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 – Pack 4

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, Oeko-Institut and Fraunhofer IZM have taken due care in the preparation of this report to ensure that all facts and analysis presented are as accurate as possible within the scope of the project. However no guarantee is provided in respect of the information presented, and Eunomia Research & Consulting, Oeko-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 led to the repeal of Directive 2002/95/EC on 3 January 2013. The Directive can be considered to have provided for two regimes under which exemptions could be considered, RoHS 1 (the 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 Oeko-Institut with support from Fraunhofer 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(1));
- The former list of exemptions has been transformed in to Annex III and may be valid for all product categories according to the limitations listed in Article 5(2) of the Directive. Annex IV has been added and lists exemptions specific to categories 8 and 9;
- The RoHS 2 Directive includes the provision that applications for exemptions have to be made in accordance with Annex V. However, even if a number of points are already listed therein, Article 5(8) provides that a harmonised format, as well as comprehensive guidance – taking the situation of SMEs into account – shall be adopted by the Commission; and
- The procedure and criteria for the adaptation to scientific and technical progress have changed and now include some additional conditions and points to be considered. These are detailed below.

The new Directive details the various criteria for the adaptation of its Annexes to scientific and technical progress. Article 5(1) 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 Oeko-Institut and Fraunhofer IZM started 14 June 2013. The overall project has been led by Carl-Otto Gensch. At Fraunhofer IZM the contact person is Otmar Deubzer. The project team at Oeko-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 requests 2013-2 (for renewal of Ex. 39) and exemption request 2013-5 regard similar applications and have thus been evaluated together. Exemption request 2013-3 was withdrawn towards the end of the project period. 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 19 August 2013 and ran until 11 November 2013, covering the five requests.

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

Information concerning the consultation was provided on the project website, including a general guidance document, the applicant's documents for 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 on the EU CIRCABC website (Communication and Information Resource Centre for Administrations, Businesses and Citizens)[1].

The evaluation of the stakeholder contributions led to further consultation including, *inter alia*, engaging with stakeholders in further discussion, further exchanges in order to clarify remaining questions, cross-checking with regard to the accuracy of technical arguments, and checks in respect of confidentiality issues. A targeted stakeholder meeting was held for exemption requests 2013-2 and 2013-5 to assist in understanding the similarities of the applications and the possibilities to reformulate both requests as a single exemption in the case of a positive evaluation.

[1] EU CIRCABC website: https://circabc.europa.eu (Browse categories > European Commission > Environment > RoHS 2014 Evaluations Review, at top left, click on "Library")

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]

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. 2013-1 through 2013-5 were submitted to the EU Commission by Oeko-Institut and Fraunhofer IZM and have already been published at the EU CIRCA website on 22 April 2014. So far, the Commission has not adopted any revision of the Annex to Directive 2011/65/EU based on these recommendations.

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

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

No.	Wording	Applicant	Recommendation	Expiry date
2013-1	Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base for substrates in amperometric, potentio-metric and conductometric electrochemical sensors	Instrumentation Laboratory Inc.	Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors used for analysis of blood and other body fluids and body gases in sub-category 8 in-vitro diagnostic devices.	31 Dec 2018
2013-2	"CADMIUM in colour converting II-VI LEDs (< 10 µg Cd per mm2 of light-emitting area) for use in solid state illumination or display systems " is suitable, though the following language: "CADMIUM in II-VI colour converting material (< 10 µg Cd per mm2 of light-emitting area) for LEDs for use in solid state illumination or display systems" would be more precise.	QD Vision Inc.	Cadmium in components for display lighting applications, containing downshifting cadmium based semiconductor nanocrystal quantum dots, where the cadmium per display screen area is limited to less than 0.2 ug/mm^2	01 Jul 2017
2013-3	"Lead in solders used in boards of heart-lung machines" exemption to expire in 2017	MAQUET Cardiopulmonary AG	Withdrawn	
2013-4	Mercury used in high speed rotating electrical connectors (slip ring) with electrical conduction paths that have sealed liquid mercury, molecularly bonded to the contacts	ACIST Medical Systems	Mercury electric-rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (>50MHz) modes of operation	22 Jul 2019
2013-5	Cadmium in light control materials used for display devices	3M	Cadmium in components for display lighting applications, containing downshifting cadmium based semiconductor nanocrystal quantum dots, where the cadmium per display screen area is limited to less than 0.2 ug/mm^2	01 Jul 2017

5.0 Links from the Directive to the REACH Regulation

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

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

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

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

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

The approach adopted in this report is that once a substance has been included into the regulation related to authorization or restriction of substances and articles under REACH, the environmental and health protection afforded by REACH may be weakened in cases where, an exemption would be granted for these uses under the provisions of RoHS. This is essentially the same approach as has already been adopted for the re-evaluation of some existing RoHS exemptions 7(c)-IV, 30, 31 and 40,[3] as well as for the evaluation of a range of requests assessed through previous projects in respect of RoHS 2.[4] Furthermore, substances for which an authorisation or restriction process is already underway are also reviewed, so that future developments may be considered where relevant.

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

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

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

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

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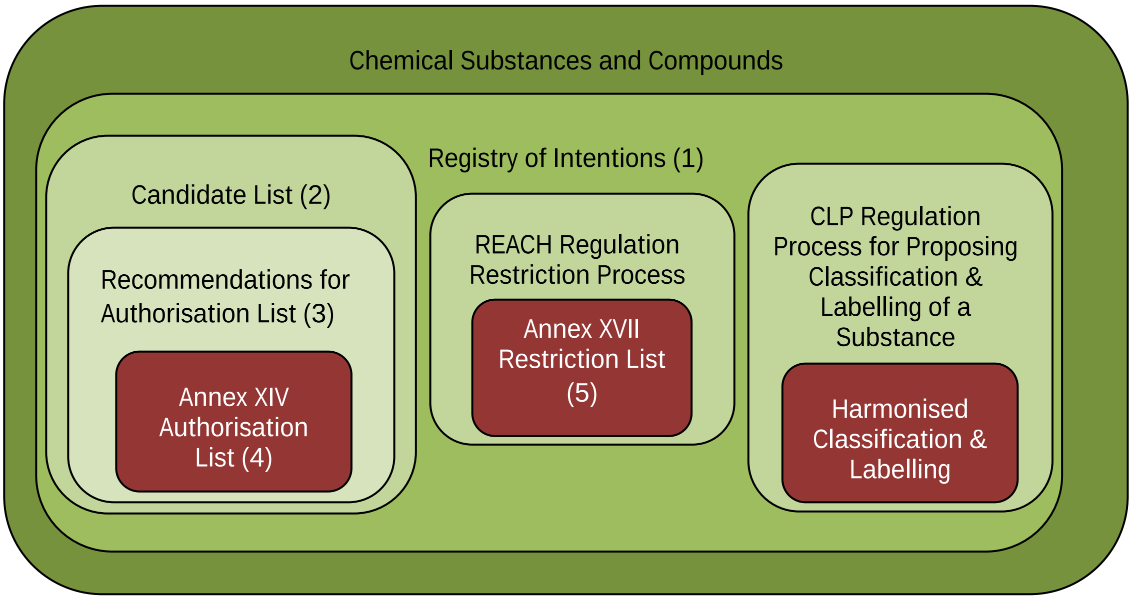
[3] See Zangl, S.; Blepp, M.; Deubzer, O. (2012) Adaptation to Scientific and Technical Progress under Directive 2011/65/EU - Transferability of previously reviewed exemptions to Annex III of Directive 2011/65/EU, Final Report, Öko-Institut e. V. and Fraunhofer IZM, February 17, 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Re-evaluations_t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

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

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



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

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

concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list;

- 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 10 of March, 2014, 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 1 July 2013, was used to check Annex XIV and XVII: The consolidated version is presented at the ECHA website: http://echa.europa.eu/web/guest/regulations/reach/legislation.

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

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

Designation of the substance, of the group of substances, or of the mixture	Transitional arrangements		Exempted (categories of)uses
	Latest application date (1)	Sunset date (2)	
10. **Lead chromate** EC No: 231-846-0 CAS No: 7758-97-6	21 Nov 2013	21 May 2015	-
11. **Lead sulfochromate yellow** (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2	21 Nov 2013	21 May 2015	-
12. **Lead chromate molybdate sulphate red** (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8	21 Nov 2013	21 May 2015	-
16. **Chromium trioxide** EC No: 215-607-8 CAS No: 1333-82-0	21 Mar 2016	21 Sep 2017	-

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

For the substances currently restricted according to RoHS Annex II: cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls and polybrominated diphenyl ethers and their compounds, we have found that some relevant entries are listed in Annex XVII of the REACH Regulation. The conditions of restriction are presented in Table 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 $2PbCO_3 \cdot Pb(OH)_2$ CAS No 1319-46-6 EC No 215-290-6	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
17. **Lead sulphates:** (a) $PbSO_4$ CAS No 7446-14-2 EC No 231-198-9 (b) Pb_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 International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
18. **Mercury compounds**	Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use: (a) to prevent the fouling by micro-organisms, plants or animals of: — the hulls of boats, — cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, — any totally or partly submerged appliances or equipment; (b) in the preservation of wood; (c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture; (d) in the treatment of industrial waters, irrespective of their use.
18a. **Mercury** CAS No 7439-97-6 EC No 231-106-7	1. Shall not be placed on the market: (a) in fever thermometers; (b) in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers). 2. The restriction in paragraph 1 shall not apply to measuring devices that were in use in the Community before 3 April 2009. However Member States may restrict or prohibit the placing on the market of such measuring devices. 3. The restriction in paragraph 1(b) shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007;

