regards areas where one of the following conditions applies:

- A wide ranged measurement capability is required;
- High reliability is required under extreme acidic/alkaline conditions;
- High accuracy is required; or
- A small sized electrode is required in cases of low volume samples.

According to the information submitted by the applicant (cf. section 7.2.4 for further details), none of the possible alternatives present a method that can be used to cover the full conductivity range. In general, AC2 electrode types that may be used to cover the conductivity range below 5mS/cm are all sensitive to relatively narrow conductivity ranges of this category, whereas the PPE can cover the complete range below this threshold. This would require using multiple electrodes in areas where a single PPE could be used. Furthermore these electrodes also exhibit limited accuracy and low resistance to corrosiveness, making their use problematic where high accuracy is required or for measurements under extreme acidic or extreme alkaline conditions. Though AC4 type electrodes and magnet coils can cover a wider range, they are limited in detection capabilities to conductivities above 1 and 10 mS/cm respectively. Both the AC4 type electrodes and magnet coils have electrodes with relatively larger size, that do not enable their use in smaller samples and therefor they are not suitable for laboratories. AC4 types also exhibit lower measurement accuracy and corrosion resistance, excluding further application possibilities.

Given the information provided by the applicant and in lack of contradicting information made available by other manufacturers approached, the consultants conclude that for specific applications, the use of lead in PPE cannot as of yet be eliminated.

7.5.4 Environmental Arguments

JBCE refers to two environmental issues that they believe show that there would be environmental harm if the exemption was not granted (see section 7.2.5). However, the information provided is not detailed and does not allow for a comprehensive analysis of the potential environmental impacts of using substitutes compared to continuing with PPEs. Therefore the consultants believe it is not possible to conclude whether it would be environmentally harmful to utilise a substitute or not in comparison with the environmental impact of utilizing devices based on the PPE. .

7.5.5 Scope

The applicant has cited ISO Standard 7888 to show that the use of PPEs is unavoidable as it is specified in regulating standards. Further inspection of ISO Standard 7888, however clarified that whilst PPE is referred to, it is not named as the only acceptable technology for performing electrical conductivity measurements in all cases. The standard states that *platinum* electrodes used in precision measurement must be platinized. In this sense it could be followed that in some cases alternative methods that did not involve *platinum* electrodes could be used. The specification of the platinizing solution is part of the standard, referring to lead acetate as the applied additive. Additionally the standard limits the use of non-platinized electrodes to field testing and routine laboratory testing, not clarifying if electrodes from other materials, that had been platinized, could be used as an alternative. This information thus raises a question as to the possibility of using alternative measurement methods and equipment for some measurement applications, thus allowing for the partial elimination of the lead present in PPEs.

Item (19) of the RoHS Directive[128] explicitly states that:

> *"Exemptions from the restriction for certain specific materials or components should be limited in their scope and duration, in order to achieve a gradual phase-out of hazardous substances in EEE, given that the use of those substances in such applications should become avoidable. "*

In this sense, an exemption could only be recommended after establishing if the scope could be limited to specific areas of application, in which case the exemption was respectively formulated to address such areas.

In light of the Directive requirement to limit the scope of possible exemptions, an effort was made to clarify what areas of application and what threshold limits could address the unique qualities that PPEs possess, beyond which (above or below) other methods could not be used.

In parallel, it is also understood that once applications using the PPE electrode are placed on the market, it impractical to survey and enforce what applications they are used for. Thus a limitation of scope based on areas of application would be complicated to enforce, and this was borne in mind whilst assessing the potential limitation of the scope. The practical challenges associated with limiting the scope should an exemption be granted are discussed in greater detail in Section 7.6.

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[128] RoHS Directive (2011) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:

The applicant was asked to suggest an adaptation of the proposed wording, so that the scope would be limited to application areas in which the use of the PPE could not be avoided. The applicant provided the following formulation.[129]

> *"Lead in platinized platinum electrodes for wide range conductivity measurements, or conductivity measurements in strong acidic or alkaline environment."*

Though this formulation reflects the areas in which it can be shown that the use of PPE is indispensable, it could also be interpreted that PPE was not required for measurements covering the full range of these areas of application. Therefore the applicant was asked to specify details of the ranges of application areas in which the PPE could not be replaced. This resulted in the following wording proposal:[130]

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

a. Wide Range Measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0.1mS/m and 5 mS/m) in laboratory applications:
   I. For unknown concentrations; or
   II. For variable concentration solutions (e.g. titration).

b. Measurements of solutions where an accuracy of +/- 1% of the sample range and where high corrosion resistance of the electrode are required for:
   IV. Solutions with an acidity < pH 1; or
   V. Solutions with an alkalinity >pH 13; or
   VI. Corrosive solutions containing halogen gas

c. Measurements of conductivities above 100 mS/m that must be performed with portable instruments"

As the use of the PPE in titration processes and for the measurement of corrosive solutions containing halogen gas had not been referred to earlier in detail, the applicant was asked to explain the relevant issues concerning these areas of application.

Concerning titration, the applicant explained that the method of obtaining the concentrations of solutions from conductivity measurements is often used in industry. In conductivity titration, a solution (A) with unknown concentration is reacted with a second solution (B) for which the concentration is known. As solution B is gradually added to solution A, the substances react, changing the conductivity of the mixture. The reaction will saturate at the point where a certain amount of B has been added (the equivalence point), and following this point, the further addition of B solution

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129 Op. cit. JBCE (2012b)

130 JBCE (2013d), Information Provided Concerning the Wording Formulation of Exemption Request 13, submitted by the applicant per Email on 4.4.2013

shall contribute to the mixture concentration respectively only to solution B's concentration. As the volumes of both solutions are known, the concentration of solution A can be extrapolated from the amount of B that is required to reach the equivalence point.[131]

In the process of titration, the PPE is needed to measure the gradually varying conductivity. In case of other electrodes, electrode changes may be required due to the limited measurement range of each electrode, disrupting the process. However, a single PPE can measure the whole course of titration in light of its wide measurement range.[132]

However, in the case of titration it is clear that the PPE is needed due to an unknown concentration that is being measured. In this sense, conductivity titration measurements would already be covered by item a.I, and it was therefore agreed with the applicant[133] that a.II could be omitted.

As for corrosive solutions containing halogen gas, the applicant explained[134] that:

> *"Many metals react readily with halogen gases in water because solutions including halogen gases such as fluorine, chlorine, bromine, iodine etc., have strong oxidative power and cause metal to corrode. For example, when chlorine dissolves in water, mixture of chlorine, hydrochloric acid and hypochlorous acid are made and the mixture cause metal[s] like SUS and titanium to corrode. Therefore PPE which is made of platinum is used because of its high resistivity, as [a] precious metal, to avoid such corrosion."*

The applicant[135] further indicated that this request and the proposed wording were supported by a number of companies represented by JBCE & JEMIMA (The Japan Electric Measuring Instruments Manufacturer's Association), including: Yokogawa, DKK-TOA and Horiba.

Further names of companies also manufacturing PPEs were specified by the applicant and the consultant contacted these in order to establish if the proposed limitations to scope indeed represented the areas of application in which the PPE was indispensable. However, no response was received from any of these contacts and so no further assessment could be made.

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[131] JBCE (2013e), Information Explaining the relevance of the Titration Process to the Scope of Exemption Request 13, submitted by the applicant per Email on 4.4.2013

[132] JBCE (2013d)

[133] JBCE (2013f), Answers to Clarification Questions Concerning the Proposed Wording, submitted by the applicant per Email on 4.4.2013.

[134] JBCE (2013d)

[135] Op. cit. JBCE (2013f)

7.5.6 Conclusions

Article 5(1)(a) of the RoHS Directive stipulates that an exemption can only be granted if one of the three main criteria detailed 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 this case it is the first criterion that is relevant to this application. The second criterion may be relevant when substitutes have been further explored, but at this time they are insufficiently understood for this to be relevant.

From the evidence available it is clear that there are a number of applications where instruments utilising PPEs are the only realistic option available. Therefore, given that this is the case, it is necessary to identify alternatives to the use of lead in the electro-deposition process. Whilst the consultants understand that there are potential substitutes for lead in this process, they have not been sufficiently developed to enable substitution in the timescale of the RoHS directive. Further research and testing is required to identify whether it is possible to substitute alternative substances for lead in the electro-deposition process. If it is found that there are suitable substitutes, these would then need to be developed and tested.

Having clarified the range of applications for which it is necessary to use PPEs, the consultants therefore recommend that an exemption is appropriate in this case as it is not currently practicable to substitute lead in this instance.

Regarding the period of time for which an exemption shall be necessary, it is unclear at this time how long it will take to develop a reliable substitute for lead acetate in platinization, or to eliminate lead use through alternative methods. However, the applicant has demonstrated that once research identifies a promising candidate (for substitution or elimination), further time shall be needed to complete initial testing, redesign of products, reliability testing of new products, and possible product requalification before alternatives are commercially available.

Though the applicant's evidence indicates that full substitution or elimination of the use of lead required for PPEs could take 6 to 7 years or longer, it has also been shown that a few candidates for possible substitution of lead in the platinization process are known. However as there is insufficient further information, we conclude that research into these candidate substitutes is still required to establish their viability.

The applicant has indicated that a research and redesign could take as little as 4-5 years for the full product range once substitution/elimination candidates are known. As a few candidates are mentioned in the literature, the consultants recommend granting an exemption for a period that would accommodate a 5 year timeline. It should be noted that if research into the existing candidates does not bear fruit, the initial research term of 1-2 years would still leave ample time to reapply for the renewal of an exemption in light of lack of practical substitutes.

7.6 Recommendation

The use of lead cannot currently be fully eliminated in PPE applications, neither through possible substance substitutes, nor through the use of alternative methods for measuring conductivity. The scope of applications for which it is not possible to currently replace PPEs has been clearly established and therefore there is sufficient clarity to recommend an exemption in line with the criteria stipulated in article 5(1)(a) of the RoHS Directive.

The consultants recommend that in the first instance a period of 5 years, sufficient to accommodate the required research into the existing substitute candidates and the respective development of possible alternatives, is granted. If research efforts are not successful, a 5 year period would also leave sufficient time to apply for the renewal of the exemption, assuming that substitution and elimination remained impractical through other means.

Furthermore, taking full account of item (19) of the RoHS Directive which requires the limiting of scope of exemptions, the consultants recommend adding an exemption with the following wording and validity to Annex IV of Directive 2011/65/EU:

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

a. *Wide Range Measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0.1mS/m and 5 mS/m) in laboratory applications for unknown concentrations*
b. *Measurements of solutions where an accuracy of +/- 1% of the sample range and where high corrosion resistance of the electrode are required for:*
    - VII. *Solutions with an acidity < pH 1; or*
    - VIII. *Solutions with an alkalinity >pH 13; or*
    - IX. *Corrosive solutions containing halogen gas*
c. *Measurements of conductivities above 100 mS/m that must be performed with portable instruments"*

Expires 31.12.2018 (5 years after exemption is granted)

Though this formulation limits the scope of a possible exemption, it is not clear how practical a limitation of use is, as once devices including PPEs are sold, it can no longer be ensured for what applications they are used in practice. Though the exemption would limit the official sale of PPEs to specific applications, it is possible that consumers would continue to use devices for further uses once they have purchased a device. Even if consumers would be expected to be supply vendors with information as to the intended use of products, once a PPE based device had been purchased it would no longer be transparent how it was utilized in practice. An exemption of limited scope may, therefore, lead to a similar result to one where the exemption was more broadly specified. If the European Commission regards the proposed limitation as impractical, and seeing as the second proposed wording suffers from some limitations,[136] the original formulation proposed by JBCE[137] could be recommended as a practical formulation alternative:

"Lead in platinized platinum electrodes for measurement instruments"

Expires 31.12.2018 (5 years after exemption is granted)

7.7 References

EPA website (2012), "Water Monitoring and Assessment", Last accessed 12.11.2012, http://water.epa.gov/type/rsl/monitoring/vms59.cfm

Feltham, A. M. & Spiro, M. (1970), "*Platinized Platinum Electrodes*", Chemical Reviews, 1971, Vol. 71, No. 2

JBCE, (2012a), Original application for exemption request no 13 submitted by applicant on 25.09.2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/platinized_platinum_electrode_exemption_application_JBCE.pdf

JBCE (2012a-1), Example pictures provided by the applicant with original application for exemption request 13, submitted on 25.09.2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/Picture_platinized_platinum_electrodes.pdf

JBCE (2012b), Further information concerning exemption request no 13 submitted by applicant, in answer to 1st Round of Clarification questions, on 29.10.2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/JBCE_response_Request_No_13_1st_Clarification_Questions_JBCE_final.pdf

JBCE (2012b-1), Corrosion Resistance Tables Second Edition, provided by JBCE as Table 2: Additional information concerning exemption request no 13 submitted by applicant, in answer to 1st Round of Clarification questions, on 29.10.2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/Table2_resistance_properties.pdf

JBCE (2012b-2), "Comparative Chart of Measurement Ranges of Sensors Used in Conductivity Meters", Additional information concerning exemption request no 13 submitted by applicant, in answer to 1st Round of Clarification questions, on 29.10.2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/Table1_Comparative_chart_of_measurement_range.pdf

JBCE (2013a) Further Information Provided by the Applicant *in Answer to 2nd Round of Clarification Questions,* Concerning Exemption Request No. 13 during the Stakeholder Consultation, on 01.02.2013; *http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/20130201_Further_Information_JBCE_2nd_round_clarification_questions.pdf*

[136] Op. cit. JBCE (2012b), *"Lead in platinized platinum electrodes for wide range conductivity measurements, or conductivity measurements in strong acidic or alkaline environment."*

[137] Op. cit. JBCE (2012a)

JBCE (2013a-2), Further Information Submitted by the applicant in Answer to 2nd Round of Clarification Questions, within the Stakeholder Consultation on 1.2.2013: *http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/20130201_Further_Information_JBCE_table_2.pdf*

JBCE (2013a-3), Further Information Submitted by the applicant within the Stakeholder Consultation on 1.2.2013: *http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/20130201_Further_Information_JBCE_figure_1_rev.pdf*

JBCE (2013b), Information Provided in Answer to 3rd Round of Clarification Questions, submitted by the applicant per email on 27.02.2013.