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	(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). 1. Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material): — polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21] — polyurethane (PUR) [3909 50] — low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] — cellulose acetate (CA) [3912 11] — cellulose acetate butyrate (CAB) [3912 11] — epoxy resins [3907 30] — melamine-formaldehyde (MF) resins [3909 20] — urea-formaldehyde (UF) resins [3909 10] — unsaturated polyesters (UP) [3907 91] — polyethylene terephthalate (PET) [3907 60] — polybutylene terephthalate (PBT) — transparent/general-purpose polystyrene [3903 11] — acrylonitrile methylmethacrylate (AMMA) — cross-linked polyethylene (VPE) — high-impact polystyrene — polypropylene (PP) [3902 10] Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01% by weight of the plastic material. By way of derogation, the second subparagraph shall not apply to articles placed on the market before 10 December 2011. The first and second subparagraphs apply without prejudice to Council Directive 94/62/EC (13) and acts adopted on its basis. By 19 November 2012, in accordance with Article 69, the Commis-

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	sion 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 undertaken at temperatures above 450°C. 9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing

<table>
<tr><th>Designation of the substance, of the group of substances or of the mixture</th><th>Conditions of restriction</th></tr>
<tr><td></td><td>fillers used for safety reasons.
10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01% by weight of the metal in:
(i) metal beads and other metal components for jewellery making;
(ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including:
— bracelets, necklaces and rings,
— piercing jewellery,
— wrist-watches and wrist-wear,
— brooches and cufflinks.
11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011.</td></tr>
<tr><td>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;</td><td>Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:
1. Shall not be placed on the market, or used,
— as substances,
— as constituents of other substances, or,
— in mixtures,
for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:
— either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,
— the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008.
Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:
'Restricted to professional users'.
2. By way of derogation, paragraph 1 shall not apply to:
(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.</td></tr>
</table>

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
29. Mutagens: category 1B or category 2 According to Appendices 3 and 4: Cadmium chloride Cadmium fluoride Cadmium Sulphate Chromium (VI) trioxide Potassium dichromate Ammonium dichromate Sodium dichromate Chromyl dichloride; chromic oxychloride Potassium chromate Sodium chromate	
30. Toxic to reproduction: category 1A or 1B or toxic to reproduction category 1 or 2 According to Appendices 5 and 6: Cadmium chloride Cadmium fluoride Cadmium Sulphate Potassium dichromate Ammonium dichromate Sodium dichromate 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	
47. Chromium VI compounds	1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002%) soluble chromium VI of the total dry weight of the cement. 2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
	ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1. 3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin. 4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1.
63. **Lead** and its compounds CAS No 7439-92-1 EC No 231-100-4	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05% by weight. 2. For the purposes of paragraph 1: (i) 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (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 Not Updated in the Last Concise Version of the REACH Regulation

Designation of the substance, of the group of sub-stances, or of the mixture	Conditions of restriction	Amended Annex	Amendment date
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 Sep 2012

Designation of the substance, of the group of sub-stances, or of the mixture	Conditions of restriction	Amended Annex	Amendment date
Addition of **Entry 62** concerning: (a) **Phenylmercury acetate** EC No: 200-532-5 CAS No: 62-38-4 (b) **Phenylmercury propionate** EC No: 203-094-3 CAS No: 103-27-5 (c) **Phenylmercury 2-ethylhexanoate** EC No: 236-326-7 CAS No: 13302-00-6 (d) **Phenylmercury octanoate** EC No: - CAS No: 13864-38-5 (e) **Phenylmercury neodecanoate** EC No: 247-783-7 CAS No: 26545-49-3	1. Shall not be manufactured, placed on the market or used as substances or in mixtures after 10 October 2017 if the concentration of mercury in the mixtures is equal to or greater than 0,01% by weight. 2. Articles or any parts thereof containing one or more of these substances shall not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than 0,01% by weight.'	Annex XVII, entry 62	20 Sep 2012

As of the 1st March 2013, the REACH Regulation Candidate list includes those substances relevant for RoHS listed in Table 5-4 (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 REACH Candidate List

Substance Name	EC No.	CAS No.	Date of Inclusion	Reason for inclusion
Cadmium sulphide	215-147-8	1306-23-6	16 Dec 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Lead di(acetate)	206-104-4	301-04-2	16 Dec 2013	Toxic for reproduction (Article 57 c);
Cadmium	231-152-8	7440-43-9	20 Jun 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Cadmium oxide	215-146-2	1306-19-0	20 Jun 2013	Carcinogenic (Article 57a); Equivalent level of concern having probable serious effects to human health (Article 57 f)
Pyrochlore, antimony lead yellow	232-382-1	8012-00-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead bis(tetrafluoroborate)	237-486-0	13814-96-5	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead dinitrate	233-245-9	10099-74-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Silicic acid, lead salt	234-363-3	11120-22-2	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead titanium zirconium oxide	235-727-4	12626-81-2	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead monoxide (lead oxide)	215-267-0	1317-36-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Silicic acid ($H_2Si_2O_5$), barium salt (1:1), lead-doped *[with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]*	272-271-5	68784-75-8	19 Dec 2012	Toxic for reproduction (Article 57 c)
Trilead bis(carbonate)dihydroxide	215-290-6	1319-46-6	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead oxide sulfate	234-853-7	12036-76-9	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead titanium trioxide	235-038-9	12060-00-3	19 Dec 2012	Toxic for reproduction (Article 57 c)
Acetic acid, lead salt, basic	257-175-3	51404-69-4	19 Dec 2012	Toxic for reproduction (Article 57 c)
[Phthalato(2-)]dioxotrilead	273-688-5	69011-06-9	19 Dec 2012	Toxic for reproduction (Article 57 c)

Substance Name	EC No.	CAS No.	Date of Inclusion	Reason for inclusion
Tetralead trioxide sulphate	235-380-9	12202-17-4	19 Dec 2012	Toxic for reproduction (Article 57 c)
Dioxobis(stearato)trilead	235-702-8	12578-12-0	19 Dec 2012	Toxic for reproduction (Article 57 c)
Tetraethyllead	201-075-4	78-00-2	19 Dec 2012	Toxic for reproduction (Article 57 c)
Pentalead tetraoxide sulphate	235-067-7	12065-90-6	19 Dec 2012	Toxic for reproduction (Article 57 c)
Trilead dioxide phosphonate	235-252-2	12141-20-7	19 Dec 2012	Toxic for reproduction (Article 57 c)
Orange lead (lead tetroxide)	215-235-6	1314-41-6	19 Dec 2012	Toxic for reproduction (Article 57 c)
Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead cyanamidate	244-073-9	20837-86-9	19 Dec 2012	Toxic for reproduction (Article 57 c)
Lead(II) bis(methanesulfonate)	401-750-5	17570-76-2	18 Jun 2012	Toxic for reproduction (Article 57 c)
Lead diazide, Lead azide	236-542-1	13424-46-9	19 Dec 2011	Toxic for reproduction (article 57 c),
Lead dipicrate	229-335-2	6477-64-1	19 Dec 2011	Toxic for reproduction (article 57 c)
Dichromium tris(chromate)	246-356-2	24613-89-6	19 Dec 2011	Carcinogenic (article 57 a)
Pentazinc chromate octahydroxide	256-418-0	49663-84-5	19 Dec 2011	Carcinogenic (article 57 a)
Potassium hydroxyoctaoxodizincatedichromate	234-329-8	11103-86-9	19 Dec 2011	Carcinogenic (article 57 a)
Lead styphnate	239-290-0	15245-44-0	19 Dec 2011	Toxic for reproduction (article 57 c)
Trilead diarsenate	222-979-5	3687-31-8	19 Dec 2011	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Strontium chromate	232-142-6	7789-06-2	20 Jun 2011	Carcinogenic (article 57a)
Acids generated from chromium trioxide and their oligomers. Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid.	231-801-5, 236-881-5	7738-94-5, 13530-68-2	15 Dec 2010	Carcinogenic (article 57a)
Chromium trioxide	215-607-8	1333-82-0	15 Dec 2010	Carcinogenic and mutagenic (articles 57 a and 57 b)
Potassium dichromate	231-906-6	7778-50-9	18 Jun 2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Ammonium dichromate	232-143-1	7789-09-5	18 Jun 2010	Carcinogenic, mutagenic and toxic for reproduce-tion (articles 57 a, 57 b and 57 c)

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

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

As at the time of writing (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, the latest authorisation or restriction process results shall be followed and carefully considered where relevant.[6]

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

[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)

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.[7]

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

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

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

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

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

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

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

At present a consultation concerning the possible identification of cadmium chloride as a SVHC is on-going. 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 (March 2014), it cannot yet be foreseen if the further investigation of this substance will result in a restriction of use; as such 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 possible decisions have not been considered in the review of the exemption requests dealt with in this report. However for the sake of future reviews, the latest authorisation or restriction process results shall be followed and carefully considered where relevant.

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

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

Request No.	Substance or compounds	Specific provisions etc. under REACH
2013-1	No relevant substitutes named	
2013-2 / 2013-5	Indium Phosphide	Entries not found in the REACH Annex XIV and ANNEX XVII
2013-4	No relevant substitutes named	

6.0 Exemption Request No. 2013-1: "Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base for substrates in amperometric, potentiometric and conductometric electrochemical sensors"

Abbreviations

AQC	Automatic Quality Control
BGA	Blood Gas Analyser
ILI	Instrumentation Lab Inc.
IQM	Intelegent Quality Management
Pb	Lead
PVC	Poly Vinyl Chloride

Instrumentation Lab Inc. [8] (ILI) has carried out a RoHS compliance program to ensure compliance for equipment falling under the scope of RoHS and supplied to the EU by ILI. As a result of this compliance program the sensor card of the GEM Premier family of analysers has been identified as a component with a content of lead (Pb) exceeding the maximum concentration value of 0,1% as specified in Annex II of RoHS. ILI explain that the equipment falls under the scope of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on invitro diagnostic medical devices, and therefore also falls under the scope of RoHS, (cf Article 2, paragraph 4(22).)

Instrumentation Laboratory Inc.[9] has thus applied for an exemption for

> "*Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base for substrates in amperometric, potentiometric and conductometric electrochemical sensors.*"

[8] IL (2013a), Original application for Exemtion Rquest 2013-1", available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/GEM_Card_Exemption_Final_-_public.pdf

[9] Op. cit. ILI (2013a)

6.1 Description of Requested Exemption

Sections 6.1 through 6.3 are heavily based on information provided by the applicant and other stakeholders and do not necessarily reflect the view of the consultants.

ILI[10] explain that Blood Gas Analysers (BGAs)[11] are used for blood testing and serve as a critical analytical instrument in hospital labs, operating rooms, emergency rooms and point of care at bedside across the global and EU health care sector. Blood testing is a core element to virtually all diagnostic and therapeutic procedures carried out in the health care sector today. Pb is used as a stabilizer in sensor cards used in the cartridges of the GEM family (the ILI BGA brand name) of critical care analysers. Cartridges are disposable, and function as the heart of the GEM analyser where the actual testing process takes place. The sensor card is the primary unit of the cartridge and represents a complicated and compact technological unit whose function is based on electrochemical processes taking place upon it during the testing process.

Compared to other existing technologies (traditional testing technologies – Automatic Quality Control (AQC)) on the market today the GEM analyser differentiates on a number of points: [12]

- Ø The ILI BGA utilises a specific system, which is called “intelligent Management System” (iQM), which automatically detects, corrects, and documents all errors, and confirms resolution, ensuring patient safety and the highest quality of test results;
- Ø In the ILI BGA, iQM continuously monitors process control solutions, reducing the time to error detection to minutes instead of the hours required by manual or automated traditional laboratory Quality Control (as regulated by CLIA in the United States and by applicable national legislation in EU Member States) that normally are run every 8 hours (see Table 6-1 for supporting data);
- Ø iQM eliminates manual intervention to correct sensor errors such as clot catcher replacement and thereby significantly reduces the time needed for the testing process and enhances convenience of use. The reduced testing time will, in critical situations, improve significantly patient safety by producing rapid and correct results thereby reducing the need for doctors interpretation of results and the need for repeat testing;
- Ø Furthermore in the ILI BGA, iQM results in a longer product lifetime of the Sensor Card compared to the existing AQC technology. The iQM system conducts quality control as an integrated part of the testing process whereas the AQC quality control counts as a separate test which will reduce significantly the overall cartridge life.

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[10] Op. cit. ILI (2013a)

[11] ILI offer this type of analyzer under the brand name name GEM, which is later refered where relevant.

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

Table 6-1: Time to error detection, as presented by Dr. James Westgard at an iQM Workshop held in July 2002: Source ILI (2013b)[13]

Average Error Detection Time	pH	PO_2	PCO_2	Na^+	K^+	Ca^{++}	Gluc	Lact	Hct
iQM	3 min.	3 min.	3 min.	10 min.	3 min.	3 min.	7 min.	3 min.	3 min.
Traditional QC	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.	≥8 hr.

Statistical presentation of an average error detection time with a 95% confidence

Note: QC = quality control

In a later communication ILI[14] provide some insight as to what is considered traditional quality control (QC): "*Traditional QC refers to the assay of liquid quality control materials on an analyser, based on time schedules mandated by regulatory agencies (for example, every 8 hours is typical, as shown in the table above). These QC materials are stable over time, have assigned concentration values for certain analytes, and are usually provided in sealed glass ampoules. The materials are usually introduced externally by the user into the analyser. Correct measurement of the analyte concentrations allows the operator to conclude that functionality of the analyser is "in control" and may be used for measurement of patient samples.*"

The sensor card has been manufactured from polyvinyl chloride (PVC), as early as the 1980s when the GEMStat and GEM 6 analysers were first launched, and the same molded card has been carried forward to the currently manufactured analysers (GEM Premier 3000, GEM Premier 3500, GEM Premier 4000 and GEM Premier 5000). According to the applicant PVC has specific advantages as a sensor card material for the electrochemical sensors used in the GEM products. Sensing membranes used for certain sensors (Na+, K+, Ca++, pH, pCO2) are based on PVC and are solvent cast directly on the sensor card from a solution of tetrahydrofuran (THF). Because THF is a strong solvent for PVC, there is strong adhesion between the cast membranes and the PVC card, which is a critical requirement for sensors to have long use life and shelf life.[15]

6.2 Applicant's Justification for Exemption

The PVC sensor card is produced by injection molding. Lead has been traditionally used as a thermal stabilizer to prevent breakdown of the polymer at the high temperatures required for the injection molding process. ILI has determined that the presence of lead in the PVC sensor card does not interfere with measurement of any analytes on the GEM family of analysers. However, alternative thermal stabilizers,

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[13] ILI (2013b), Summary of Information presented at an IQM Workshop, submitted by applicant along with Application, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/iQM_Workshop.pdf

[14] ILI (2014a), Answers to 2nd round of clarification questions, submitted 18.03.2014

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

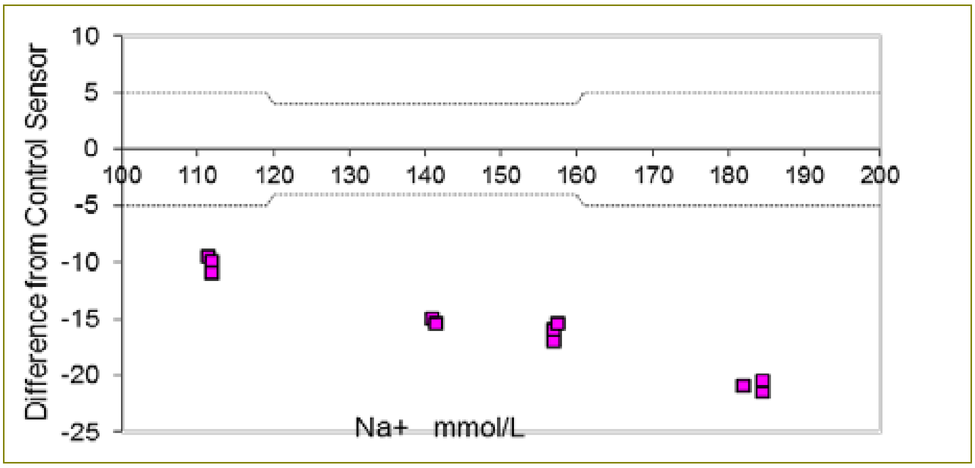
*Sections 6.1 through 6.3 are heavily based on information provided by the applicant and other stakeholders. Alterations have been made mainly to ensure comprehension and to avoid repetition.

such as tin, have been shown to produce interference, especially with measurement of electrolytes. [16]

ILI[17] was later asked to elaborate on the possible source of interference experienced with alternatives that have been tested. They state that "*The mechanism of interference is not completely understood. However, we speculate that metals, such as tin, present in the thermal stabilizers are blocking the ion carrier sites in the ion-selective membranes, preventing the ion carrier sites from complexing the ion of interest. This problem is not seen when lead is present in the thermal stabilizer.*"

They further supply Figure 6-1 below to illustrate the problem for the measurement of sodium ion, explaining that "*along the x-axis is the concentration of sodium (Na+) in blood samples. The y-axis is the difference between results obtained using a PVC sensor card stabilized with tin, minus results obtained using a PVC sensor card stabilized with lead (control sensor). For the tin-based card to be a direct replacement for the lead-based card, differences must lie within the dashed lines, which reflect acceptable bias from one device to another for measurement of sodium ion. Significant negative biases are seen, indicating unacceptable interference from the tin. Similar results are seen for measurement of other ions in blood, such as K+ and Ca++. These data were collected early in the service life of the sensor card. No data is available on how this interference may change throughout the service life of the sensor card*." [18]

Figure 6-1: Illustration of the Difference between Measurement of Sodium Ion Between a Tin Based Stabilizer Sensor Card and a Lead Based Stabilizer Sensor Card



Source: ILI (2014a)

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

[17] Op. cit. ILI (2014a)

[18] Op. cit. ILI (2014a)

ILI[19] explains that the continued use of lead in the sensor card of the GEM analysers is required while the search continues for an alternative thermal stabilizer. They provide a number of qualities that are to be provided by alternative stabilizers in order to ensure compatibility with the GEM system:

- Ø The alternative stabilizer must not interfere with measurement of any analyte on the system over the sensor card's service life.
- Ø To ensure comparable reliability, the product shelf life is required to be at least 9 months when stored at room temperature; and
- Ø The sensor card use life (operation within the cartridge) is required to be 4 weeks in the analyser, through which performance does not deteriorate.

In light of the requested exemption formulation, ILI explains that amperometric, potentiometric and conductometric electrochemical sensors are 3 subclasses of electrochemical sensors, used for measurement of different analytes in blood. All 3 types of sensors are built on the sensor cards used in the GEM 3000 and GEM 4000 devices. When evaluating alternative thermal stabilizers in the PVC sensor card, performance of all 3 types of sensors needs to be tested.[20]

ILI[21] claim that an exemption is justified as substitution is currently impractical as the possible alternatives do not provide sufficient performance over the product lifetime. It is further estimated that, assuming the exemption is granted, an amount of 25.89 kg of lead is expected to come onto the EU market annually through the sensor cards used in the GEM analyser.

ILI provides data as to the concentrations of lead in sensor cards manufactured for various models of their device (see Table 6-2 below). The PVC compounds shown in the table are explained to be commercially available products, supplied to Instrumentation Laboratory by compounding vendors specializing in vinyl resins. "*Specific formulations, except for lead content, are proprietary and unknown to us. The reason for choosing the lead content in a particular resin likewise is unknown to us, but is presumably related to ease with which the resin can be molded*."