JBCE (2013c) Information Provided in Answer to 4th Round of Clarification Questions, submitted by the applicant per email on 8.3.2013

JBCE (2013d), Information Provided Concerning the Wording Formulation of Exemption Request 13, submitted by the applicant per email on 4.4.2013

JBCE (2013e), Information Explaining the relevance of the Titration Process to the Scope of Exemption Request 13, submitted by the applicant per email on 4.4.2013

JBCE (2013f), Answers to Clarification Questions Concerning the Proposed Wording, submitted by the applicant per email on 4.4.2013.

Thermo Fischer Scientific (2013a), Information Provided by Stakeholder Following Request, submitted per email on 18.02.2013.

8.0 Exemption Request 14: “Lead in Solder for Ignition Modules”

The “Andreas STIHL AG & Co KG” (STIHL) applied for an exemption of:

> *“Lead in solders for the ignition module and other electronic engine controls mounted directly on or close to the cylinder of hand-held engines (classes SH: 1, SH: 2, SH: 3 of 2002/88/EC).”*

STIHL[138] requests an expiry date in mid 2025.

8.1 Description of Requested Exemption

Sections 8.1 and 8.2 are heavily based on information provided by the applicant and other stakeholders and do not necessarily reflect the view of the consultants.

8.1.1 Technical Background

STIHL[139] explains that regulation 2002/88/EC regulates emissions and type-approval procedures for non-road mobile machinery. The classification in the classes SH: 1, SH: 2, SH: 3 in this regulation is based on the displacement of the engine as illustrated in Table 8-1.

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[138] STIHL (2012a), Andreas STIHL AG & Co KG original exemption request no. 14, document “RoHS_Ex_request_14_lead_solder_ignition_modules_2012_09_18.pdf”, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_14/RoHS_Ex_request_14_lead_solder_ignition_modules_2012_09_18.pdf, last accessed 8 February 2013

[139] Op. cit. STIHL (2012a)

Table 8-1: *Classification of small engines according to Directive 2002/88/EC*

Main class S: small engines with a net power ≤ 19 kW

The main class S shall be divided into two categories:

H: engines for hand-held machinery

N: engines for non-hand-held machinery

Class/category	Displacement (cubic cm)
Hand-held engines Class SH:1	< 20
Class SH:2	≥ 20 < 50
Class SH:3	≥ 50
Non-hand-held engines Class SN:1	< 66
Class SN:2	≥ 66 < 100
Class SN:3	≥ 100 < 225
Class SN:4	≥ 225

Source: Directive 2002/88/EC[140] referenced in (STIHL 2012b)

According to STIHL[141], classes SH:1, SH:2 and SH:3 are all hand-held products with spark-ignition engines. As typical product examples for the classes, STIHL[142] indicates:

- SH 1
  - Very small hedge trimmers
- SH 2
  - Small chain saws
  - Hedge trimmers
  - Lawn trimmers
  - Blowers

140 Directive 2002/88/EC, retrieved from *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:035:0028:0081:en:PDF*; last accessed 8 February 2013

141 STIHL (2012b), Andreas STIHL AG & Co KG document "20121029_RoHS_Request_No_3_Clarification__Answers_GEHealth.pdf" submitted for the online stakeholder consultation, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_14/20121029_RoHS_Request_No_3_Clarification__Answers_GEHealth.pdf; last accessed 8 February 2013

142 Op. cit. STIHL (2012b)

- SH 3
    - Large chain saws
    - Brush cutters
    - Cut-quicks
    - Backpack blowers

STIHL[143] indicates the average life spans of hand-held combustion-powered garden, forest and construction equipment with 5 - 9 years in professional and up to 20 years in private use The typical use and life time of such equipment used in rental business and in professional use is around 300 h over 5 - 9 years.

The ignition modules for small spark ignition engines have a compact design and are located in direct proximity to the engine and must operate reliably under harsh conditions, as detailed in section 8.2.1 - Technical Constraints.[144, 145]

According to STIHL,[146] to withstand these harsh conditions, materials and design have had to be optimized and thoroughly tested. For additional mechanical stability and protection against water, fuel and oil, the electronic circuits are sealed with epoxy resin.

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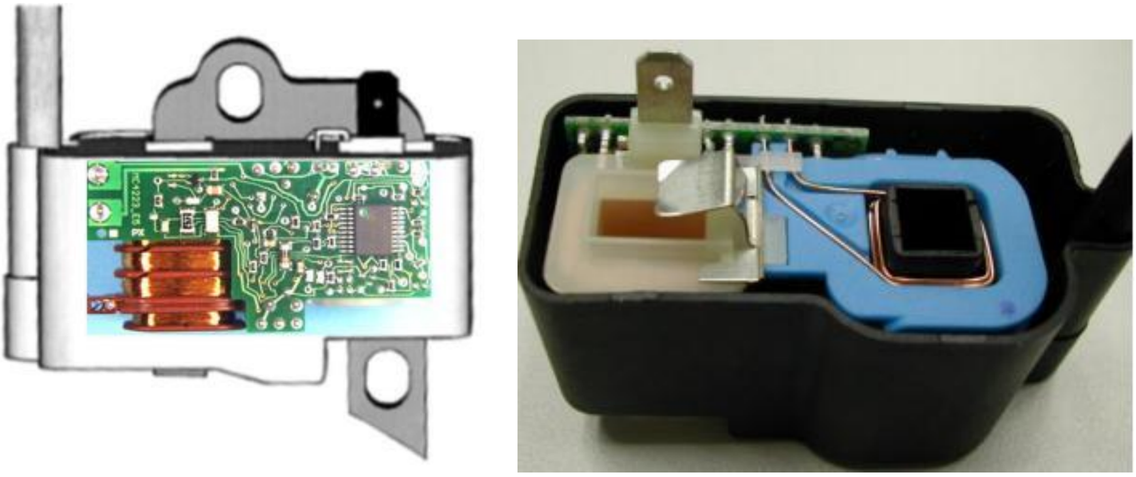
[143] STIHL (2013a), Andreas STIHL AG & Co KG, document “2nd-Questionnaire-Exe-req 14_Answers_2013_02_25.docx” submitted via e-mail by Mrs. Christina Wedel per Email, on 25 February 2013

[144] Op. cit. STIHL (2012a)

[145] Op. cit. STIHL (2012b)

[146] Op. cit. STIHL (2012a)

Figure 8-1: PCB and coil of the ignition module (left), and an ignition module before sealing



Source: STIHL (2012c), Andreas STIHL AG & Co KG, document "RoHS_II_exemption_request_ignition_modules_for_publication_2012_10_30.pdf" submitted for the online stakeholder consultation, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_14/RoHS_II_exemption_request_ignition_modules_for_publication_2012_10_30.pdf; last accessed 8 February 2013

Figure 8-2 illustrates the position of the ignition module in a chain saw.

Figure 8-2: Position of the ignition module in a chain saw

Source: STIHL (2013a)

STIHL[147] presents images of typical failure modes observed in ignition modules as a result of the harsh environmental conditions.

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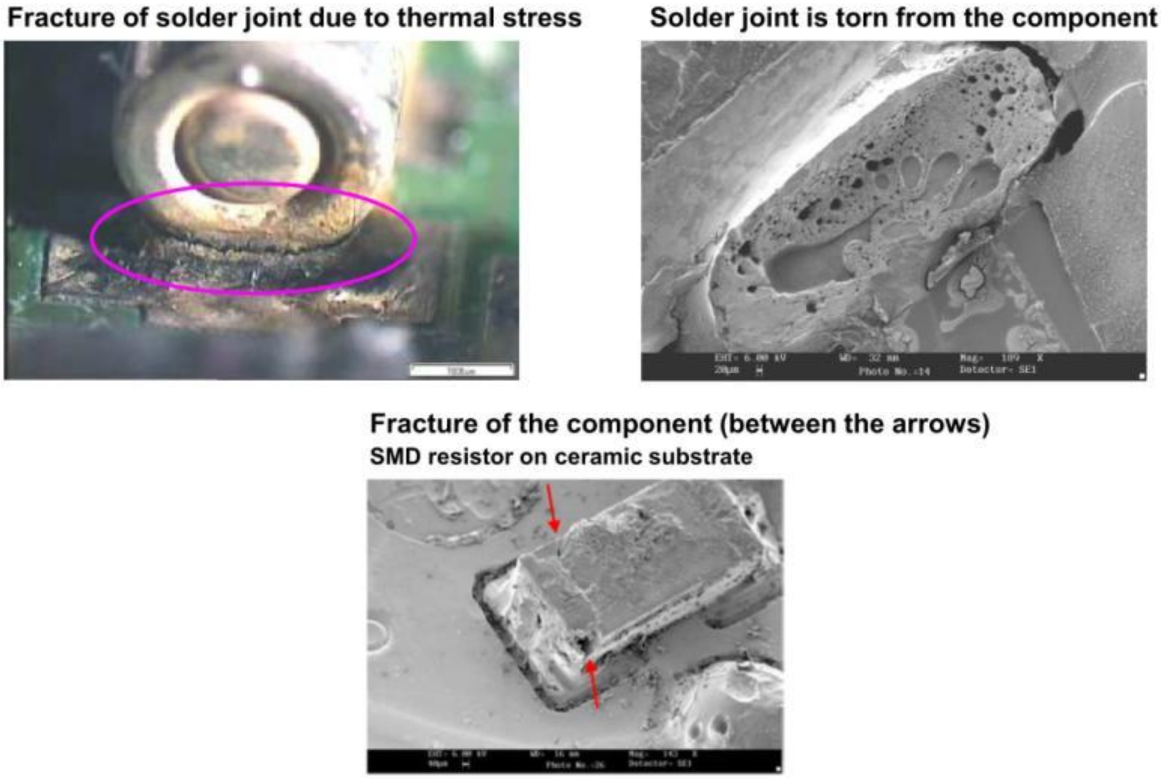
[147] STIHL (2012c), Andreas STIHL AG & Co KG, document "RoHS_II_exemption_request_ignition_modules_for_publication_2012_10_30.pdf" submitted for the online stakeholder consultation, retrieved from

Figure 8-3: Typical failures observed in ignition modules



Source: (STIHL 2012c)

Over the last years, STIHL[148] considerably invested in R&D efforts to include new electronic functions for the reduction of exhaust emissions in the ignition module and minimize the failure rate at the same time. STIHL has now reached a failure rate that allows the ignition module to have the same life-time as the product. These effects currently can only be achieved using lead solder in the ignition modules.

STIHL[149] categorizes all of the products as category 11 (other EEE, not covered by categories 1-10,[150], or alternatively as newly included in category 6 (electrical and

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http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_14/RoHS_II_exemption_request_ignition_modules_for_publication_2012_10_30.pdf; last accessed 8 February 2013

[148] Op. cit. STIHL (2012a)

[149] Op. cit. STIHL (2012c)

[150] According to Annex I of Directive 2011/65/EU (RoHS 2) RoHS Directive (2011) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:

electronic tools[151]) through the changed scope of the RoHS Directive. STIHL[152] states that in any case the products would have to fulfil the substance restrictions from July 2019 on.

8.1.2 Amount of Lead Used under the Requested Exemption

STIHL[153] does not have data for the worldwide sales of hand-held garden equipment, but claims that the amount of lead put on the market outside of the EU is not likely to be affected by the requested exemption. According to (STIHL 2012 a), an ignition module contains around 0.75 g of lead.

Based on BIOIS,[154] STIHL[155] estimates the amount of lead put on the EU market as follows:

- Annual sales in EU 15 in 2005 for non-professional hand-held domestic combustion-engine powered garden equipment (without lawn mowers and riding mowers):
  2,101,230 units

  Correction for market share and EU 27 (with the same factor used in (BIOIS 2012 a)):
  2,101,230 units * 1.53 = 3,209,000 units
- Estimated total of lead in ignition modules:
  3,209,000 units * 0.75 g/unit = 2.4 t

The total annual amount of lead put on the European market due to this exemption would thus be around 2.4 t.

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[151] According to Annex I of Directive 2011/65/EU (RoHS 2) RoHS Directive (2011) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:

[152] Op. cit. STIHL (2012c)

[153] Op. cit. STIHL (2013a)

[154] BIO (2012), Bio Intelligence Service, Document submitted via e-mail by Mrs. Christina Wedel, STIHL, to Otmar Deubzer on 25 February 2013; section from the report “Measures to be implemented and additional impact assessment with regard to scope changes, pursuant to the new RoHS Directive” prepared by BIO Intelligence Service for the European Commission, DG ENV, published on 6 July 2012, retrieved from

[155] Op. cit. STIHL (2013a)

8.2 Applicant's Justification of the Exemption

8.2.1 Substitution of Lead

8.2.1.1 Technical Constraints

According to STIHL,[156] solutions for lead-free soldering exist on the market, but today not all electronic components used in the ignition module are available in a version that is suitable for lead-free soldering. In addition to that, extensive field testing and optimization cycles are needed before the alternative can be used in the market.

STIHL[157] explains that the ignition module for small spark ignition engines has to withstand high vibrations (> 80 g) and must operate reliably in the temperature range of cold weather conditions up to the operating temperature of the engine (-30 °C to +110 °C). The solder joints have to be suited for a high number of temperature cycles between ambient temperature and operating temperature. Research on the ignition module allowed reducing exhaust emissions and failure rates using lead-solders. The ignition module now has the same life-time as the product.

STIHL[158] has no reliable data on the use of lead-free solder in ignition modules for small engines. As the products have an average life-time of over 10 years on the market, this poses a high risk for a decrease of durability. Lead-free solders differ from the solder used today in process temperature (20 °C higher), porosity and adhesion on the component. The overall effect poses a high risk for a decrease of durability.

STIHL[159] needs a comprehensive study and field testing to minimize this risk. STIHL[160] puts forward that some components appropriate for lead-free soldering are only available in sizes different from those used nowadays in the lead-soldered ignition modules. Therefore, the switch to lead-free soldered ignition modules requires a complete redesign of the printed circuit board, which requires additional time. Only if lead-free modules prove to have a comparable life-time as today's lead-containing modules, is a change for all modules feasible. Failing modules would have to be replaced more often during the life time of the product. Therefore, more waste is produced, which is difficult to recycle because of the necessary sealing with epoxy resin.