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

[20] ILI (2013c), Answers to first clarification questions, submitted by the aplicant on 08.07.2013, avalable uner: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/Questionnaire-1_Ex_Req-2013-1_with_IL_Responses_revised_08_07_13.pdf

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

Table 6-2: Comparison of various parameters of sensor cards of different device models. Source: ILI (2014a)

Product	PVC Compound	Weight of card (g)	Amount of lead in card (mg)	Percentage lead in card
GEM 3000/3500	CMX 2151 GRY 10	3.641	238.85	6.56%
GEM 4000	JLD 91221	5.163	96.55	1.87%
GEM 5000	CMX 2151 GRY 10	3.773	247.51	6.56%

6.2.1 Possible Design Alternatives

Concerning design alternatives, ILI[22] mention that their research is looking into alternatives for PVC in light of the understanding that the availability of this substance to industry is also decreasing, however at present such an alternative is not known.

6.2.2 Possible Substance Alternatives

ILI[23] state that in close cooperation with the supplier of the PVC material for the sensor card as well as independent scientific centres of excellence (Massachusetts's Institute of Technology – MIT – University of Massachusetts, Lowell, Department of Plastic Engineering) they have investigated the alternative thermal stabilizers Tin and Zinc, which are the only alternatives technically available today, *"The investigated alternative stabilizers have been shown to produce interference, especially with measurement of electrolytes, on the GEM family of instruments and cannot therefore be considered to be technically practical or viable alternatives as they impede the reliability of test results carried out with the sensor card when using the alternative stabilizer thereby preventing the analyser to perform its sole function*. "In this regard, ILI[24] elaborate that Pb-based cards were compared to performance of cards made with alternative (non-lead) thermal stabilizers from at least 3 different commercial sources. The alternatives included PVC cards with organo-tin thermal stabilizers and other metal-based stabilizers, proprietary to the suppliers of the PVC resins. In all cases, performance of the sodium ion sensor in the GEM 3000 and 4000 was adversely affected, producing incorrect readings, in the presence of metal-based thermal stabilizers other than lead. Early testing of non-metallic organic stabilizers is promising; however, more testing is required before a conclusion can be reached regarding suitability as a substitute for lead in sensor cards.

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[22] Op. cit. ILI (2013a)

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

[24] Op.cit. ILI (2013c)

6.2.3 Environmental Arguments

ILI[25] do not use environmental arguments to support their request, however they provide some information as to the handling of waste created at the end-of-life of the sensor cards. ILI state that the GEM cartridge is treated as medical waste, and its disposal is handled in each country according to the local, state, and federal laws. In most cases, medical waste is incinerated in specific designated facilities according to national requirements and supervision of the respective EU Member States.

6.2.4 Road Map for Substitution

ILI[26] estimate that the search for practically and viable substitutes for lead as a stabilizer in the PVC material of the sensor card will possibly be concluded within the coming 4-5 years. Upon identification of the substitute, they state that additional time will be needed for development and approval of a new sensor card according to applicable EU legislation and other applicable requirements on Medical Devices. ILI[27] later elaborated some of the stages relevant in this regard:

- Screening of several PVC formulations using substitute stabilizers: 6 months
- Supplier agreements, scale up, and verification of lot to lot consistency: 6 months
- Verification and validation of a final PVC formulation in GEM 3000 and 4000 systems (detail below): 9 months
    - Use life testing in the GEM 3000 and 4000 systems
    - Evaluation of interfering substances
    - Evaluation of limits of detection
    - Method comparison to prove equivalency with existing product
    - Clinical studies at customer sites
    - Shelf life (stability) equivalent to existing product
- Submission to and approval by regulatory agencies: 6 months
- Total: 27 months

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

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

[27] Op cit. ILI (2013c)

6.3 Stakeholders' Contributions

Radiometer Medical ApS[28] have submitted a contribution in support of the requested exemption. Radiometer uses lead as a thermal stabilizer in polyvinyl chloride (PVC) in a similar application. The PVC material is used for containing an electrochemical sensor and a sensor membrane for measurement of e.g. calcium (Ca++) and potassium (K+) in human blood samples. Radiometer explain that though the chemical properties of the material seem to be of a similar type, the physical environment is a little different, and therefore Radiometer propose a slightly changed wording, so the exemption will focus on the chemical properties of the materials and not on the surrounding materials:

"Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors."

Concerning possible substitutes, Radiometer has also tested an alternative stabilizer, which is applied in other sensor types, but for the device in question, the alternative resulted in poor performance when measuring K+ and Ca++ ions. The alternative material shows both a lower sensitivity and a number of unstable measurements during the 90 days lifetime test of the sensor. Its application as a substitute would result in poor and degrading performance, meaning significantly inferior clinical performance specifications. As for further alternatives, Radiometer explain that testing of alternative stabilizer materials is time consuming; each material needs to be tested for at least 90 days, and also a shelf stability test of 26 months has to be passed. Radiometer expects it will take at least 3-5 years to substitute lead as the stabilizer for the K+ and Ca++ sensors.[29]

Radiometer[30] also claims that the PVC base material needs to be compatible with the rest of the sensor unit; otherwise this cannot be assembled with the sensor membrane. This means that substituting the PVC material will require a major redesign, clinical re-validation and re-approval of the device by the authorities.

The Swedish Ministry of Environment[31] have submitted a contribution, expressing their concern that the exemption should be specified more clearly, to avoid its application to other uses than intended. The Ministry suggests the exemption be specified to only include equipment for medical diagnosis of human blood.

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[28] Radiometer (2013), Contribution to 2013 stakeholder 1 concerning Ex. Re. 2013-1, submitted by stakeholder on 07.11.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/20131107_Radiometer_Support_Re_ex_No__2013-1.pdf

[29] Op. cit. Radiometer (2013)

[30] Op. cit. Radiometer (2013)

[31] Swedish Ministry of Environment (2013), Contribution to RoHS Stakholder 2013 Consultation 1, submitted 11.11.2013, available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/SE_Comments_on_stakeholder_consultation_RoHS_Aug_Nov_2013.pdf

6.4 Critical Review

6.4.1 REACH Compliance - Relation to the REACH Regulation

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 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. Pb used as a stabilizer in PVC used for sensor cards in blood analysis devices 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. Pb is part of an article and as such, entry 30 of Annex XVII of the REACH Regulation would not apply. Additionally, such medical devices are products that are not provided to the general public, but to users other than private ones, e.g. to hospitals, clinics etc.

No other entries relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status March 2014).

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.

6.4.2 Scientific and Technical Practicability of Lead Substitution

The relevance of the exemption request to devices of other manufacturers was unclear from the application. To justify an exemption for the device of a single manufacturer, the advantages of the device in comparison with devices on the market performing similar functions would need to be shown to be significant. ILI were thus asked if additional manufacturers market similar devices, and provided the following list in this regard:

- Radiometer Medical: ABL 800 and ABL 90 systems
- Siemens Healthcare: Rapidlab 800 and Rapidpoint 500 systems
- Abbott Laboratories: i-STAT handheld monitors

Radiometer Medical provided a contribution in support of the request (see section 6.3 above). Although an effort was made to contact the other suppliers to establish the relevance of this request to their devices, no response was received. From available literature[32] it can be understood that the Repidlab devices are similar in function and

[32] See "Siemens Rapidlab 800 Series (Model 865) System Analyzer" available under http://pathology.uchc.edu/pdf/uid1801.pdf

also have sensors for Na^+ (sodium), as well as K^+, Cl^-, and in some models Ca^{++}. The i-STAT devices are also understood to be similar[33]. Information on the Abbott webpage explained the following:

"*i-STAT cartridge technology streamlines traditional lab technology, yet contains many of the components found in complex lab testing systems. Each test cartridge contains chemically sensitive biosensors on a* ***silicon chip*** *that are configured to perform specific tests. To perform a test, 2 to 3 drops of blood are applied to a cartridge, which is then inserted in to the i-STAT handheld. Prior to running a test, each cartridge initiates a series of preset quality control diagnostics, from monitoring the quality of the sample to validating the reagent*."[34]

From this information, it can be understood that the card is based on silicon, and it is thus possible that the silicon mentioned is used instead of PVC. In this case it may also be that the use of silicon allows eliminating the use of lead. Despite the attempt to contact Abott, further information was not made available and so it could not be established if substitution of lead or of PVC (i.e., elimination of lead) had been achieved and if the alternatives would also be relevant for other BGAs, such as those manufactured by ILI and Radiometer.

The applicant, as well as one of the stakeholders, provides information and data showing, that though research of substitutes for lead, used as a stabilizer in PVC sensor cards, is on-going, a suitable alternative is yet to be found. In this regard the applicant claims that tested metal based stabilizers adversely affect the performance of the sodium ion sensor. Further research of non-metallic organic stabilizers is said to be promising, however more time is required to find and verify a possible alternative. In the consultants' opinion, it can be followed that the performance of tested alternatives does not match the requirements of the lead stabilizer, as it interferes with results. On the basis of the available information, substitution has not been shown to be practical at present.

6.4.3 Conclusions

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

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

[33] See general device information available under http://www.abbottpointofcare.com/Products-and-Services/iSTAT-Cartridges.aspx

[34] http://www.abbottpointofcare.com/products-and-services/istat-cartridges.aspx; Last accessed 11.3.2014.

In the consultants' opinion, it can be followed that substitutes for lead, used as a stabilizer in PVC sensor cards, are not yet available for this specific application. Substitution is thus understood not to be scientifically or technically practical at present, in line with the first criteria detailed in Article 5(1)(a). From the submitted information it is also understood that elimination, through the use of a different material for the sensor card, is also not yet possible. In light of fulfilment of one of the Article 5(1)(a) criteria, an exemption would be justified.

Concerning the formulation of a possible exemption, the applicant had proposed the following wording:

"*Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base for substrates in amperometric, potentiometric and conductometric electrochemical sensors*".