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[156] Op. cit. STIHL (2012a)

[157] Op. cit. STIHL (2012a)

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

[159] Op. cit. STIHL (2012a)

[160] Op. cit. STIHL (2013a)

*Sections 8.1 through 8.2 are heavily based on information provided by the applicant and other stakeholders. Alterations have been made mainly to ensure comprehension and to avoid repetition.

8.2.1.2 Supply Chain Constraints

STIHL[161,162,163] argues that its suppliers of ignition modules have little experience and no equipment for lead-free solders. Most other customers of these suppliers do not demand lead-free soldered parts. Considerable investment in production facilities is hence needed since a lot of equipment would have to be doubled, so that the suppliers can offer production lines for lead containing and for lead-free soldered products. A switch between lead-containing and lead-free solder on the same machine is economically not feasible.

STIHL[164] explains that, even though there are many other assembly service providers that have a lot of experience with lead-free soldering, a change of suppliers would create a lot of new problems. STIHL's suppliers are experts for ignition systems, and they are not only the manufacturers of the ignition modules, but also development partners for new technologies. Besides ignition modules for forest and garden equipment, they manufacture ignition modules and control electronics for products like snow mobiles, outboard engines for boats and auxiliary heating systems for cars, for which there is no legislation demanding lead-free solder for these products today.

8.2.2 Elimination of Lead

The applicant did not submit any information with its exemption request on possibilities to eliminate lead in this application.

8.2.3 Environmental and Socioeconomic Arguments

STIHL[165] says that lead-free ignition modules must prove to have a comparable life-time as today's lead-containing modules, as failing modules would have to be replaced more often during the life time of the product. Therefore, more waste is produced, which is difficult to recycle because of the necessary sealing with epoxy resin.

As mentioned in section 8.2.1 - Supply Chain Constraints, STIHL[166] argues that considerable investment shall be needed in production facilities, before suppliers of the ignition modules can provide lead free alternatives.

STIHL[167] assumes that most of the other manufacturers are not yet able or willing to invest time and money into the research of lead-free soldering for ignition modules, since they still see a chance of being taken out of scope in the 2014 review of the

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[161] Op. cit. STIHL (2012c)

[162] Op. cit. STIHL (2012a)

[163] Op. cit. STIHL (2013a)

[164] Op. cit. STIHL (2013a)

[165] Op. cit. STIHL (2012a)

[166] Op. cit. STIHL (2012c)

[167] Op. cit. STIHL (2013a)

scope of the RoHS Directive.[168] STIHL[169] puts forward that the smaller manufacturers most likely do not have the manpower to start working on the question right now. The clarification of the situation in the company and supply chain alone is a significant administrative burden. Manufacturers will probably start their research and application for exemptions after the review of the RoHS Directive.

8.2.4 Roadmap to Substitution or Elimination of Lead

8.2.4.1 Timing of the Exemption Request

STIHL[170] says that the equipment in the scope of the requested exemption would only come under the RoHS Directive in 2019. STIHL[171] explains that the RoHS Directive applies to "making available on the market" from July 2019 on. That means the complete supply chain would have to be changed to lead-free products. Since this definition includes also products in the rental business, these products would have to be replaced well before 2019, in order to serve their normal life time in rental business. This means that the products would have to comply with RoHS at least three years before July 2019.

8.2.4.2 Schedule to RoHS Compliance

In order for STIHL[172] to research proper alternatives that fulfil the customer expectations for product durability and prevent the unnecessary waste produced through premature product failure, at least one exemption period until 2025 is needed. For the investments needed in R&D and production, STIHL[173] needs the legal certainty of this exemption. Without the exemption, STIHL would need an immediate emergency plan to keep being able to deliver its products after July 2019. With the exemption STIHL[174] claims to be most likely able to manage a proper changeover until 2025.

Table 8-2 details STIHL's steps towards RoHS compliance.

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[168] Art. 24 of the RoHS Directive 2011/65/EU stipulates that "No later than 22 July 2014 [...] the Commission shall examine the need to amend the scope of the Directive [...] with respect to any additional exclusions [...]" from the scope of the RoHS Directive.

[169] STIHL 2013b STIHL (2013b), Andreas STIHL AG & Co KG, document "3rd-Questionnaire-Exe-req 14_2013_03_08.docx" submitted via e-mail by Mrs. Christina Wedel per Email, on 8 March 2013

[170] STIHL 2012b STIHL (2012b), Andreas STIHL AG & Co KG document "20121029_RoHS_Request_No_3_Clarification__Answers_GEHealth.pdf" submitted for the online stakeholder consultation, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_14/20121029_RoHS_Request_No_3_Clarification__Answers_GEHealth.pdf; last accessed 8 February 2013

[171] Op. cit. STIHL (2012c)

[172] Op. cit. STIHL (2012c)

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

[174] Op. cit. STIHL (2012c)

Table 8-2: Steps and timelines towards RoHS compliance

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

Source: STIHL (2013c)

STIHL[175] explains that if it starts right away and if there are no major technical complications, STIHL could change the whole product range to lead-free solders in 8 years. To account for reaction time and time for design changes, if failures occur in the field tests, an exemption until 2025 is needed. Until then the change to lead-free solder can be completed, if no major technical barriers are encountered. If the tests prove that major technical barriers exist, STIHL[176] predicts that an extension of the exemption will be necessary.

[175] Op. cit. STIHL (2013a)

[176] Op. cit. STIHL (2013a)

8.3 Critical Review

8.3.1 REACH Compliance - Relation to the REACH Regulation

This exemption request concerns lead in solders used in handheld equipment with combustion engines.

Entries 10, 11, and 12 of Annex XIV (for further details see Section 5.0 above) concern lead chromate, lead sulfochromate yellow and lead chromate molybdate sulphate red, respectively. These compounds can only be further used once a request for Authorization has been applied for and granted, concerning the application in which it should be allowed for use. As from the consultants' knowledge, these compounds are not in use as solder alloys, these entries have no further implications for this request.

Entries 16 and 17 in Annex XVII concern lead compounds applied in specific articles which are irrelevant in the context of this request for exemption (for further details see Section 5.0 above).

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

In the consultants' understanding, the restriction for substances under entry 30 of Annex XVII does not apply to the use of lead in this application. The application of lead in the ignition modules of handheld equipment placed on the market, in the consultants' point of view is not a supply of lead and its compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, entry 30 of Annex XVII would not apply.

No other entries, relevant for the use of lead in the requested exemption, were identified in Annex XIV and Annex XVII (status June 2013).

Various processes that may result in future restrictions of the use of lead are detailed in Section 5.0 above. In all these cases, it cannot yet be assumed if the processes shall result in a new restriction or in the addition of lead in certain compounds to the list of substances requiring an authorization. Therefore, at present these processes could not be assumed to have implications for this request for exemption in terms of ensuring the protection afforded by REACH.

As the intended restriction for lead and its compounds in consumer articles currently is not yet enacted, based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

8.3.2 Situation of RoHS Compliance in the Sector

No contributions were made from stakeholders during the online stakeholder consultations and therefore it has not been possible to identify whether this request for exemption is supported by other stakeholders. The applicant was therefore asked if the requested exemption was needed solely for STIHL products or if it is relevant for other manufacturers of hand-held machinery addressed in this request for exemption. STIHL[177] says that using lead-containing solder for ignition modules is the state of the art technology in this industry. STIHL claims Husqvarna, a competitor of STIHL, to face the same difficulties. Husqvarna[178] confirmed this information and supports STIHL's exemption request. According to STIHL,[179] STIHL and Husqvarna together have a market share of over 60% for chain saws in Europe.

Furthermore, according to STIHL[180], the products in the scope of this exemption request have at least 20 manufacturers, including the following main manufacturers: STIHL, Husqvarna, Honda, Makita/Dolmar, Solo, Shindaiwa, Eco/Kioritz, Ryobi, Komatsu/Zenoah, Hilti and Wacker Neuson.

STIHL was asked why only STIHL and Husqvarna support this exemption request. STIHL[181] assumes that most of the other manufacturers are not yet able or willing to invest time and money into the research of lead-free soldering for ignition modules, since they still see a chance of being taken out of scope in the 2014 review of the scope of the RoHS Directive.[182] According to STIHL,[183] these hopes are based on the ongoing discussion about which products are and will actually remain in the scope of the RoHS Directive. Article 2(4)(g) of the RoHS Directives excludes "non-road mobile machinery made available exclusively for professional use" from the scope of the RoHS Directive. Since STIHL[184] finds it difficult to draw a clear line between professional and non-professional products, STIHL[185] believes that manufacturers probably hope for a new wording in the review, which will exclude their own products from the scope.

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[177] Op. cit. STIHL (2013a)

[178] Husqvarna (2013a), Husqvarna Group, document „Husqvarna 2013 a.pdf" submitted by Dan Ericsson per Email on 20 February 2013

[179] Op. cit. STIHL (2013a)

[180] Op. cit. STIHL (2013b)

[181] Op. cit. STIHL (2013a)

[182] Art. 24 of the Directive 2011/65/EU (RoHS Directive) stipulates that "No later than 22 July 2014 [...] the Commission shall examine the need to amend the scope of the Directive [...] with respect to any additional exclusions [...]" from the scope of the RoHS Directive.

[183] Op. cit. STIHL (2013b)

[184] Op. cit. STIHL (2013b)

[185] Op. cit. STIHL (2013b)

Additionally, STIHL[186] puts forward that the smaller manufactures most likely do not have the manpower to start working on RoHS compliance. The clarification of the situation in the company and supply chain alone is a significant administrative burden. Manufacturers will probably start their research and application for exemptions after the review of the RoHS Directive.

STIHL was asked why it follows a different approach and applies for this exemption. STIHL[187] stated that it is possible for most parts in the STIHL product range – except the ignition module – to comply with the RoHS substance bans without significant trade-off to the technical performance. Therefore, an exemption for the remaining technical barrier (the lead-containing solder in the ignition module) seems to be a more realistic option than to hope for an exclusion from the scope and start too late with the testing of alternatives.

8.3.3 Technical Practicability of Lead Substitution and Elimination

Technically, it is plausible that ignition modules are exposed to harsh conditions, which require the ignition modules to be carefully designed in order to achieve sufficient reliability. STIHL claims that its ignition modules' lifetime in has been extended in recent years to match the lifetimes of the combustion engine handheld products they are built in.

Lead-free soldered ignition modules are expected to achieve a comparable lifetime and reliability as the lead-soldered ones, in order to be considered sufficiently reliable, as otherwise the combustion engine products' lifetime either becomes shorter or they must be repaired, exchanging the ignition modules for new ones which may lead to greater waste.

STIHL does not claim that the substitution of lead in ignition modules is in principle scientifically and technically impracticable, but it claims that it would require seven to eight years to achieve a sufficiently reliable lead-free soldering solution for the ignition modules. As until 2011, combustion engines with ignition modules were not in the scope of the RoHS Directive, lead-free soldered ignition modules have not been state of the art, and like any other part of an EEE, it is plausible that a changeover to lead-free soldering requires research and technical development.

STIHL was also asked whether alternative interconnection technologies like conductive adhesives or others may facilitate eliminating the use of lead in ignition modules. STIHL[188] answered that no alternative interconnection technology could be identified besides soldering, which is able to withstand the vibrations (> 80 g) and temperature changes (-30 °C ... + 110 °C) in the ignition modules over the life time of the products.

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[186] Op. cit. STIHL (2013b)

[187] Op. cit. STIHL (2013b)

[188] STIHL (2013c), Andreas STIHL AG & Co KG, document "4th-Questionnaire_Exe-req-14_2013_03_14.docx", submitted by Mrs. Christina Wedel per e-mail, on 18 March 2013

Article 5(1)(a) justifies an exemption if “the reliability of substitutes is not ensured”. Given the evidence presented in this case, an exemption granting time to ensure a reliable RoHS-compliant solution would therefore be justified under this criterion, but the duration of the exemption needs to be assessed.

8.3.4 Clarification of the Exemption Scope

8.3.4.1 Inclusion of “*Other Electronic Engine Controls*” into the Scope

The scope of STIHL’s wording proposal includes, besides the ignition modules, other electronic engine controls as well, mounted directly on or close to the cylinder of engines:

“Lead in solders for the ignition module and other electronic engine controls mounted directly on or close to the cylinder of hand-held engines”

In its justification, STIHL argues, however, only concerning ignition modules. It is therefore necessary to clarify what “other electronic engine controls” would be and why they should be included in the exemption as well.

According to STIHL[189], the ignition module also contains the engine management system controlling the fuel quantity for engines with the “STIHL M-Tronic” system. The M-Tronic technology uses an additional electronically controlled valve to regulate the fuel flow into the carburetor. STIHL[190] says that a conventional carburetor has to be adjusted manually by the user, the M-Tronic system and the low pressure injection both control automatically the air/fuel mixture ratio for the combustion. The advantage is that the machine always runs with the optimum air/fuel ratio. The machine is never in a too rich setting and therefore it uses less fuel and causes less exhaust emissions than a conventional carburetor. The M-Tronic system is not a standard technology, but nevertheless some other competitors use this or similar technologies as well, but under different names, e.g. AutoTune for Husqvarna.

Besides the M-Tronic engine management system and ignition module, STIHL[191] has a new product with a low pressure fuel injection system that uses additional components. STIHL[192] says that the low pressure injection is a STIHL technology, which optimizes the starting behavior and engine performance. STIHL[193] explains that a P/T sensor and an injection valve with a small circuit board are placed in the crankcase (see Figure 8-8 on page 88). This system has no carburettor because the fuel is injected into the crankcase. STIHL[194] explains that the P/T sensor measures

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[189] STIHL (2013e), Andreas STIHL AG & Co KG, document “6th-Questionnaire_Exe-req-14_2013_04_15.docx”, submitted via e-mail by Mrs. Christina Wedel per Email, on 25 April 2013

[190] STIHL (2013f), Andreas STIHL AG & Co KG, document “7th-Questionnaire_Exe-req-14_2013-05-08.docx”, submitted via e-mail by Mrs. Christina Wedel per Email, on 8 May 2013

[191] Op. cit. STIHL (2013e)

[192] Op. cit. STIHL (2013f)

[193] Op. cit. STIHL (2013e)

[194] Op. cit. STIHL (2013f)

pressure and temperature of the air in the crankcase. Here the fuel is injected and the mixture is then transferred into the combustion chamber. According to STIHL[195], the sensor is needed to determine the air efficiency at the engine operating point. As both the sensor and the injection valve need to operate in the crankcase, no other position more distant from the crankcase is possible.