Radiometer (2014) explains that despite the similarity in the operation of devices and in the chemical properties of the material, the physical environment in the Radiometer device is a little different. They propose changing "*base for substrates" to "base material*". The consultants view this change to make the exemption somewhat more general. However as the application of lead is still otherwise limited, this change is understood to ensure that the exemption would be available to other blood analysis devices, so long as it is used as a stabilizer in PVC used for sensor applications.

As it is understood that the interferences were apparent in blood analysis, when testing sensor cards manufactured with alternative lead-free stabilizers, a limitation to such applications is also viewed to be relevant to eliminate the risk for misuse of the exemption. This is also in line with the concerns of the Swedish Ministry of Environment, who have recommended limiting the exemption for use in devices for analysis of blood samples. It can be understood that both the devices of the applicant and the supporting stakeholder (Radiometer) are used for analysis of blood. As the need for this exemption for use in other applications was not expressed by other stakeholders, the consultant agrees that the exemption wording should be adjusted in this regard.

The consultants thus discussed the following wording with the applicant as well as Radiometer who have expressed their need for the requested exemption for their devices:

'Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors used for analysis of blood in sub-category 8 in-vitro diagnostic devices.'

Radiometer[35] requested that the reference to "analysis of blood" be extended to "analysis of blood and other body fluids and body gases", explaining that "*intended use of this type of in-vitro diagnostic devices, besides analysis on blood samples, also includes tests on human body fluids such as pleural fluid samples and expired air samples*".

[35] Radiometer (2014), Answers to clarification questions concerning Ex. Re. 2013-1, submitted 14.03.2014

ILI[36] agreed to this adjustment, however conditioning their support with that of the EU COM. They explain that "*the revised wording was not known at the time of the stakeholder consultation and as any supporting documentation possibly submitted in support of the revised wording has not been available to Instrumentation Laboratory, we suggest that the EU Commission considers to draft a separate exemption to cover the additional equipment comprised by the revised wording as appropriate*".

In the consultants view, the addition of "other body fluids and body gases" to the exemption wording, results in an extension of its scope of applicability. In light of the extended scope, and as other stakeholders have not expressed their need for the exemption for additional devices beyond the suggested scope, the consultants cannot conclude that this change would exclude applicability of the exemption for devices already excluded from the original requested wording.

It should be said that it was not possible to clarify if the devices are also in use by the veterinary medical sector. To the consultants understanding, such products do not fall under Cat. 8 and would thus be excluded from use of the recommended exemption. As the applicant clearly stated that the device falls under the definitions of the in-vitro diagnostic medical devices directive, stakeholders requiring the device for applications falling under other categories would have been expected to express their support and need for this request, were it of relevance. As stakeholders have not clarified that the devices are also relevant for veterinary applications, the consultants cannot conclude that limiting the exemption to sub-category 8 in-vitro would have a negative impact on this sector.

The reference to diagnosis of blood, body fluids and body gases and to sub-category 8 in-vitro diagnostic devices is understood to limit the area of application considerably to the areas in which these devices are in use, as requested by the Swedish Ministry of Environment. It is further recommended to add a possible exemption to Annex IV as there is no evidence that the request is needed for non-medical devices.

As for the duration for which an exemption should be recommended, the applicant and Radiometer estimate that 4–5 years or 3–5 years (respectively) are expected to be needed before a substitute can be applied in products in use on the market. The contribution of Radiometer was made towards the end of 2013, and thus this period is understood to be relevant starting the beginning of 2014. As sub-category 8 in-vitro is only to come into scope of the RoHS Directive in mid-2016, it is understood that in practice, an exemption is requested for a few additional years in order to ensure substitution without having a negative impact on the relevant medical services. It can be understood that the exact time required would depend on the time needed before a suitable candidate is identified. As it is difficult to predict the time needed for this initial research the consultants do not oppose to the longer 5 year duration. The requested duration would result in an exemption available for use until the end of 2018, which practically means extending the exemption period by a further 2.5 years.

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[36] ILI (2014b), Answers to 2nd round of clarification questions, submitted 20.03.2014

6.5 Recommendation

For the application of lead in PVC used as a base material for the manufacture of electro chemical sensors, the consultants recommend granting an exemption as follows:

'Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors used for analysis of blood and other body fluids and body gases in sub-category 8 in-vitro diagnostic devices.' *31.12.2018*

Should an exemption be added, it should be added to Annex IV of the RoHS Directive.

6.6 References Exemption Request 2013-1

ILI (2013a), Original application for Exemption Request 2013-1", available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/GEM_Card_Exemption_Final_-_public.pdf

ILI (2013b), Summary of Information presented at an IQM Workshop, submitted by applicant along with Application, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/iQM_Workshop.pdf

ILI (2013c), Answers to first clarification questions, submitted by the applicant on 08.07.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/Questionnaire-1_Ex_Req-2013-1_with_IL_Responses_revised_08_07_13.pdf

ILI (2014a), Answers to 2nd round of clarification questions, submitted 18.03.2014

ILI (2014b), Answers to 2nd round of clarification questions, submitted 20.03.2014

Radiometer (2013), Contribution to 2013 stakeholder 1 concerning Ex. Re. 2013-1, submitted by stakeholder on 07.11.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-1/20131107_Radiometer_Support_Re_ex_No__2013-1.pdf

Radiometer (2014), Answers to clarification questions concerning Ex. Re. 2013-1, submitted 14.03.2014

Swedish Ministry of Environment (2013), Contribution to RoHS Stakeholder 2013 Consultation 1, submitted 11.11.2013, available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/SE_Comments_on_stakeholder_consultation_RoHS_Aug_Nov_2013.pdf

7.0 Exemption Request 2013-2 “Cadmium in Color Converting II-VI LEDs (< 10 µg Cd per mm² of Light-Emitting Area) for Use in Solid State Illumination or Display Systems”; and Exemption Request 2013-5 “Cadmium in Light Control Materials Used for Display Devices”

Abbreviations

BEF / DBEF	Brightness enhancement film / Dual brightness enhancement film
BLU	Back light unit
CCFL	Cold cathode fluorescent (LCD)
Cd	Cadmium
CF	Colour filter
CFL	Compact Fluorescent bulbs
CFQD	Cadmium-free quantum dots
CIE	International Commission on Illumination
CRT	Cathode ray tube
FWHM	Full width at half maximum
InGaN	Indium gallium nitride [based LED]
InP	Indium phosphide
LCD / LCM	Liquid crystal display / Liquid Crystal Module
LED	Light-emitting diode
OLED	Organic light-emitting diode
QD / QLED	Quantum dot / Quantum-dot-based LEDs
RGB	RGB colour model with the three additive primary colours: red, green, and blue
NTSC	National Television Systems Committee
QDs	Quantum Dots
QDEF	Quantum Dot Enhancement Film
RoHS 2	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)

RoHS 1	Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment
TV	Television
UCS	Uniform colour space
YAG	Yttrium aluminium garnet

7.1 General Issues Concerning Exemption Requests 2 and 5

QD Vision, Inc. and 3M Optical Systems Division have submitted exemption requests No. 2 and No. 5

- Cadmium in II-VI LED Down-conversion (Request No. 2, applicant QD Vision, Inc.[37])
- Cadmium in LCD Quantum Dot Light Control Films and Components (Request No. 5, applicant 3M Optical Systems Division[38])

Both the applications have been subjected to stakeholder consultation. Following the stakeholder consultation, a one day stakeholder meeting was organised to allow a discussion and better understanding of technical details. The participants included both applicants as well as several stakeholders from industry[39].

Besides information that is specific for each of the requested exemptions, both applicants put forward overarching arguments related to the general features of quantum dots (QDs) technology and concerning unit components intended for use as part of a liquid crystal display (LCD) system. This information, as well as some of the information provided by stakeholders is reflected in Sections 7.2 to avoid repetition. This is followed by individual sections relaying information relevant as background information for each of the requests in Section 7.3. A brief description of the environmental arguments made by the applicants appears in Section 7.3.4. Afterwards information concerning substance alternatives and design alternatives is compiled in Section 7.4.1 and Section 7.4.2 respectively, followed by the information

[37] QD Vision (2013a), QD Vision original exemption request document concerning exemption request 2; available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-2/20132301_NON-CONFIDENTIAL_Request_for_renewal_of_exemption_39.pdf, retrieved on 12.12.2013

[38] 3M (2013a), 3M Optical Systems Division original exemption request document concerning exemption request 2; available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-5/3M_QDEF_Exemption_Dossier.pdf, retrieved on 05 June 2013

[39] Documentation of the presentations held at the meeting are available under: the exemption request 2 webpage: http://rohs.exemptions.oeko.info/index.php?id=182 and under the exemption request 5 webpage http://rohs.exemptions.oeko.info/index.php?id=185

*Sections 7.1 through 7.5 are heavily based on information provided by the applicant and other stakeholders. Alterations have been made mainly to ensure comprehension and to avoid repetition.

contributed by stakeholders summarized in Section 7.5. Finally, a critical review of the various issues of interest resumes the report in Section 0.

Sections 7.2 to 7.5 are mainly based on information provided by the applicants and other stakeholders and do not necessarily reflect the views of the consultants, unless specifically stated.

7.2 Background

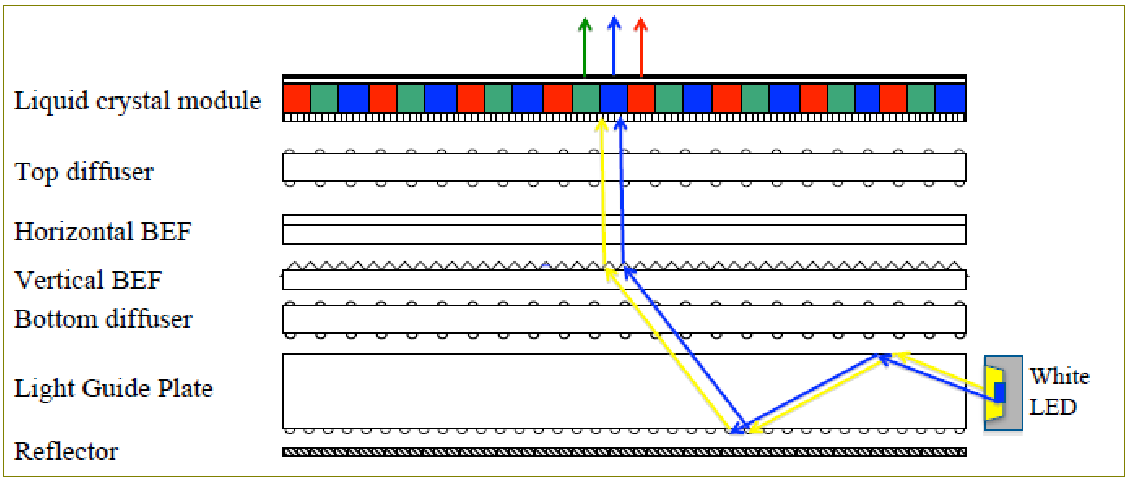
Sections 7.2 through 7.5 are heavily based on information provided by the applicant and other stakeholders and do not necessarily reflect the view of the consultants.

7.2.1 Display Lighting Applications

According to Coe-Sullivan et al.[40], LEDs are used as the source of light in most backlights of cell phones, tablets, laptops, most monitors, and roughly half of all TVs. This is due to the thin dimensions in which they can be manufactured, their high energy efficiency and their decreasing costs as blue light sources. In most of these systems, the components in use are referred to as white LEDs, since they are based on a blue indium gallium nitride (InGaN) LED chip coated with down-conversion material, which mixed with the source light produces white light. These white lights are used in combination with a series of diffusers and [brightness enhancing] films (see Figure 7-1 below) to produce a uniformly spread light over the display area. The white light passes through the liquid crystal array and then through colour filters to create the three primary colours that make up the colour gamut of the display.

[40] S. Coe-Sullivan, W. Liu, P. Allen & J.S. Steckel (2013), "Quantum Dots for LED Down-conversion in Display Applications", ECS J. Solid State Sci. Technol., 2013, 2, R3026

Figure 7-1: Illustration of LCDs with White LEDs as a Light



Source: Nanosys (2013)[41]

According to 3M[42], there are two classes of LCD lighting approaches; edge lighting and direct lighting. The edge lighting approach uses LEDs coupled into a light guide plate to provide uniform back lighting. The direct lighting approach uses a matrix of LEDs to directly illuminate the LCD panel. In the direct lighting approach, particularly common in TV application, there is no "edge" (no light guide plate) to which to place the QDs. It is estimated that in 2013 the direct lit TV sales were 34% of the total TV market, and by 2017 it is projected that 65% of TV sales will be direct lit systems[43].

3M[44] provide background information concerning the application, stating that LCD refresh rates, resolution, and contrast levels have all improved dramatically. However, they indicate colour performance as the one area where development is still forthcoming. They emphasize that this is particularly true for smaller sized displays, such as smartphones and tablets, where the range of colours that can be presented is only 50%-70% that of cathode ray tube (CRT) technology, when it was first introduced. 3M continue to name a number of relatively new display technologies, claiming that none of these exist commercially for high quality colour displays at a state which is easily adoptable for all applications, as well as being energy efficient.

[41] Nanosys (2013), Presentation held at Stakeholder Consultation concerning Ex. Re. 20132 and 2013-5 on 13.12.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/RoHS_Nanosys_12_13_2013_final.pdf

[42] 3M (2014b), Additional Information provided by 3M in response to clarification questions, Document submitted 06.02.2014

[43] Quoted in 3M (2014b) as iSuppli TV tracker Q1 2013

[44] Op. cit. 3M (2013a)

These include:

- Traditional LED LCDs (higher absorptive colour filters);
- Organic light emitting diode (OLED) displays;
- Red/Green/Blue (RGB) LEDs;
- Wide colour gamut phosphors;
- Hybrid LEDs.

A main factor that determines the maximum colour performance of an LCD is the spectral interaction between the light emitted from the backlight and the liquid crystal panel colour filters. An LCD has two main components, the liquid crystal panel and the back light unit (BLU). The panel consists of millions of individually addressable pixels, each of those made up of red, green and blue sub-pixels. The sub-pixels get their colour properties from absorptive colour filters (CFs) that overlay them. The BLU contains light sources (typically white yttrium aluminium garnet (YAG) based LEDs at present) and provides spatially uniform light to the back side of the panel. The spectral distribution of the light sources in the BLU convolved with the spectral transmission of the panel colour filters mainly determines the final spectra of the light exiting an LCD. The white LED based spectral output of the BLU passes through the three (red, green, and blue = RGB) colour filters (CF) to produce the final LCD spectral distribution. This distribution then determines the colour quality of the display (See Figure 7-1 above for illustration of typical spectral distribution for display with white-LED back lighting).[45]

To maximize the colour performance of an LCD, the output spectral distribution of each sub-pixel should be as narrow as possible. Narrow spectral distributions of the primary RGB sub-pixels result in a large colour gamut area. Colour gamut[46] is a measure of a display's ability to generate a range of colours, and is typically defined by the tristimulus RGB area in the CIE (International Commission on Illumination) 1931 2° Chromaticity space or the CIE 1976 UCS (Uniform Colour Space) Chromaticity Space. The blue horseshoe shape in Figure 7-2 represents all of the colours visible to the human eye, and the red and green triangles represent the colours that a standard LED-LCD and a QD film based LCD are capable of displaying. The narrower spectral distributions (particularly the red and green distributions) of an LCD with QD films produce a larger colour gamut (~94% NTSC) than a traditional LCD (~65% NTSC). BLU+CFX denote the spectral light distribution coming from the BLU through the blue, green or red colour filter (CFB, CFG, and CFR respectively). [47]

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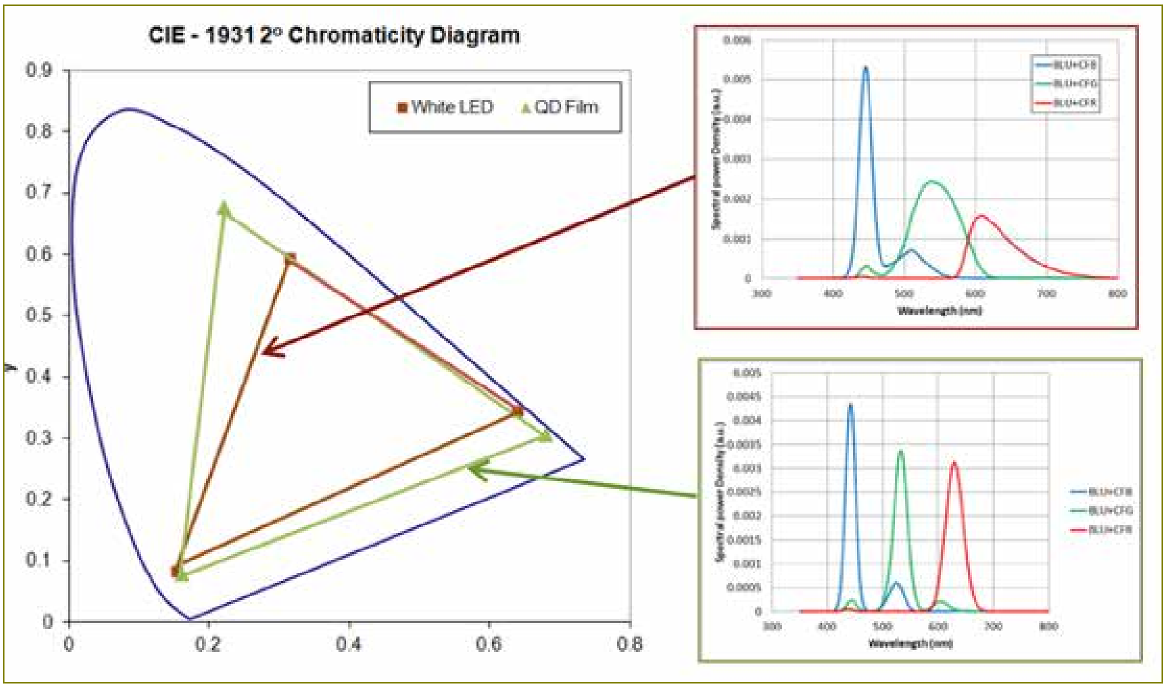
[45] Op. cit. 3M (2013a)

[46] Colour gamut is often represented as percentage of area relative to a standardized colour gamut space, such as the 1953 NTSC (National Television System Committee) colour space. A larger colour gamut area (with a higher % NTSC) means that the display can generate a larger range of colours than a display with a lower % NTSC.

[47] Op. cit. 3M (2013a)

Figure 7-2: Primary Sub-pixel Spectra and Colour Gamut Size



Source: 3M (2013a)

To achieve narrow sub-pixel output spectral distributions in an LCD, either:[48]

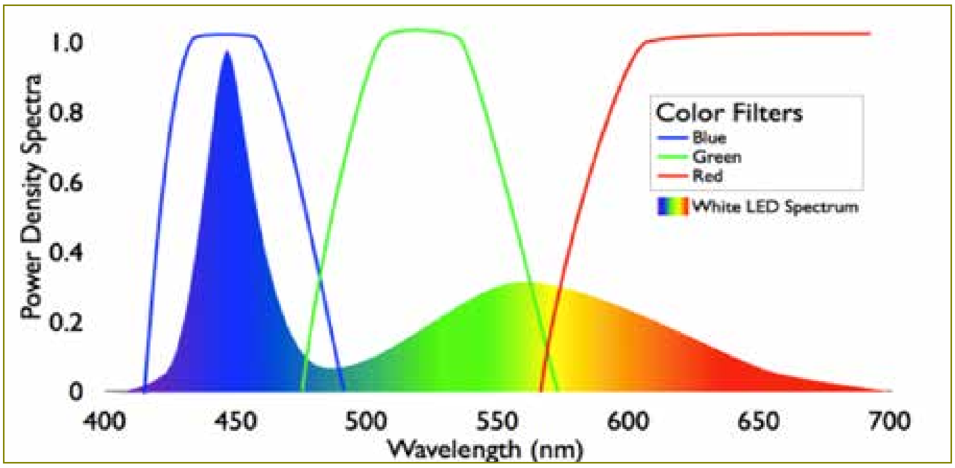
- Ø The colour filters have to be highly absorptive, which is not desirable due to significantly lower efficiency (of coloured light output as a % of BLU light output) and higher energy consumption; or
- Ø The input spectral distribution from the BLU must have narrow spectral ranges and be closely matched in peak wavelength to the transmission of the colour filters.