Figure 8-4: Injection valve (left) and P/T sensor (STIHL 2013e)

With the term *"other electronic engine controls" in the proposed* exemption wording, STIHL[196] wants to make sure the exemption comprises the components for the M-Tronic system as well as the above injection valve and P/T sensor for the low pressure fuel injection system.

8.3.4.2 Proximity of Systems to the Cylinder

STIHL justifies the exemption request with the harsh environmental conditions – in particular temperature and vibrations - the ignition modules and other electronic engine controls are exposed to. The root cause for these harsh conditions is the components' proximity to the cylinder.

STIHL's proposed exemption wording only allows the use of lead in ignition modules and other electronic engine controls if they are *"mounted directly on or close to the cylinder"* of hand-held engines. This wording raises three questions:

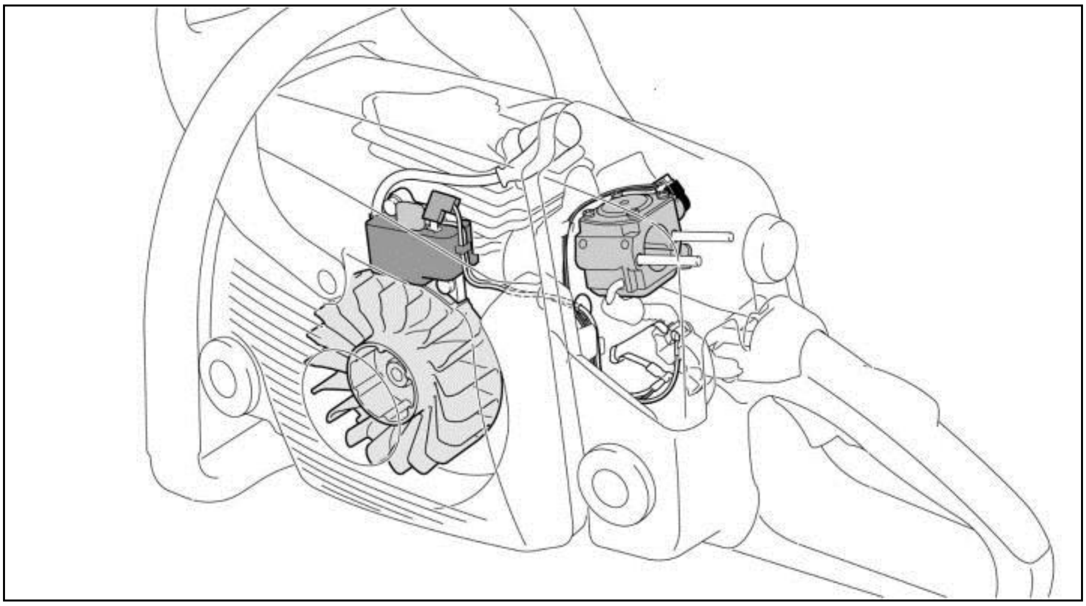
1. Why must the ignition modules and other electronic engine control systems be mounted directly on or close to the cylinder?
2. If the mounting of these components on or close to the cylinder is indispensable, why can vibrations and high temperatures not be mitigated with damping elements and insulators?
3. How exactly should "*close to*" the cylinder be interpreted in terms of distance from the cylinder?

[195] Op. cit. STIHL (2013e)

[196] Op. cit. STIHL (2013e)

STIHL provided the drawing in Figure 8-5 showing the position of the ignition module in a chain saw in order to make the subsequent explanations more comprehensible.

Figure 8-5: Position of the Ignition Module (dark grey left) and the Carburettor (grey right) in a Chain Saw

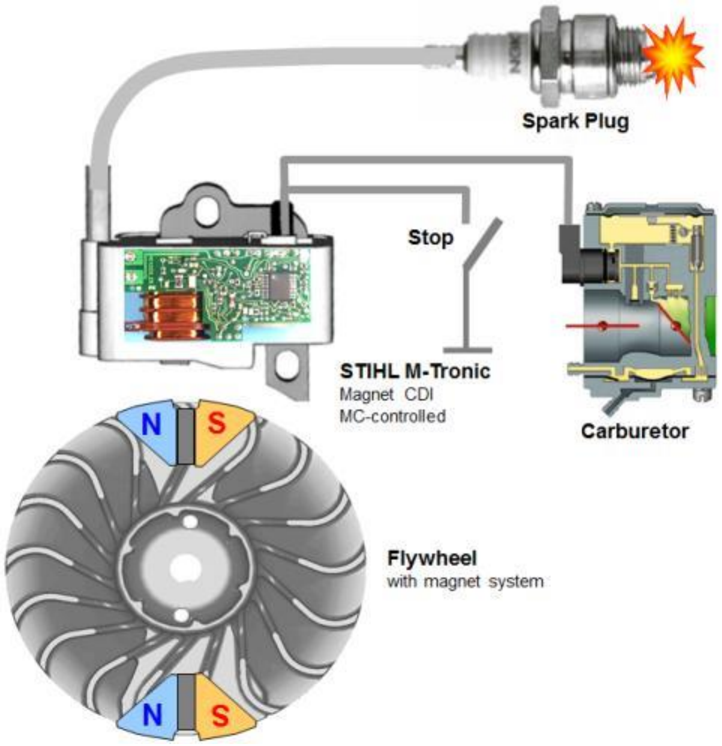


Source: (STIHL 2013e,f)

STIHL[197] explained that the electric current for the engine management system and the spark ignition is generated by induction from permanent magnets integrated in the flywheel as shown in Figure 8-6.

[197] Op. cit. STIHL (2013e)

Figure 8-6: Schematic drawing of the magnetic powered STIHL M-Tronic engine management system

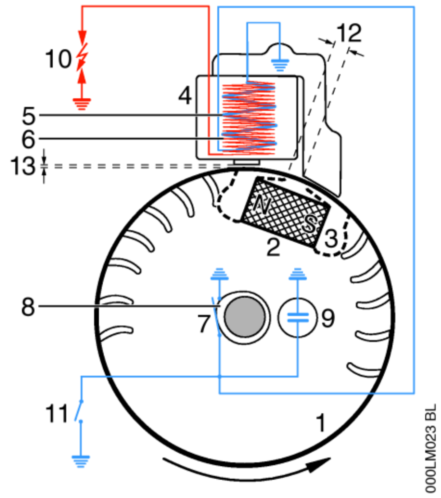


Source: (STIHL 2013e)

STIHL[198] puts forward that the size of the air gap between the permanent magnet and the ignition module is 0.15 to 0.45 mm depending on the model. Figure 8-7 illustrates the overall situation.

[198] Op. cit. STIHL (2013e)

Figure 8-7: Schematic drawing of an ignition system

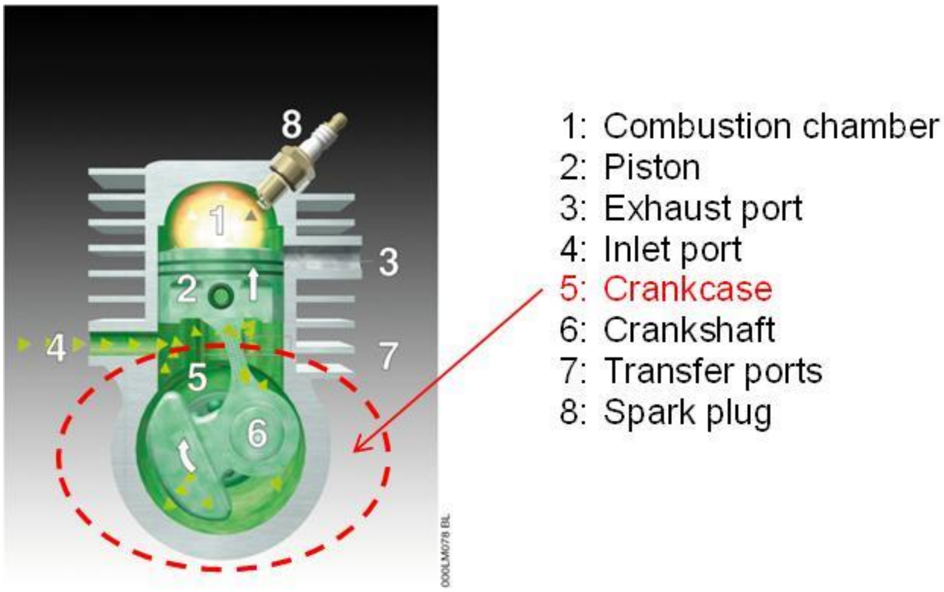


1 = Flywheel
2 = Permanent magnet
3 = Pole shoe
4 = Ignition coil
5 = Primary winding
6 = Secondary winding
7 = Breaker point
8 = Cam
9 = Condenser
10 = Spark plug
11 = Ignition switch
12 = Magneto edge gap
13 = Air gap

Source: (STIHL 2013e)

STIHL[199] says that this gap width is critical for the correct function of the ignition system. The ignition module therefore needs a stable, low distance fixation at the diameter of the flywheel. This is only achievable if mounted on the cylinder and the crankcase. The crankcase is part of the core engine block. It is the lower part of the engine block which houses the crankshaft as displayed in Figure 8-8.

Figure 8-8: Crankcase and cylinder



Source: (STIHL 2013e)

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199 Op. cit. STIHL (2013e)

As STIHL[200] plausibly explained, the ignition module needs the proximity to the flywheel to function properly. According to STIHL (2013f), this technology is the standard technology in this industry.

STIHL[201] states that the other electronic engine control systems need the proximity to the cylinder or the crankcase as well, because the electricity for their control and operation comes from the ignition unit, and/or these control systems can only provide their functions at the cylinder or the crankcase. On account of this, the electronic modules have to be connected directly to the engine block (crankcase and/or cylinder) to ensure a defined size of the air gap. According to STIHL,[202] vibration damping hence is not possible since it would enable relative movements of the module. Insulation rings are, however, used to reduce the temperature of the electronic module by about 15 °C, but the screws have to be fixed directly to the engine block.

8.3.4.3 Rewording of the Proposed Exemption

STIHL could show that the exemption is required for ignition modules and for other electronic engine control systems. In the proposed exemption wording, STIHL proposed to restrict the exemption to engine control systems "*mounted directly on or close to the cylinder"* of hand-held engines. The term "close to the cylinder" is too vague and hence needs to be clearly defined.

In consultation with the applicant, the following wording was elaborated and finally agreed upon with STIHL.[203]

> *Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH: 1, SH: 2, SH: 3 of 2002/88/EC)*

The reference to the direct mounting on the cylinder or crankcase clearly defines the location of the exempted engine control systems. The addition "which must be mounted" excludes that alternatives to the direct mounting on the cylinder or crankcase, the root cause of the harsh conditions hampering the shift to lead-free soldering. Though technical reasons are not specified for the enforcement of market surveillance, mentioning this term in the wording requires manufacturers to detail such reasons in technical specifications and data sheets of relevant products. In case

[200] Op. cit. STIHL (2013e)

[201] Op. cit. STIHL (2013e)

[202] Op. cit. STIHL (2013e)

[203] STIHL (2013g), Andreas STIHL AG & Co KG, document", submitted via e-mail by Mrs. Christina Wedel per Email, on 15 May 2013

of a control by competent authorities, this data is to prove that an alternative installation with less harsh environmental conditions is technically not viable.

8.3.5 Applicant's Roadmap to RoHS Compliance

8.3.5.1 Total Time Required to Achieve RoHS Compliance

STIHL claims seven to eight years' time to achieve the RoHS compliance of the ignition modules and presented the roadmap as detailed in Table 8-2 above. The applicant was asked how long it took STIHL to approximate the lead-soldered ignition module's life time to the product life time. STIHL[204] puts forward the example of a certain ignition module, for which it took five years and three improvement packages to lower the failure rate from 22% down to 0.1%.

The applicant was asked whether some of the supplier-related steps could not be shortened, or be conducted parallel to other steps in the roadmap. Even though suppliers of ignition modules are development partners as well, the pure assembly of the designed ignition module could be contracted to an assembly service provider which is experienced in working with lead-free solders and has a separate assembly line available for lead-free soldering. The roadmap indicates that it takes suppliers up to two years to invest and startup new equipment just for the production of a worst case product. It can be concluded from this that the investment as well as the time and related cost for this step must be considerable, and then the equipment would not be used for many months until the equipment can be used again in step 6 of the roadmap. In the consultant's understanding, such a procedure is economically questionable and supports the contracting of the lead-free assembly to an assembly service provider, at least in this early phase. Step 3 could thus be reduced to a few weeks.

STIHL[205] replied that this is not possible. The ignition modules have a compact and specialized design and integrate special coils onto the circuit board. Only for step 2, the production of samples for laboratory testing, it would be possible to use lead-free PCBs manufactured elsewhere (e.g. assembly service providers), which are then completed with prototype technologies. After that, STIHL would need to qualify the series processes and therefore needs to invest in the lead-free production equipment for the existing suppliers.

The consultants also proposed that step 6 can at least partially be done in parallel to step 5. Even though final results from step 5 might not yet be available, at least the planning of the new production line or facility can be prepared already. As the supplier has spent up to two years already in step 3, respective production equipment should at least in parts already be available. The consultants hence asked STIHL whether step 6 could not be reduced to around 6 months. STIHL (2013d) admitted that the planning could be done in parallel with step 5, but that it would have no large effect

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[204] STIHL (2013d), Andreas STIHL AG & Co KG, document "5th-Questionnaire_Exe-req-14_2013_03_21.docx", submitted via e-mail by Mrs. Christina Wedel to per Email, on 25 March 2013

[205] Op. cit. STIHL (2013d)

on the total time line. The long time needed in step 6 is due to the change-over phase for all products. To minimize the risk of premature failure of a wide range of products, STIHL claims to need this time to minimize this risk.

STIHL[206] therefore is confident to manage the change-over to lead-free soldering in the estimated time frame of 8 years. STIHL[207] says that it may be possible to reduce this time, but STIHL would need time to work out a detailed action plan together with its suppliers, that is shorter, but still limits the technical risk to an acceptable level.