Currently, the YAG based white LEDs used in most LCDs have broad spectral distributions in the green and red regions and do not match the colour filters in peak wavelengths (see Figure 7-3). [49]

[48] Op. cit. 3M (2013a)

[49] Op. cit. 3M (2013a)

Figure 7-3: Spectrum of a Typical White YAG Based LED BLU, Compared with an Example set of Red, Green and Blue Colour Filters



The spectrum of the light sources does not match well with the colour filters (CFs) resulting in a limited colour gamut size.
Source: 3M (2013a)

7.2.2 Quantum Dot Technology

3M[50] explain that Quantum dots (QDs) are a new class of non-naturally occurring materials that can be tuned to efficiently emit narrow spectral distribution light at the optimum wavelength for LCDs.[51]

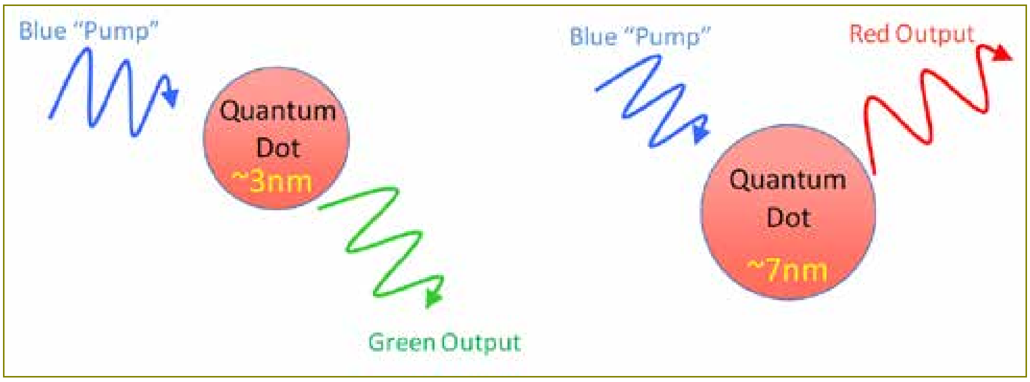
QDs are semiconductor nano-crystals, on the order of 3-7nm in size, in which excitons (an electron and hole excited pair) are confined on all three spatial dimensions. The wavelength of the light output from a semiconducting material is dependent on the band gap between normal and excited electron energy states. The spatial confinement of the electrons and holes of the quantum dot materials leads to higher band gaps compared to the band gap of same material in bulk. As a result, the band gaps of the quantum dots can be changed continuously by changing their physical size. Quantum dots are typically synthesized via solution chemistry (carefully controlled precipitation processes). By controlling different synthesis conditions, e.g., precursor; ligand concentrations; temperature; and time of the reaction, QDs of different sizes can be obtained. Quantum dot emission can be tuned across most of the visual spectrum by controlling the size of the quantum dot as it is fabricated; larger quantum dots emit light of longer peak wavelengths, see Figure 7-4.[52]

[50] Op. cit. 3M (2013a)

[51] Quoted by 3M (2013a) as: Hartlove, J. 2011. Quantum dots unleash high-colour-gamut performance in LED-backlit displays. LEDs Magazine

[52] Op. cit. 3M (2013a)

Figure 7-4: Effects of Quantum Dots Size on Spectral Output (Smaller QDs emit shorter wavelength light when exposed to a blue source)



Source: 3M (2013a)

Quantum dots can be pumped with a blue source, such as the GaN LED, to emit at any wavelength beyond the pump source wavelength. The emission spectra of QDs have narrow line-widths and are free of satellite peaks, thus making them ideal candidates for display backlights to achieve high colour purity and increased system energy efficiency. QDs convert light with very high efficiency (>88% quantum efficiency) and with very narrow output spectral distribution of only 30 – 40nm full width at half maximum (FWHM). Due to their tuneability, narrow spectral output distributions, and high quantum efficiencies, quantum dots are ideal for creating BLU light sources to increase colour gamut size and maximize LCD colour performance.[53]

QD Vision[54] provides some information concerning qualities of Cadmium in the application that are of relevance for possible substance alternatives. Cadmium functions as the group II element in the II-VI semiconductors described in the exemption. The group II element functions to complete the 8 electron bonding that is characteristic of tetrahedral sp^3 hybridized, tetrahedral bonded semiconductors. As such, cadmium contributes two outer orbital electrons to the bonding of such a semiconductor solid, and the result is a material with a completely filled valence band and unfilled conduction band. Other Group II elements provide a band-gap that is either too high and hence luminescence in the deep blue and ultraviolet (e.g. zinc), or too low and hence luminescence that is in the infrared (e.g. mercury), and/or makes a material that is more salt than semiconductor and hence decomposes in aqueous or humid environments (e.g. magnesium) and fails to meet reliability requirements. Cadmium is thus essential to the light emitting property of the material. Unlike any other known materials, these Cadmium-containing II-VI down-conversion materials (quantum dots) emit very *narrowband* light, which can be *tuned* throughout the visible spectrum. These materials are *stable* enough for long-lived (25,000 hours) LED lit products. They are also extremely efficient (essentially 100% at room temperature), and unlike most known down-conversion materials, can now be made to maintain

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[53] Op. cit. 3M (2013a)

[54] Op. cit. QD Vision (2013a)

97% of this room temperature efficiency at high operating temperatures up to 140°C. Characteristics are described to include:

- Efficient: In the context of both lighting and display products, narrowband light is equivalent to more efficient light (see explanation below). Narrowband spectra means that all of the light produced comes out with the same narrow range of colour. In all down-conversion applications, one is essentially converting light of an undesirable colour to one that is more useful in an application. Emitting all of the down-converted light in a narrow range at the desired colour means that less total photons are used to have the same effect, and are not 'wasted' – e.g. by emitting deep red or infrared photons that humans cannot see. II-VI down-conversion materials can routinely achieve a spectral full width at half maximum (FWHM) of 30nm or less, compared to conventional LED phosphors that have FWHM of greater than 60nm, and in most cases greater than 90nm (e.g. the most common LED phosphor Yttrium Aluminium Garnet doped with Cerium, YAG:Ce). Such a step change in FWHM is equivalent to getting twice as many lumens for the same number of photons in the red and blue regions of the spectrum. This factor of 2× in the red is what leads to the 20-40% increase in overall white light efficiency in warm white lighting.
- Tuneable: because down-conversion is in essence tailoring a light spectrum to be more desirable, the tuneable nature of II-VI down-conversion materials allows precise control and selection of the light that is most desirable, and hence most efficient, (see explanation below) for a particular application. Colour can typically be tuned in 2nm increments for customers, improving the quality and efficacy of light production as a result.
- Stable: Many other down-conversion materials have a limited lifetime, which limits the lifetime of the overall product. The cadmium containing II-VI down-conversion materials now have sufficient lifetime to be included in the longest lived, most reliable products on the market, those that rely on LEDs as the primary light source. By combining these materials with LEDs, lighting bulbs and fixtures with high colour quality and lifetime in excess of 25,000 hours can be created. Similarly, displays which can be rated at 30,000+ hours can be delivered to the market. This parameter of reliability is another key factor in determining environmental effects, along with efficiency.

In a later communication, QD Vision[55] elaborates as to the use of the term efficiency in the above text excerpts. They explain that they generally use the term concerning the creation of light for an application such that it meets that application's needs, while consuming less power. "*The original application covers the two applications of lighting and displays.*

[55] QD Vision (2014c), Respnose to 4th round of clarification questions, submitted per email on 17.03.2014

- *For **lighting**, the most useful metric of efficiency is lm/W (lumens per Watt, or sometimes LPW). Lumens are units of perceived brightness, and in this context the Watts are electrical Watts of input power to the system. However, optimizing for lumens per Watt without taking into account colour would mean creating narrowband green lighting fixtures, since 555nm green light is perceived the brightest of any colour by the human eye. Colour must be taken into account to create light that meets the applications needs. Hence, the tuneable nature of QDs allows as much of the light as possible to be emitted where the human eye perceives it brightly, while simultaneously meeting the need of the application to emit white light of a certain colour temperature (warmth) with a certain colour rendering (CRI, or how accurately colours look when illuminated by a light source).*
- *For **displays**, the arguments are quite similar. The white light spectrum that is desired by the application is different, emphasizing colour gamut and saturation over colour rendering. However, the need to deliver the light that is desirable, at wavelengths where it is perceived brightly, also requires a narrowband and tuneable light source. Lm/W are still relevant units, but are much harder to isolate since the system has many more optical components (colour filters, polarizers, etc.) that are part of the system efficiency. Hence, the industry (and our own* [the applicant's] *writings) will usually quote efficiencies on a relative basis to some well-known reference. Today, that reference is usually an LCD system lit by a white LED comprised of a blue LED with yellow [cerium doped] YAG:Ce phosphor."*

7.2.2.1 Implementation of QDs into Display Lighting Applications

Nanoco-Dow[56] explains that **three potential strategies** exist through which QDs can be integrated into conventional LCD BLUs: "on-chip", "on-edge" and "on-surface", as defined by Coe-Sullivan et al.[57] (see Figure 7-5 below):