The consultants assume that some time may be saved through the parallelization of some of the required activities. However, in any case, the maximum duration of an exemption from the RoHS Directive for categories 1-7, 10 and 11 is 5 years. As it can be followed that parallelization of activities would not shorten the time frame to a degree relevant for establishing the duration of a possible exemption, this aspect is not further discussed.

8.3.6 Starting Date of the Exemption Validity Period and Setting of the Expiry Date for the Exemption

STIHL requests the exemption until 2025. According to the Commission, the validity periods of exemptions related to equipment addressed by RoHS Art. 2(2) start running on 2 January 2013 at the earliest, or at the latest with their publication in the Official Journal of the European Union. The maximum validity period for exemptions used by EEE, other than categories 8 and 9 of RoHS Annex I, is five years. Even though it can be followed that up to eight years may be needed to guarantee RoHS compliance, the exemption can only be granted for a maximum of five years.

8.4 Recommendation Exemption Request 14

Based on the information submitted, the consultants recommend granting the requested exemption. Ignition modules and other electrical and electronic combustion engine control systems which have to be mounted close to the cylinder or crankcase are exposed to harsh environmental conditions. Possible alternatives need additional time to overcome reliability issues and to be worked in to design before RoHS compliant products can be made available on the market. It can thus be followed that achieving RoHS compliance of the products in the scope of this exemption request, with a degree of reliability comparable to the current status, justifies granting an exemption for five years in line with Art. 5(1)(a).

The consultants and the applicant agreed upon the following wording for the exemption to be added to Annex III of the RoHS Directive:

> *Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical*

[206] Op. cit. STIHL (2013d)

[207] Op. cit. STIHL (2013d)

and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH: 1, SH: 2, SH: 3 of 2002/88/EC)

8.5 References

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STIHL 2013a STIHL (2013a), Andreas STIHL AG & Co KG, document "2nd-Questionnaire-Exe-req 14_Answers_2013_02_25.docx" submitted via e-mail by Mrs. Christina Wedel per Email, on 25 February 2013

STIHL 2013b STIHL (2013b), Andreas STIHL AG & Co KG, document "3rd-Questionnaire-Exe-req 14_2013_03_08.docx" submitted via e-mail by Mrs. Christina Wedel per Email, on 8 March 2013

STIHL 2013c STIHL (2013c), Andreas STIHL AG & Co KG, document "4th-Questionnaire_Exe-req-14_2013_03_14.docx", submitted via e-mail by Mrs. Christina Wedel per Email, on 18 March 2013

STIHL 2013d STIHL (2013d), Andreas STIHL AG & Co KG, document "5th-Questionnaire_Exe-req-14_2013_03_21.docx", submitted via e-mail by Mrs. Christina Wedel to per Email, on 25 March 2013

STIHL 2013e STIHL (2013e), Andreas STIHL AG & Co KG, document "6th-Questionnaire_Exe-req-14_2013_04_15.docx", submitted via e-mail by Mrs. Christina Wedel per Email, on 25 April 2013

STIHL 2013f STIHL (2013f), Andreas STIHL AG & Co KG, document "7th-Questionnaire_Exe-req-14_2013-05-08.docx", submitted via e-mail by Mrs. Christina Wedel per Email, on 8 May 2013

STIHL 2013g STIHL (2013g), Andreas STIHL AG & Co KG, document", submitted via e-mail by Mrs. Christina Wedel per Email, on 15 May 2013

9.0 Request No. 15: "Hand Crafted Luminous Discharge Tubes (HLDT) Used for Signs, Decorative or General Lighting and Light-Artwork"

Abbreviations

ANIE	Italian Federation of Electrotechnical and Electronic Industries,
CCFL	Cold-cathode fluorescent lamps
CFL	Compact fluorescent lamps
ESF	European Sign Federation
HLDT	Hand crafted luminous discharge tubes
LED	light-emitting diode

9.1 Exemption Background

The European Sign Federation (ESF) has applied for an exemption[208] for:

> *"Hand crafted luminous discharge tubes (HLDT) used for signs, decorative or general lighting and light-artwork."*

This exemption is a reformulation of three requests, submitted in the past, and subsequently withdrawn in the fall of 2012, in light of similarities and of an effort to reformulate requests for three exemptions into a single one. The first of these requests was submitted in 2011 by ESF[209] (handled through the course of the RoHS 2 Project 1), and the other two requests[210],[211] were submitted at the beginning of

[208] ESF (2012a), Original exemption request no. 15, Submitted by European Sign Federation (ESF), October 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_15/RoHS_EX_Request_15_Mercury_in_Lamps_ESF_ANIE.pdf

[209] ESF (2011), Original exemption request no.19 (withdrawn), submitted by European Sign Federation (ESF) (RoHS 2 Project 1), September 2011 http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_19/19_STZ_COM_EU_571_check_list_for_exemption_Final_-_ESF.doc

[210] ANIE (2012a), Original exemption request no. 8 (withdrawn), submitted by ANIE Federation (RoHS exemptions, Pack 1); , February 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_8/ANIE_Exemption_Request8_Mercury_in_general_lighting_CCFL_2012-02-23.pdf

*Sections 9.1 through 9.4 are heavily based on information provided by the applicant and other stakeholders. Alterations have been made mainly to ensure comprehension and to avoid repetition.

2012 (handled in the course of the RoHS 2 Pack 1 Project) by ANIE Federazione - Italian Federation of Electrotechnical and Electronic Industries,

The cooperation of both organizations has resulted in the current request, and though it has officially been submitted by ESF, it is understood that both organizations - the European Sign Federation (ESF) and ANIE Federazione - Italian Federation of Electrotechnical and Electronic Industries (ANIE) - support this request. In light of the official aspects, ESF shall be named as the applicant throughout this report, however the cooperation and support of both organizations is noted.

9.2 Description of Requested Exemption

Sections 9.2 and 9.4 are heavily based on information provided by the applicant and other stakeholders and do not necessarily reflect the view of the consultants.

According to the applicant,[212] HLDTs exist in an extreme variety; some examples are neon signs (Figure 9-1), individual architectural illumination and special light emitters in the chemical analytical research. ESF believes that this exemption is absolutely necessary and justified due to the fact, that discharge lamps today need mercury for the generation of energy efficient light.

Figure 9-1: Example for a HLDT neon tube

Source: Author: Rolf Süssbrich Date: 10/2005 Own picture, Wikipedia Commons: *http://en.wikipedia.org/wiki/File:Neon_light.jpg*

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[211] ANIE (2012b), Original exemption request no. 9 (withdrawn), submitted by ANIE Federation (RoHS exemptions, Pack 1); February 2012; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_9/ANIE_exemption_request9_Mercury_in_luminous_signs_for_advertising_CCFL_2012-02-23.pdf

[212] Op. cit. ESF (2012a)

ESF[213] has formulated the following main arguments:

- There is almost no light output in HLDT without or with insufficient mercury in the lamp, hence a minimum small quantity of mercury needs to be added. As these HLDT are used for indoor and outdoor applications and with an individual colour spectrum composition, they have to work reliably under sensitive and cold conditions with very high life expectations because they are often difficult to access.
- The longevity of HLDT is closely related to its mercury content. HLDT can operate for up to 20 years which is equivalent to 130,000 hours without replacement, thereby outperforming any other light source in efficiency, life span and versatility regarding shape and light spectrum.
- HLDT are individually handcrafted products to which standardised requirements cannot be applied. They can thus not be considered to be classified as cold-cathode fluorescent lamps (CCFL) falling under existing exemption 3.
- The manufacturing of HLDT is labour intensive. It provides jobs to many individuals that completely depend on the production of this application for their livelihood. A denied exemption would mean that these manufacturers and other individuals related with the installation of such lamps would to some extent lose work and all HLDT manufacturing companies in Europe as well as some HLDT manufacturers overseas would need to close.

The applicant suggests covering the scope of indoor and outdoor applications for which the following wording formulations have been provided:[214]

Mercury, used in hand crafted luminous discharge tubes (HLDT) used for signs, decorative or general lighting and light-artwork:

- *For **outdoor applications and indoor applications** exposed to temperatures below 20°C; 20 mg mercury per pair of electrodes plus 15 mg mercury per 50 cm of tube length, but not exceeding 80 mg mercury per tube.*
- *For **indoor applications** exposed to temperatures above 20°C; 15 mg mercury per pair of electrodes plus 8 mg mercury per 50 cm of tube length, but not exceeding 80 mg mercury per tube.*

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213 Op. cit. ESF (2012a)

214 Op. cit. ESF (2012a)

9.3 Applicant's Justification for Exemption

ESF[215] indicates that HLDTs have a very large range of diameters from 4 to 25 mm and lengths of up to 3 m (in special cases up to 12 meters realized) and are available in a very large range of whites and colours. HLDT can be pre-formed to architectural shapes and provide readily dimmed, efficacious linear lamps.

Although all technologies used in mass produced CFLs or in CCFLs are equally used in HLDT, the exemption must be restricted only for HDLT and not for CFL or CCFL. This is because regular fluorescent lamps and CFLs usually use a hot cathode technology, based on thermal electron emission, while CCFLs and HLDT (colloquial: neon tubes) are based on a cold cathode which emits electrons by a process known as secondary emission. Additionally, HLDTs vary from one another in terms of custom shape; design; dimension; and colour/spectrum leaving no room for standardization.[216]

ESF[217] has stated that HLDT operates with high voltage and on the other hand, HLDT can also be made (if the parameters of design permit) to operate as a standard fluorescent lamp. This is a further reason why HLDT are no standard product and are exclusively made by hand.

As these HLDT are also used outdoors, they have to work reliably under severe and cold conditions with very high life expectations, because they are often difficult to access.[218]

The applicant makes a distinction between the required mercury content in relation to the lifetime of the lamp. The lifetime of HLDT could be up to 130,000 hours without replacement.[219]

The applicant[220] further claims explicitly that HLDT's are not consumer products, therefore, not handled by the consumer, but only by highly trained and skilled specialists regarding installation, maintenance, replacement and removal.

9.3.1 Use and Possible Reduction of Mercury

ESF[221] indicates that the use of mercury results in generating about 99.8% of the light output, through its UV-emission inside the discharge tubes, which are converted

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[215] ESF (2013a), Answers to further clarification questions, following the consultation, submitted by the applicant, European Sign Federation (ESF), April 2013

[216] ESF (2012b) Answers to first clarification questions no. 19 (withdrawn), submitted by the applicant, European Sign Federation (ESF), http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_19/HLDT-Ans_Questionnaire_Exe-19.pdf

[217] ESF (2012c) Further Information provided, submitted by the applicant, European Sign Federation (ESF) via e-mail, received 27 August 2012.

[218] Op. cit. ESF (2012a)

[219] Op. cit. ESF (2012a)

[220] Op. cit. ESF (2012a)

[221] Op. cit. ESF (2012a)

into visible light via fluorescent coatings. At low vapour pressures, no other atom or substance, besides mercury vapour, is known to have better efficiency in converting electrical energy into ultraviolet light.[222]

The lifetime of HDLT is closely related to the mercury content. In general, the operating conditions of HLDT vary so widely, that there must always be enough mercury or the HLDT will stop operating.[223]

The applicant[224] further states that a technical calculation of the mercury quantity required per lamp would not be applicable as a general limit, due to the wide field of application, as well as too many variables influencing the total amount of mercury. Only a broad testing, under all these complex conditions, can lead to the probability that a tube manufactured with similar parameters as the test tube would also work under all these conditions. Concerning HLDT – in contrast to mass produced lamps – neither systematic, nor scientific research of amount of mercury needed, has been carried out in the past or at present.[225]

The applicant has promoted several programmes to reduce the amount of mercury per HLDT in the last 10 years. This has helped to reduce the quantity of mercury per tube substantially, by approx.75%. A reduction of the quantity of mercury per tube for all HLDT manufacturers is impracticable at this point, due to the fact of the wide variety of operating conditions, and would seriously affect the lifespan of the tube.[226]

This would result in multiplying the energy consumption and effort required to make and install replacement lamps in order to cover the same total period of service.[227] Furthermore, HLDT with lower quantities of mercury per tube could only be used in stable temperature controlled environments at or above 20°C (indoor), ruling out the common application of HLDTs in- and outdoors and cancelling all advantages stated above.

However, the applicant explains that manufacturers are working together in the EU to minimize the total use of mercury for HLDTs down to the lowest practicable level.

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[222] Op. cit. ESF (2012c)

[223] Op. cit. ESF (2012c)

[224] Op. cit. ESF (2012a)

[225] Op. cit. ESF (2013a)

[226] Op. cit. ESF (2012a)

[227] Consultants Note: This regards the multiplication of resources needed for producing, installing, using and recycling multiple lamps. Assuming that the amount of mercury in HLDT lamps would be reduced, according to the applicant, the lifetime of lamps would consequently also decrease. In this case, an alternative for providing the required lighting over a parallel period of time, would be to use multiple lamps consecutively. The applicant refers in this sense to the multiple resources that this would require in comparison to the resources required for a single HLDT.

9.3.2 Possible Design Alternatives

ESF[228] admits that LEDs used for most signs now, are known to work well in outdoor environments, have a high efficiency and a very long lifetime. However, the applicant[229] claims that there are limited numbers with particular geometries for which there is no LED-technology-based alternative to their knowledge. The general distinction is that LEDs are point and directional light sources whereas HLDTs are linear and omnidirectional light sources.[230]

The colour spectrum is impossible to obtain with LEDs because LEDs are narrow-band emitters with fixed wavelengths. Thus, even by using three "RGB"-LEDs, not all colours could be generated. For "white" LEDs there is always a blue LED used in combination with yellow/orange fluorescent materials, resulting in a very intense blue radiation which cannot be reduced. In comparison, the colour spectrum of a HLDT can be individually adjusted by the manufacturer who usually mixes the fluorescent components according to the customer's request of colour and spectrum.[231]

Moreover LED's cannot operate in the high-temperature environment found in outdoor signs (especially enclosed rooftop installations facing south). Many signs that were converted from HLDT to LED failed and are still failing due to overheating of LEDs, causing premature breakdowns. ESF[232] explains that this can only be remedied by active air-conditioning of such sign bodies which is a waste of energy compared to simply using HLDT.

ESF claims[233] that there are applications were the sign needs to be invisible when turned off and also needs a high quality of illumination, linearity and consistency. Apart from HDLTs, no other commercially available lamp can achieve this.

9.3.3 Environmental Arguments

ESF[234] presents data about the quantity of mercury used per year by all European sold HLDT's. The total absolute maximum of mercury used in Europe per year for HLDT is 20 kilograms, which means less than 0.4% of the quantity of mercury sold per year in energy saving lamps.

ESF have submitted information concerning negative environmental, health and/or consumer safety impacts:

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[228] Op. cit. ESF (2013a)

[229] Op. cit. ESF (2012a)

[230] Op. cit. ESF (2012c)

[231] Op. Cit. ESF (2012b)

[232] Op. cit. ESF (2013a)

[233] Op. cit. ESF (2013a)

[234] ESF (2012d) Answers to first clarification questions no. 15, submitted by the applicant, European Sign Federation (ESF), November 2012
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_15/20121107_RoHS_Ex_Req_No_15_1st_Clarification_Questions_ESF_reply.pdf

- HDLTs are 100% recyclable[235] and have waste recycling programme provisions in place, through which mercury is recycled by specialized companies. If necessary, it can tap into recycling systems that already exist for regular fluorescents and CFLs at end of life because the raw materials are similar (glass, phosphor, mercury).[236]
- HLDTs are always handled and installed by experienced technicians. For this reason the risk of exposure to mercury by HLDT lamp breakage is practically non-existent.[237] Moreover the risk from making HLDT lamps has long been recognised and regular health checks, and good working practices (safety of workers) have been implemented for many years.[238]
- As mentioned above HLDT are offered in the widest range of colours and dimensions in order to correspond in the most efficient way to the needs of architectural design and visual communication. If the market would be forced to use a different light source, not linear and not perfectly adaptable, ESF[239] stated that this would lead to an increase in the usage of more polluting or less available materials, like arsenic, indium, antimony or gallium on the one hand and on the other hand plastics of various kinds, to imitate the look of linear light sources.
- As the physical qualities of the substitution (LEDs – consultants comments) cannot match those of rigid and continuous HLDT the imitation would require additional fixtures with e.g. aluminium profiles and insulated copper wires. In addition diffusers and filters required by these applications will decrease substantially the luminous efficiency of such alternatives, with negative impact in terms of global pollution. The lower life span of all other light sources and increased usage of plastic materials will lead to more frequent maintenance, with more polluting transports and waste generated.[240]

9.3.4 Road Map for Substitution

According to the applicant[241] there is continuous improvement concerning innovations for reducing the mercury consumption in HDLTs. A team of experts and scientists has committed to follow up and evaluate technological development and field experience with the aim to comply with lower limits of indoor and outdoor applications in increments until 2018.

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[235] Op. cit. ESF (2012a)

[236] Op. cit. ESF (2013a)

[237] Op. cit. ESF (2012a)

[238] Op. cit. ESF (2012b)

[239] Op. cit. ESF (2012a)

[240] Op. cit. ESF (2012a)

[241] Op. cit. ESF (2012a)

- For outdoor applications and indoor applications exposed to temperatures below 20°C, 10 mg mercury per pair of electrodes plus 7 mg mercury per 50 cm of tube length.[242]
- For Indoor applications exposed to temperatures above 20°C; 8 mg mercury per pair of electrodes plus 6 mg mercury per 50 cm of tube length,

In general ESF[243] indicates that in the field of HLDT, practically all developments are propriety and often protected by patents. Therefore, it is practically impossible to foresee today what future developments are expected. Even if a new patent has been applied for recently, it could be that the presented technology is applicable only in a few cases and not for HLDT in general.

On the European Level ESF[244] are looking into introducing the EQN (Eco Quality Neon) Label[245] to minimize the total use of mercury for HLDT's down to the lowest practicable level and to maximize the life expectancy of HLDT's, thereby saving energy and reducing the cost of ownership

9.4 Stakeholder Contributions

This exemption request is complex, as it includes different lines and levels of technical argument. Additionally, several stakeholders were involved in the consultation and the exemption review process, expressing diverging standpoints.

CCLA[246] fully supports the applicant's request and their supporting documentation. CCLA emphasise the substantial lifetime benefits of HLDT and the need for an adequate quantity of mercury to support the regarded long lifetime. Moreover, there is no known substitute for mercury in fluorescent lamps such as HLDT. According to CCLA[247] LED is a point source. HLDT are linear (but not necessarily straight) sources.

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242 Reviewers Note: No upper limit for the mercury contents per tube was given.

243 Op. cit. ESF (2012d)

244 ESF (2012e) Applicant document submitted by European Sign Federation (ESF), on 19 March 2013 within the consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_19/ESF_contribution_request_19_submitted_19032012.pdf

245 According to ESF (2012e), The EQN (Eco Quality Neon) Label was created by the Belgian Sign Organization (BSO) for HLDT glasshops. EQN has been enthusiastically adopted by the majority of glasshops in Belgium, others have applied for certification. The EQN system is expanding into other European countries.

246 CCLA (2013a) Stakeholder document submitted by Cold Cathode Lighting Association (CCLA) on 05 February 2013 within the consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_15/20130128_CCLA_SHC-Contribution_5f576d6755_4__Q_A_HLDT_Feb_2013.pdf

247 Op. Cit. CCLA (2012a)

To convert the LED source to emulate linear sources requires the use of complex (expensive) plastic lenses and plastic diffusers which substantially reduce the overall efficacy (in Lumen per Watt) of LED systems.

The European Lamp Companies Federation[248] (ELC) [249] does not agree with the scope of the exemption as proposed by the applicant. ELC proposes a definition without the term general lighting, however, including the word "architectural lighting":

> *"Mercury in hand crafted, cold cathode fluorescent lamps used for signs, decorative or architectural lighting and light-artwork"*

According to ELC "general lighting" would create a loophole whereby hand-made cold cathode fluorescent lamps with extremely high mercury content in general lighting applications would be exempt. The requested mercury levels are well above those that mass produced CFLs may contain in the EU and in many other countries and regions.[250]

Moreover ELC believes that the term outdoor and indoor is not necessary, and just creates legal confusion, when it comes to market surveillance. The necessary mercury content depends on the temperature of the operational environment, and not on the physical location:[251]

> *"These lamps might be used from Sweden to Cyprus, where inside and outside temperature means something else."*

ELC further suggest adding a labelling requirement for lamps, which are expressly designated as a cold temperature, hand crafted, cold cathode fluorescent lamp. Labelling should be placed on the lamp and labelling information should be made available in marketing materials, including but not limited to catalogues, sales literature, and promotional material.[252]

NP Lighting[253], [254] submitted a couple of technical descriptions of the mercury quantity in relation to lamp dimensions and further effects of mercury "consumption" during operation.

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[248] Note: The Federation includes leading European lamp manufacturers; however, ELC members do not manufacture HDLTs.

[249] ELC (2013) Stakeholder document submitted by European Lamp Companies Federation (ELC) on 01 February 2013 within the consultation http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_15/20130201_ELC_contribution_RoHS_Ex_Re_15_HTLD_final.pdf

[250] Op. Cit. ELC (2013)

[251] Op. Cit. ELC (2013)

[252] Op. Cit. ELC (2013)

[253] NP Lighting (2013a) Stakeholder document - Die Menge macht's - submitted by NP Lighting (Holding) GmbH on 01 February 2013

[254] NP Lighting (2013b) Stakeholder document - Wie viel Quecksilber braucht ein Neonrohr in der Lichtwerbung?- submitted by NP Lighting (Holding) GmbH on 01 February 2013

The European Environmental Bureau (EEB) and Green Purchasing Institute (GPI) strongly[255] oppose the proposed exemption request as presented since the need for it has not been demonstrated and if adopted would encourage the production of inherently high-toxicity illuminated lamps and signs, while safer alternatives are readily available, practical, and beneficial for users, workers and the environment. The two major reasons named by EEB and GPI are that the exemption request firstly sets mercury limits that are far too high in comparison with standard CCFLs used for these applications; and secondly the limits are not justified for high-mercury HLDTs (such as those used to make traditional illuminating signs) because this out-of-fashion, highly energy-inefficient technology can be readily replaced by both LEDs and CCFLs, which are already beginning to dominate the market.

Moreover EEB and GPI urge the Commission to carefully scrutinize this exemption due to the fact that it seems that it will create a loophole and go against the intention of the RoHS directive and the EU Mercury strategy of reducing, and where feasible, eliminating mercury use where adequate mercury-free alternatives are available.[256]

CCLA submitted two further documents[257],[258] which refer to the stakeholder contributions submitted by ELC and EEB & GPI.

CCLA welcomes the submission from ELC even though they do not represent HLDT lamp manufacturers. On the other hand, CCLA claims that the contribution made by EEB and GPI is prejudiced, not always correct and often referring to other lamp types for comparison purposes, for example comparing LED lighting with mass market fluorescent lamps, which is not relevant to the application.

Below there are some key aspects extracted from the EEB & GPI and CCLA contributions.

- CCLA agrees with EEB & GPI that many signs already use LED technology. Some estimates regard the replacement rate of HLDT with LED in signs as high as 90%. However, LED technology is not applicable in all signs and HLDT are also used in decorative or general lighting and light-artwork. HLDT includes CCFLs with larger diameters and lengths (but not those used to backlight laptops and displays). In addition the HLDT manufacturers are highly regulated and have robust recycling policies. This is often not the case for other mercury content lamp sources (such as CFL).

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[255] EEP and GPI (2013) Stakeholder document submitted by European Environmental Bureau and the Green Purchasing Institute on 02 February 2013 within the consultation http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_15/20130202_EEB_GPI_contribution_RoHS_consult_exempt_15.pdf

[256] Op. Cit. EEP and GPI (2013)

[257] CCLA (2013b) Stakeholder document - CCLA comments on ELC submissions -submitted by Cold Cathode Lighting Association (CCLA) on 05 February 2013 within the consultation;

[258] CCLA (2013c) Stakeholder document - CCLA comments on EEB/GPI SUBMISSION.-submitted by Cold Cathode Lighting Association (CCLA) on 05 February 2013 within the consultation;

- EEB & GPI claims that decorative and advertising signs (for indoor and outdoor applications) can be made using LED flexible light strips. CCLA replies to this that LEDs may be more efficient in themselves, but when incorporated in "LED flexible light strips" the efficacy is reduced to very low levels due to the lensing and diffusion required. Unfortunately it is difficult to substantiate this without considerable experiments as the LED light strip manufacturers do not publish independently determined efficacies. Further, at end of life, the LED flexible light strips are not readily recycled, incorporating various plastics, printed circuits, wires and LEDs.
- EEB & GPI explain that cold-cathode fluorescent lamps (CCFLs) used in signs, artwork and general lighting applications could also be seen as another practical alternative to high-mercury HLDTs. CCLA oppose this view because, CCFLs are mass market and mass produced miniature lamps used principally for back lighting applications, whereas HLDTs are hand crafted for bespoke applications and are typically 10 times the diameter and length.

9.5 Critical Review

9.5.1 REACH Compliance - Relation to the REACH Regulation

Section 5.0 in this report lists restrictions stipulated in the REACH Regulation, for the use of mercury in certain applications; inter alia items 18 and 18a of the REACH regulation Annex XVII state that mercury shall not be placed on the market when used as an anti-fouling agent or when used in measuring devices (such as manometers, barometers, sphygmomanometers, and thermometers other than fever thermometers).

As Category 9 products, for which this exemption has been requested, are not considered to fall under the scope of applications mentioned in entry 18 and 18a, the use of mercury in question is understood not to be subject to any restrictions by REACH.

The consultants assume that in case an exemption is granted, the use of mercury in this application would not weaken the environmental protection afforded by the REACH Regulation.

An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

9.5.2 Scientific and Technical Practicability

As with other mercury based lamps, the consultant can follow HLDTs need a sufficient amount of mercury, to function properly. In this sense the two main issues that need to be clarified before an exemption could be recommended for this request regard:

- Defining the scope of use of HLDTs – dealing also with the possibilities of substitution; and
- Establishing the amount of mercury required for proper function in cases where HLDTs cannot be replaced.

Concerning the question of scope, the consultant would first like to note that some applications of HLDTs are assumed to fall beyond the scope of the RoHS Directive:

- The RoHS Directive applies to EEE "designed for use with a voltage rating not exceeding 1000 volts AC or 1500 volts DC. As the applicant has pointed out that HLDT operates with high voltage and on the other hand, HLDT can also be made (if the parameters of design permit) to operate as a standard fluorescent lamp, [259] the consultant understands that some lamps would fall under the scope of RoHS and others without. It is further supported that some installations operate above the specified voltage, as in the original application (Project 1, Ex. 19 - withdrawn) the applicant refers to HLDTS" *in fixed or portable installations as per definition in EN50107-1(2002) "1 Scope" and in prHD60364-7-719 number 719-1"*.[260] Standard EN50107-1 is relevant for

[259] Op. cit. ESF (2012c)

[260] Op. cit. ESF (2011a)

"installations operating from a no-load rated output voltage exceeding 1 000 V but not exceeding 10 000 V".

- Furthermore Article 2(4)(e) excludes *"Large Scale Installations" (LSFI) from the Directive. LSFI are defined (Article 3(4)) as "a large-scale combination of several types of apparatus and, where applicable, other devices, which are assembled and installed by professionals, intended to be used permanently in a pre-defined and dedicated location, and de-installed by professionals;* from the information provided by the applicant it can be understood that indeed HLDTs are installed and de-installed by professionals, and as they are custom made for specific purposes, it is also understood that they are intended for use in pre-defined and dedicated locations. However the question remains as to how large an installation must be, to qualify as LSFI, and it is assumed that some HLDT may fall under this scope and some without. Furthermore, though it is clear that HLDTs operate within an installation that must be assembled, often with multiple tubes and fixtures, it is here too unclear what degree of complexity would suffice to fall under the LSFI definition.

In this context the applicant[261] provided some information:

> *"The HLDT is a discharge lamp that can be connected in series to match a high initial voltage. Immediately after the starting of a tube the voltage is reduced to keep the current constant near a preset value between 25 and 100 mA. This current limiting is done with a ballast function, integrated in the supply unit which can be a traditional shunted transformer or an electronic converter with a similar ballast function. Hence it is correct to say that in all cases HLDT are connected to special power supply units which in their term are connected to the grid. The output voltage of that special power supply unit can be low voltage (e.g. 990V) or up to 10 kV"*

In this sense, though it remains unclear what portion of HLDT would fall under the EEE definition, it is clarified that some would be required to comply with the RoHS substance restrictions where as some would not.

It thus remains unclear, which HLDT applications fall out of the scope of the RoHS Directive, therefore not needing an exemption. However, it can also be understood that in some cases HLDT installations will not conform to the above definitions, meaning that the RoHS restrictions apply and thus that an exemption would be needed to allow for the further use of mercury for products placed on the EU market. It therefore must be clarified in what cases possible substitutions can be applied.

From the information provided by the applicant and other stakeholders, it is clear that in general two forms of substitution would be possible.

The more relevant form regards **LED applications**, for which information has been submitted addressing the relevant issues for such substitution. These are reviewed below.

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[261] ESF, (2013b), further information provided by the applicant concenring Exemption request 15, submitted per Email on 7.8.2013.

Additionally, it is clear that in some cases **mass-produced neon tubes** could be used for some of the applications for which HLDTs can be used. In this context, however it is clear that mass-production is relevant only for specific dimensions and forms as well as for a limited amount of colours and for shorter service-lives. In the consultants' opinion, this form of substitution is thus relevant only for a limited amount of cases, for which the economic incentive would probably lead to substitution where possible, as mass-production items are generally cheaper than hand-crafted items, As this form of substitution is assumed to have a negligible contribution to the limitation of the scope of applications for which an exemption is needed, it is not further discussed.

As for LEDs, the applicant as well as CCLA, admit that they are already in use as substitutes for some HLDT applications. CCLA[262] states that some estimates "put the replacement of HLDT in signs by LED at 90%". ESF[263] explains that though alternatives exist in the form of LED, they cannot be used for all geometries. It thus must further be understood in which cases LED can be used and in which they cannot.

Various arguments have been provided by the applicant and stakeholders regarding the practicability of substitution, but there was insufficient information provided to enable a clear demarcation of application areas for which substitutes are not available. The evidence provided included:

- Variation in geometries and forms: ESF[264] mentions that LEDs cannot be used for all geometries. Further explanation of this statement that would allow demarcating in what cases the LED substitutes fail in this concern has not been provided.
- ESF[265] states that a further complication is the basic difference in light distribution between LEDs and HLDTs; LEDs are generally point sources that can provide directional light. Where omni-directional and linear light distribution is needed, this can sometimes be achieved through the use of plastic lenses and diffusers that on the one hand require the use of additional materials and on the other hand lower the efficiency of the dispersed light. Though this logic can be followed, quantifiable information was not provided to allow a comparison in terms of the resources needed for similar application in terms of materials and energy.
- Regarding the colour spectrum that can be achieved with each technology, ESF[266] states that LEDs are narrow band emitters with fixed wavelengths with which not all colours can be obtained. No quantification is made in this

[262] Op. cit. CCLA (2013c)

[263] Op. cit. ESF (2012a)

[264] Op. cit. ESF (2012a)

[265] Op. cit. ESF (2012c)

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

respect and thus this statement can only be reviewed in terms of the aesthetic result. In this sense, it is understood that though LEDs can be designed in different colours, their colour range in terms of achieving various hues and tones is rather limited; e.g. LED could provide a certain shade of blue but not in all tones available with HLDT. This is understood as a product that is similar though not equivalent. Without a technical explanation why a certain tone is essential for the proper function of the lamp, it could only be evaluated as a matter of taste and fashion. As it has been established in past evaluations[267] that such matters would not justify an exemption, this argument is not further discussed.

- Another aspect raised by ESF[268] regards the temperature conditions under which an installation must operate reliably. The applicant claims for instance that as LEDs heat up during use, they require the application of air conditioning devices to prevent overheating, which may result in earlier failures, i.e., a shorter service life. This claim is verified in publications such as an article by Reitberger,[269] explaining that "*If the operating temperature Ts*[270] *of medium brightness LEDs is increased from 25 °C to about 85 °C, its average lifespan drops to a fifth of expected values – from about 50,000 to a mere 10,000 operating hours.*" However, this source also goes into the possibilities of mitigating overheating through proper design and manufacture: "*Outdoor... applications are especially subject to extreme changes in temperature and other ambient factors, which can lead to unpredictable effects in lighting. While the indispensable employment of cooling materials increases production costs, the careful choice of suitable heat management materials and the early reckoning in the device development process can minimise any additional costs.*" To demonstrate this, Reitberger gives heat measurements of an LED with and without the use of cooling elements and thermally conductive materials. While after 10 minutes the former heats up to 130 °C, the latter reaches a mere 43.3 °C. Though it can be assumed that heat mitigation is not always applied in LEDs, the consultant assumes that as lamps used for the applications mentioned in this exemption are not intended for standard consumer use, that the LED substitutes could also include

[267] See evaluation of Ex. Re. 5 under 2012 Project 2, Pack 1 in Gensch, C., Baron, Y., Blepp., Deubzer, O., Manhart, A. & Moch, K., (2013), Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance Restrictions in Electrical and Electronic Equipment (RoHS Directive), Final Report:http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/20130412_RoHS2_Evaluation_Proj2_Pack1_Ex_Requests_1-11_Final.pdf

[268] Op. cit. ESF (2013a)

[269] Reitberger, W. (2010), "LED Heat Management", Kunze Folien Gmbh, Available under: http://www.heatmanagement.com/local/media/news/wrmemanagement-bei-leds-7/photonik_intl_2010_040.pdf

[270] Ts – Operating Temperature at the soldering point – though the operation temperatures are relevant in the junction are, access for measuring tmperatures is difficult. The Ts is therefore used as a basis for an estimation of the difference tot he junction temperature.

heating mitigation. As a technical comparison was not provided by the applicant to prove otherwise, it is thus understood that through the mitigation of heating, additional energy consumption and service life shortening are not significant.

- The applicant mentions that LEDs are also not comparable in terms of service life, and indeed, as an example, the average service lives of various types of LED chains is only 50,000 hrs, as compared to the service life of HLDTs which, can be as high as 130,000 hrs. However 130,000 hrs is understood to regard the best case and not the average lifetime of manufactured HLDTs. Furthermore, without a detailed life cycle, it cannot be concluded how the lifetime aspect is to be compared with further aspects such as use of materials and energy consumption that are relevant for comparing the two alternatives. As it has been mentioned that LEDs are already used as a substitute, it is also not clear if such a justification is always relevant or only in certain cases.

In the consultants view, though it can be understood that LEDs do not provide an equivalent outcome, the fact that their use in signs is becoming prevalent deems them to be an acceptable alternative in many cases. Though the information provided suggests that there may be cases in which HLDT are indispensable, information has not been provided that gives credence to this argument, clarifying in what cases alternatives can be applied and in in what cases they cannot.

9.5.2.1 Mercury Content Limits

Though it remains vague, in what cases substitutes are in place and in what cases, HLDTs cannot be done without, a further question is what amount of mercury is indeed required for ensuring the proper functionality of HLDTs. Shown in Table 9-1, the applicant has provided a basic formula in the proposed exemption wording, as well as a general contents limitation of 80 mg per tube.

Table 9-1: Applicant Proposed Exemption Formulation

Mercury in hand crafted luminous discharge tubes (HLDT) used for signs, decorative or architectural and specialist lighting and light-artwork:	Where *EP* represents electrode pairs and *L* is tube length in cm the mercury content shall be limited as follows:
For outdoor applications and indoor applications exposed to temperatures below 20°C	$=20\text{ mg}/\,EP + 15\text{mg} * L/50 \leq 80\text{ mg}$
For Indoor applications exposed to temperatures above 20°C	$=15\text{ mg}/\,EP + 12\text{mg} * L/50 \leq 80\text{ mg}$

It should be noted that it is unclear from this formulation if the 80 mg limit is in any case allowed, or if it becomes relevant only once the result of the equation in Table 9-1 is above 80 mg. As the first option would render the result of the equation meaningless, the consultant assumes that the 80 mg limitation is meant as an upper cap for cases where the equation would result in an allowance higher than 80 mg, but this is not to say that 80 mg can be used in any case.

In the consultants view the calculation of the mercury quantity required per lamp for guaranteeing proper and reliable operation, could be made more transparent and easier to understand, through dimension categorizing or other kinds of categorizing. The information provided by the applicant points out that there are indeed a few factors that influence the amount of mercury needed for ensuring the proper function of an HLDT lamp. These include:

- The climate conditions of operation (inside, outside, variance in temperature etc.) – these have been integrated into the proposed formulation
- The service life for which the lamp is designed – the longer the service life, the more mercury shall be needed
- The dimensions of the tube – this regards the length of the tube as well as its diameter and complexity of form – of which only the dimension length plays a role in the formula proposed in the exemption formulation.

The applicant was asked, before the online consultation, whether the calculation of the mercury quantity per lamp tube lengths could be more transparent and comprehensible, to guarantee a proper and reliable operation for each lamp type. ESF[271] explains that the operating conditions of HLDT vary so widely, that a definition of the amount of mercury per tube length is not taken into account. According to the applicant, many other parameters are involved in the amount of mercury needed throughout the lifetime of the HLDT. In a further communication[272], though the applicant enables some categorisation according to indoor and outdoor performance and according to tube length, it is further stated that “Classification is not possible as HLDT is hand crafted and custom made!” The applicant did not provide results or protocols on research and development activities, nor was a detailed list of the mentioned parameters provided.

Concerning possible categorization the applicant[273] states that “*There are no fixed fixtures, dimensions or characteristics for HLDT and all should have long life. That is part of their uniqueness – a very large range of diameters, any length (up to about 300 cm, in special cases up to 12 meters realized), a very large range of whites and colors available which are not available from the standard LED. Further, standard straight fluorescent lamps cannot be bent into any shape and are not readily flashed, repeatedly. HLDT are custom built by definition (hand crafted) and many can be readily and repeatedly flashed any number of times without affecting lifetime.*”

To further justify why HLDT mercury limits should be higher than those available to other forms of neon tubes, the applicant has provided an example[274]:

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[271] Op. cit. ESF (2012b) and Op. cit. ESF (2013a)

[272] OP. cit. ESF (2013a)

[273] Op. cit. ESF (2013a)

[274] Op. cit. ESF (2013a)

*"Let us take the 3.5 mg in a 50 cm CCFL for backlighting displays and screens as a starting point. These lamps typically have an internal diameter of about 2.4 mm, and one 50 cm long has an internal surface area of about 37 cm^2. (Pi*0.24*50). Let us compare that to a typical HLDT for lighting. This might have an internal diameter of 18 mm and be 195 cm long. This has a surface area of 1100 cm^2. This is 30 times the surface area of the CCFL for backlighting. We might therefore expect it to need 30 times the mercury to counter the absorption during lamp life. 3.5 X 30 = 105 mg of mercury. And we have not talked about the mercury allowance for the much bigger electrodes and current. The 80 mg limit we ask for is therefore less per unit area of light source than that already allowed under RoHS in CCFL for backlighting."*

Though this example clearly demonstrates that the 80mg limit would be justified in this case, the applicant has explained that HLDTs can be produced with diameters from 4 to 25 mm. Using the same logic, a tube of 4mm diameter and 195 cm in length would have a surface area of 244 cm^2, which is about 6.6 times as big as the example CCFL, requiring 6.6*3.5=23 mg of mercury for proper function. Assuming this lamp was used outdoors, the proposed exemption formulation would allow 20mg for the electrode pair and an additional 15 mg*195/50 for the tube length, making up for 78.5 mg of mercury, which is almost 3 times as high as the amount needed based on the surface area and the CCFL comparison. In other words, though it is understood that additional factors may influence the amount of mercury needed, it seems that the proposed formulation still provides a rather general relation between the amount of mercury needed and the actual specifications of the tube in question.

The information submitted by the applicant and the stakeholders supports the fact that establishing the amount of mercury required for the reliable operation of HLDT lamps based on a simple formula is quite complex.

9.5.3 Environmental Arguments

The applicant as well as some stakeholders emphasize that in the last 10 years the industry has promoted several programmes to reduce the amount of mercury per HDLT. Based on technical progress and research, it has been possible to reduce the mercury contents from 300 mg to 80 mg per tube.

Due to the fact that HDLTs are far from being mass-market and thus, in total, small amounts of mercury are used at present (in comparison with the total amount consumed in the CFL industry), it may be understood that the subsequent environmental effects are not extensive in comparison. ESF claims that at the end of life, the HDLTs can be reused or recycled in recycling systems that are widespread and that have been in place for many years. That is to say, HDLTs is very likely to be recycled by professional recyclers using well controlled safe processes.

ESF present no environmental data and statements comparing the life cycles with potential alternatives such as LEDs or CCFLs suggested by EEB & GPI[275].

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[275] Op. cit. EEP and GPI (2013)

Though it is understood from other sources that LEDs contain various substances that introduce aspects such as toxicity, rareness of certain resources and possibly lower efficiency of recyclability, information was not available to allow a comprehensive comparison of these aspects where LED and HLDTs are concerned. From a general perspective, though as the applicant explains, various substances are used in the production of LEDs[276] that may have some toxicity aspects, from the provided information, none of these are RoHS substances. In this sense, a simple comparison of the toxicity aspects of each product is not straightforward.

Though the consultants can follow that in certain cases a justification may be relevant in light of higher negative impacts associated with LED substitutes, based on the available information, a line could not be drawn to understand when such impacts would justify an exemption and when not.

9.5.4 Socio-Economic Impacts

The applicant mentions in various correspondence, the consequences that are at stake concerning this request. *"The manufacturing of HLDT is labour intensive; it provides jobs to many individuals that completely depend on that product. Not obtaining an exemption would mean all these manufacturers and the related installation people would be pushed out of work and all HLDT manufacturing companies in Europe as well as some HLDT manufacturers overseas will need to close."*[277]

In a later communication[278] the applicant provided the following estimations to clarify how many individuals depended on HLDT for their livelihood:

> *"a. An average HLDT glass shop has 3 people in the production.*
> *Two of these do bending work (= shaping the glass tubes) only a third one does electrode fitting and processing.*
> *Processing takes 15mins per tube with traditional methods. So output of a glasshop is appr. 40 HLDT per day.*
> *Throughout Europe there are about 750 HLDT glass shops, in proportion some more in Eastern Europe than in Western Europe.*
> *That makes 2250 people doing nothing but producing HLDT, estimated output 30000 HLDT. (35% of these HLDT contain neon - or other- gas, only 65% contain argon gas with mercury.)*
>
> *b. In the companies supplying raw materials and components to these glass shops there are another 1200 people involved.*

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[276] For instance, arsenicum amalgam was named in the Original Request (ESF 2012a), Arsenic, Indium, Antimony, Gallium in the ESF (2011b) reference and the use of aluminium as a heat sink and of plastic for diffusers and lenses was addressed in ESF (2013)

[277] Op. cit. (2012a)

[278] ESF, (2013b), further information provided by the applicant concenring Exemption request 15, submitted per Email on 7.8.2013.

It is estimated that these people spend 25% of their working time on HLDT related items, as they also supply other things.
That makes 300 worker-units.

c. HLDT installation and servicing companies have an average of 6 people (there are companies with 300 workers but many more with 4 workers).
10% of the working time is related to HLDT, bringing the average to 0,6 worker-units per company working on HLDT only.
For Europe there are 500 worker-units related to HLDT only.

The total of the above is 2250+300+500= 3050 worker-units related to HLDT only."

Though socio-economic impacts can be regarded in the evaluation of a request for exemption from the RoHS Directive, they must be substantial to be regarded as an argument that may lead to a request's approval. The applicant has provided an estimate as to the amount of workers to be directly affected if HLDTs were to be removed completely from the market. This is the total number in the industry, and given that some HLDT applications fall outside the scope of RoHS and 35% of HLDT do not contain mercury anyway, it can be understood that the number of workers that would be affected by RoHS restrictions will be fewer than the 3050 stated. If operations were ceased due to lack of exemption under RoHS, though it may be argued that some of these workers may find alternatives to their current employment in the HLDT industry, it can be assumed that in any case HLDT craftsman would be affected to some degree. It thus remains to be verified by the EU COM what degree of social impacts would suffice to justify an exemption.

To properly assess this issue, a clear line would need to be drawn to establish what degree of HLDT fall under the definition of EEE and thus need to comply with the RoHS substance restrictions. Though this aspect has been reviewed (see section 9.5.2) it remains unclear how this definition of scope corresponds to the socio-economic effect of not granting an exemption on this industry.

In this context, if the impacts can be understood to be so severe as to destroy an industry, as claimed by ESF[279] (in this case the art of hand crafted luminous discharge tubes), then it could be perceived equivalent to a situation in which substitution is impractical in light of the grave results.

However, to argue along these lines would require that such impacts be quantified in detail, to explain why the disruption of an industry was anticipated. Though the applicant provides some information, it remains unclear if removal of this product from the market leads to the fall of an industry. Additionally information is lacking to clarify what proportion of products could be produced with less mercury. There is therefore at present no possibility to draw a line between a mercury limit that

[279] OP. cit. ESF (2011b): „*"The sign industry as well as the architectural linear lighting industry can only produce HLDT if the exemption is granted. The livelihood of several thousand people is at stake."*

corresponds with an acceptable degree of social cost, or indeed what the true social cost would be. Furthermore, the debate is not complete without consideration of the potential social and environmental benefits associated with substitution by LEDs in the market.

Though it can be followed that arguments around the disruption of the HLDT industry may indeed hold a certain degree of merit, without further detail the consultants cannot further address this point so as to conclude as to how this aspect could be reflected in the allowed mercury contents.

9.5.5 Scope and Wording

ELC[280] is concerned about the applicant's use of the term general lighting. *"Using this term in this exemption would create a loophole, a wide highway for hand-made CCLFs with extremely high mercury content in general lighting applications. The requested mercury levels are well above of those that mass produced CFLs and LFLs may contain in the EU and in many other countries and regions."* In the view of consultants, the HDLTs do not fall in the general lighting category. Therefore, the consultants agree that this expression should be deleted from the wording formulation.

ESF[281] have agreed to replacing the term "general" with "architectural and specialist".

ELC[282] also stated that the term outdoor and indoor should be deleted from the exemption so as to avoid legal confusion, when it comes to market surveillance. ELC also suggests that the threshold between the two mercury contents is solely conditioned according to the temperature of the intended operational environment and not according to the physical location

According to the consultant the ELC arguments regarding the wording "indoor" and "outdoor" can be followed. CCLA also confirmed that there is no need for the indoor/outdoor designations. On the other hand ESF[283] states on this aspect that "*Outdoor the effect of wind and rain can aggravate the negative effect caused by low temperature. Indoor there can be minor airflow from the air-con system but there won't be any moisture. It's the combined effect that makes outdoor applications more critical below 20 °C.*" As further information was not provided elaborating on this issue, the consultants can neither agree nor disagree on this point.

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[280] Op. Cit. ELC (2013)

[281] Op. cit. ESF (2013a)

[282] Op. Cit. ELC (2013a)

[283] Op. cit. ESF (2013a)

9.5.6 Conclusions

According to the information provided by the applicant the consultant can follow that each HLDT tube is, in contrast to CFLs and CCFLs, custom made, individually designed and made by hand. It can also be understood that HLDTs are handled throughout the whole lifecycle by professionals and not by consumers.

ESF[284] state that there is no "lamp type" which could be defined. However, information provided by the applicant as well as through personal communication with experts clarifies most HLDTs are produced in diameters ranging from 4 to 25 mm and in lengths of up to 3m.

In the consultants understanding, HDLTs often consist of curved tubes. Diameters and lengths vary a lot from case to case and categorization into groups that would allow referring mercury content per category is complex. Moreover, the lamps require sufficient mercury vapours for converting electrical energy into ultraviolet light mixed with rare gasses of the tube in order to operate up to 130,000 hours with a vast range of colours. However, the consultants were not provided evidence in the form of research reports or third party confirmed data in this concern, to clarify what mercury content is indeed required in various cases.

In the consultants view, the formula proposed by ESF makes a minimal distinction between lamps operating inside and outside (referring to a threshold[285] temperature of the use environment) and between lamps with various lengths. Assuming that all lamps are designed with a life time of 130,000 hrs, from the lack of reference to various diameters, as explained above, it can be followed that some lamps would be manufactured with more mercury than actually needed. The complexity of form may also play an important role here, however it is also clear that adding this to the exemption formulation would make market surveillance even more complicated to implement. The requested mercury content limitations aim to suffice for all HLDT lamps, irrespective of dimensions, colours, operation conditions or other variables, and could lead in some cases to more mercury being used than needed.

In the consultants view, though it can be understood that LEDs do not provide an equivalent outcome, the fact that their use in signs is becoming prevalent deems them to be an acceptable alternative in many cases. Although the case may still be debated as to whether there may be instances in which HLDTs are indispensable, information has not been provided that gives credence to this argument.
Recommendation

To begin with, as explained above, it is assumed that a part of the product range is excluded from the scope of RoHS, either through the LSFI exclusion or in light of the definition of EEE, excluding applications operating at higher voltages.

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[284] Op. Cit. ESF (2013a)

[285] Though the 20C temperature is specified as a threshold temperature of the environment in which the lamp operates, in light of the indoor/outdoor aspects, its relevance as an actual threshold for distinctions between applications is minimal.

The scientific and technical arguments for why LED technology is not equivalent to mercury containing HLDT technology, with regards technical functionality, can be followed to some degree. However, neither does this suffice to support that LEDs cannot be used as alternatives, nor does the provided information shed light on the degree of which LEDs are expected to have reliability issues or to entail negative impacts that outweigh the benefits associated with their use as a substitute.

As the products in question are already in scope, denying an exemption altogether at present would demand that all products be pulled out of circulation and production be discontinued. Though there may be some cases in which alternatives may not cover all required characteristics, or in which they are not beneficial in terms of environmental performance and reliability, the provided information does not clarify the scope of such cases.

Alas, the case has been presented by the ESF that the possible impact that not granting an exemption could have on the HLDT industry is of concern. Though a partial estimation of the number of individuals to be impacted has been made, it remains unclear what portion of HLDT installations need to comply with the RoHS substance restrictions and thus what portion of these individuals would indeed be affected. To add to that, the EU COM would need to verify that the amount of individuals estimated to be at risk would be considered as a substantial risk to the industry that would justify an exemption in light of the impracticability of substitution.

The RoHS Directive stipulates 3 main criteria for justifying an exemption, at least one of which must be 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."*

As for the first two criteria, though it can be followed from the provided information that in some cases substitutes may not be practical or may not be reliable, it is also understood that this does not cover the full range of HLDT products. As for the last aspect, impacts have not been quantified to allow comparing between HLDTs and possible substitutes (namely LEDs) in terms of environmental and health impacts.

That said the proposed mercury content limitation is still perceived as a general limitation. The information provided does not allow a quantitative understanding of the various factors requiring more or less mercury. It can be understood that the LED substitutes could potentially be applied to a significant portion of the product range. Therefore, without further establishing the scope of products for which substitutes are indeed not available or not reliable, etc., the consultant cannot recommend an exemption with the requested wording in line with the criteria stipulated in Article 5(1)(a).

It is, however, also understood that not granting an exemption will have some potential impact on the HLDT industry. Although information enables a partial estimation of the size of the industry, it remains unclear what proportion of this industry would be 'destroyed' should the exemption be denied; indeed an alternate outcome may be that the market would be stimulated to diversify and innovate. From the consultants' point of view, as information to allow a comprehensive evaluation of this aspect is not available, deciding on the future of an industry lies beyond the mandate of this evaluation process which is based on the Article 5(1) criteria.

According to Clause 18 of the Directive: "*Exemptions from the substitution requirement should be permitted if substitution is not possible from the scientific and technical point of view, taking specific account of the situation of SMEs…".* As the HLDT industry is understood to be a traditional and small scaled industry, the EU Commission may choose to take this aspect into consideration before reaching a final decision as to this request for exemption.

If the EU COM finds this aspect relevant in terms of rendering substitution as impractical, the wording proposed by the applicant (after agreeing to substitute "general" with "architectural and specialist") is as shown in Table 9-2 (note this is the same formulation as in Table 9-1).

Table 9-2: Potential Exemption Formulation

Mercury in hand crafted luminous discharge tubes (HLDT) used for signs, decorative or architectural and specialist lighting and light-artwork, where *EP* represents electrode pairs and *L* is tube length in cm the mercury content shall be limited as follows:	
a) For outdoor applications and indoor applications exposed to temperatures below 20°C	$=20$ mg/ EP $+15$mg* L $/50 \leq 80$ mg
b) For Indoor applications exposed to temperatures above 20°C	$=15$ mg/ EP $+12$mg* L $/50 \leq 80$ mg

As in the consultant opinion, the proposed formulation is not completely clear, an alternative is proposed that addresses the various limitations of mercury content established in the proposed formulation. This is shown in Table 9-3.

Table 9-3: Potential Exemption Formulation Following Revision

Mercury in hand crafted luminous discharge tubes (HLDT) used for signs, decorative or architectural and specialist lighting and light-artwork, where *EP* represents electrode pairs and *L* is tube length in cm the mercury content shall be limited as follows: $Mercury\ Content\ (mg) \leq \left\{ \begin{matrix} (\alpha \times EP) + \left(\frac{\beta \times L}{50}\right) \\ 80 \end{matrix} \right\}$	
a) For Indoor applications exposed to temperatures continuously above 20°C	$\alpha = 15$ $\beta = 12$
b) For all other applications	$\alpha = 20$ $\beta = 15$

It should be noted that additional factors could be worked into this wording, such as diameter and lifetime. However, in light of the information provided, the consultants can follow that each additional factor would add to the complexity of the formulation. This would also add to the complexity of market surveillance. A complex formulation also has more of a chance to be misunderstood and for the exemption to be misused. Most importantly, though adding additional factors may make the formulation more specific, from the various examples provided by the applicant and in light of the applications custom-made nature, it is also assumed that exceptions shall exist to every rule. In this sense, it is unclear if the gains from a more detailed formulation would balance out with the harm that may come in areas where the formulation prevents the use of HLDT applications, for which their substitutes are unsatisfactory.

9.5.7 References

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APPENDICES

A.1.0 Appendix 1: The Principle of Electrode Function and the Relation between Electrode Size and Accuracy

Source: JBCE (2013a) Further Information Provided by the Applicant Concenring Exemption Request No. 13 during the Stakeholder Consultation, on 01.02.2013; *http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VII/Request_13/20130201_Further_Information_JBCE_2nd_round_clarification_questions.pdf*

The importance of surface area can be understood from how the electrode functions and how conductivity values are deduced from measurements.
JBCE explain the following:

- Resistivity is equivalent to electrical resistance per unit area and unit length. The resistance between two electrodes R (Ω) is:

  $R = \rho_0 (L/A)$ ----------------- (1)

  Where ρ0 is the electrical resistivity, A (m^2) is the area, and L (m) is the length.

- Therefore, the electric conductivity (which is defined as the inverse of resistivity) K0 (S/m) is:

  $K0 = 1/\rho_0 = (1/R)(L/A)$ --------(2)

  When L/A is known, K0 can be obtained by measuring R (Ω) between electrodes.

- The cell constant C1 (/m) is given as equation (3):

  $C1 = L1/A1$ (/m) ---------------(3)

  Where A1 (m^2) is the Surface area of electrode and L1 (m) is the distance between electrodes.

- Therefore, the electric conductivity K0 (S/m) is given as equation (4):

  $K_0 = (1/R)\,C1$ -----------------(4)

- The polarisation impedance of capacitance at the surface boundary between electrode and solution is:

  $1/(2\pi fC)$ --------------------- (5)

  Measurement error occurs, when the polarization impedance is added to the resistance of the solution.

- For accurate measurements, 2πfC must be large (i.e., large surface area). In order to obtain the large 2πfC, both the accelerated frequency and the capacitance created between electrodes should be high. This can be achieved either by platinised platinum that can enlarge surface area of electrode for solution by approximately 1000 times the surface area of the flat electrode or by enlarging the surface area of the electrode itself. For example, if f=1 [kHz]

and C=10,000 [μF], the polarisation impedance is equal to
1/(2×3.14×1000×10-2) = ~ 0.02Ω

and the error is negligible.

- If platinized platinum is not used, the surface area of the electrode itself will need to be larger.