- In '*on-chip technology'*, the QDs are placed on the LED surface, encapsulated within its package. This technology requires the lowest amount of QD material, however in light of the proximity to the light source, practical application is difficult to accomplish as the QD material undergoes thermal degradation in light of the proximity to the light emitting source.
- *'On-edge technology'* has QDs incorporated into a remote component situated in close proximity to the LED chips. This can be done for instance in an

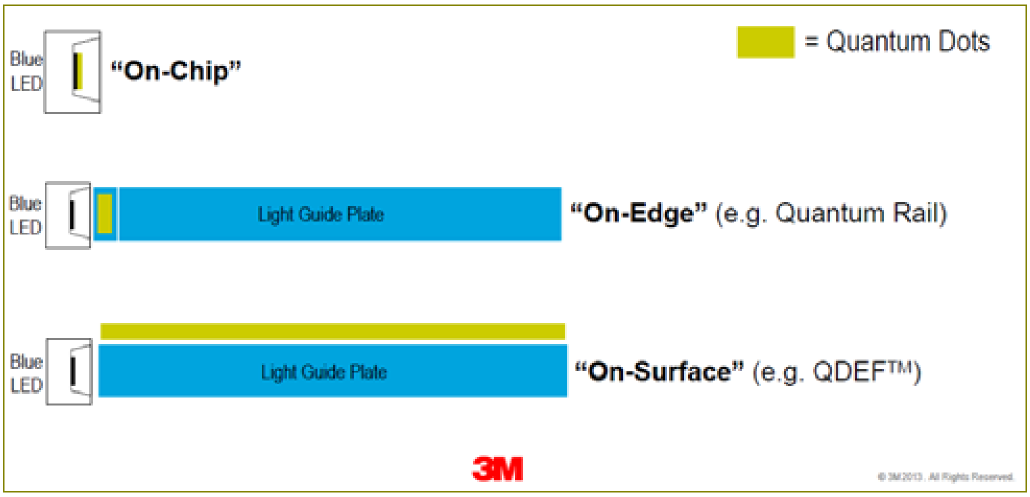
[56] Nanoco-Dow (2013a), Contribution made concerning Ex. Re. 2013-2 – answers to RoHS Consultation Questionnaire, submitted by Nanoco Technologies Limited & Dow Electronic Materials on 06.11.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-2/20131106_Nonoco_Dow_Contribution_Ex_2013-2_Response_to_RoHS_Questionnaire.pdf

[57] Quoted in Nanoco-Dow (2013a) as: S. Coe-Sullivan, W. Liu, P. Allen and J.S. Steckel, *ECS J. Solid State Sci. Technol.*, 2013, 2, R3026

adjacent capillary. On-edge technologies allow a compromise between the risk of thermal degradation and the respective QD material requirements.

- In '*on-surface technology'* the QDs are encapsulated in a film that covers the complete display area. This technology is the most intensive in terms of QD material usage, but can operate at near room temperatures, so that the thermal degradation risk is not an obstacle for practical application. On-surface technologies are also known as QD-films.

Figure 7-5: Possible Configurations for Integrating QDs into an LCD System



Source: 3M (2013b[58])

Nonoco-Dow further provides an estimation of the amounts of Cd that would be allowed in the QD material based on the allowances that the current exemption (Ex. 39) allows per mm^2. The comparison is estimated for the light emitting area relevant in the application of each configuration for a 40" screen, based on the various technologies, as specified in Table 7-1 below.

[58] 3M (2013b), Presentation given at Targeted Stakeholder Meeting, held on 13.12.2014, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/12-13-13_3M_RoHS_Exemption_Request_2013-5__Meeting_-_Presentation_Handouts_01.pdf

Table 7-1: Estimated Light-emitting Area and the Corresponding Maximum "Allowed" Cadmium Concentration (according to the proposed exemption request) for On-chip, On-edge and On-surface QD BLU Designs for a 40" screen

Design	Estimated Light-Emitting Area, mm^2	Maximum Cd Content "Allowed" (Ex. 39)
On-chip	48 (light-emitting area, based on LED area within each chip of the two LED light bars)	480 µg
On-edge	1×10^4 [=10,000] (surface area of two glass capillaries)	100 mg
On-surface	4×10^5 [=400,000] (display area of a 16:9, 40" screen)	4 g

Source: Nanoco-Dow (2013a)

It should be noted that the comparative estimation made by Nanoco-Dow does not necessarily correspond to the amounts present in actual applications, but rather to the allowances that the current Ex. 39 would allow for each configuration. This is calculated based on an interpretation of the term "light emitting area" referenced to in the current Ex. wording, relevant for each configuration. Table 7-5 in Section 7.6.3 provides some additional information in this regard. In the provided example, on-chip configurations are estimated to have the lowest of Cd allowance per product, whereas on-surface configurations are estimated to have the highest allowance, in light of the reference to the emitting area.

The relation of these estimations with the actual Cd quantities required in the application of various configurations is unclear. However, in the consultants view it clarifies that the quantities relevant for different applications, along with the limitations of using a specific configuration throughout the product range need to be better understood. The differences between the application of on-edge and on-surface technologies are thus further explained in the following sections, based on the material submitted by each applicant.

7.3 Description of Requested Exemptions

7.3.1 Exemption No. 2

QD Vision, Inc.[59] has requested an exemption for *"Cadmium in II-VI LED Down-conversion"* and asks for a renewal of existing exemption 39 under RoHS 2, currently valid until 30 June 2014.

Exemption 39, listed in Annex III of the RoHS 2 Directive is worded as follows:

> *Ex. 39: "CADMIUM in colour converting II-VI LEDs (< 10 µg Cd per mm^2 of light-emitting area) for use in solid state illumination or display systems*
> *Expires on 1 July 2014"*

[59] Op. cit. QD Vision (2013a)

A further alternative for the exemption wording was proposed in the application as follows:

> *"Cadmium in II-VI colour converting material (< 10 µg Cd per mm^2 of light-emitting area) for LEDs for use in solid state illumination or display systems"*

Furthermore, QD Vision requests the renewal for an additional period of 5 years pursuant to Article 5(2) of Directive 2011/65, as well as the possibility that cadmium may be used in spare parts for EEE placed on the market before the "expiry date".

According to the applicant, this exemption renewal is required to enable manufacturers to bring to the market a quantum dot down-conversion material for use in lighting and displays. The II-VI down-conversion materials (e.g. quantum dots), due to their narrowband, tuneable, stable and efficient properties, will provide consumer products with the superior performance, efficiency, and net benefit to the environment for which there currently is no substitute available. In lighting, narrowband emission translates to warmer light sources with 20 - 40% greater efficacy. Such products have already been placed on the market in the US. In the display market, narrowband emission translates to televisions, monitors, tablets and cell-phones that can achieve 100% of colour gamut (as defined by NTSC). This property has the added benefit of increasing light throughput through the display, which can in turn reduce energy consumption for identical perceived brightness by as much as 20%.[60]

QD Vision[61] describes the applications relevant for this request:

- *A backlighting unit component that includes a colour-converting II-VI semiconductor material (including cadmium bound in a crystalline material), which is bound in an organic polymer host, which is further sealed within glass (e.g. a sealed glass tube) and which is positioned between and in optical communication with one or more LEDs and a light guide plate. The colour-converting II-VI semiconductor converts at least a portion (the amount is predetermined) of the light emitted by the LED into one or more predetermined colours to provide colour converted light. This backlighting unit component is intended to be included as a part of a liquid crystal display (LCD) system.*
- *Similarly, the substance has been used as a colour-converting plate between one or more LEDs and the light output face of a general illumination device (lamp / lightbulb).*

7.3.1.1 History of the Exemption

The original request for exemption 39 was submitted in 2008 by 3M as part of an earlier evaluation in 2008 and 2009.

Originally the requested exemption was formulated as follows:

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[60] Op. cit. QD Vision (2013a)

[61] Op. cit. QD Vision (2013a)

"Cadmium within a colour converting single crystal semiconductor film for use in solid state illumination or display systems"

3M submitted this request for exemption from the RoHS Directive because the II-VI-LEDs were intended to be used as replacements for Hg-containing lamps and conventional LEDs – especially in the mobile projector sector. At the time of the request, the technology was not yet commercial – even on the US market – but was planned to be placed on the European market by 3M in 2009.

Based on the evaluation of the submitted information, Gensch et al.[62] recommended a re-wording and restructuring of the above wording, resulting in the existing exemption No. 39. The Commission adopted this recommendation.

7.3.1.2 Applicant's Justification for Exemption No. 2

QD Vision[63] state that the net benefit to the environment, of allowing the use of cadmium in the mentioned applications, is a result of the system level increase in efficiency that is achieved using the II-VI down-conversion materials, due to their narrowband, tuneable, and efficient nature (for further detail see section 7.3.4). QD Vision[64] provides estimations for the Cd content that is present in various products manufactured with Cd QDs:

- *"Large Display (TV): Average = 500-1500ppm, 1200 ppm (µg/gram) of homogeneous material (quantum dots distributed in polymer matrix) typical, 1.5mg total cadmium per unit.*
- *Medium Display (Computer Monitor): Average = 1000-3000ppm, 2000 ppm typical, 0.2mg cadmium per unit.*
- *Small display (Cellphone): Average = 1000-5000ppm, 3000 ppm typical, 10 ug cadmium per unit.*
- *Lighting device (bulb/fixture): Average = 1000-5000ppm, 3000 ppm typical, 20 ug cadmium per unit.*

...At 100% penetration of II-VI down-conversion materials for both lighting and displays, our calculations show that a maximum of 120kg of cadmium could enter the EU annually under this exemption. Given the current lack of product on the market, a reasonable product ramp projection and the proposed 2019 expiry of the renewed exemption, 44kg of total cadmium would enter the EU over the

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

[63] Op. cit. QD Vision (2013a)

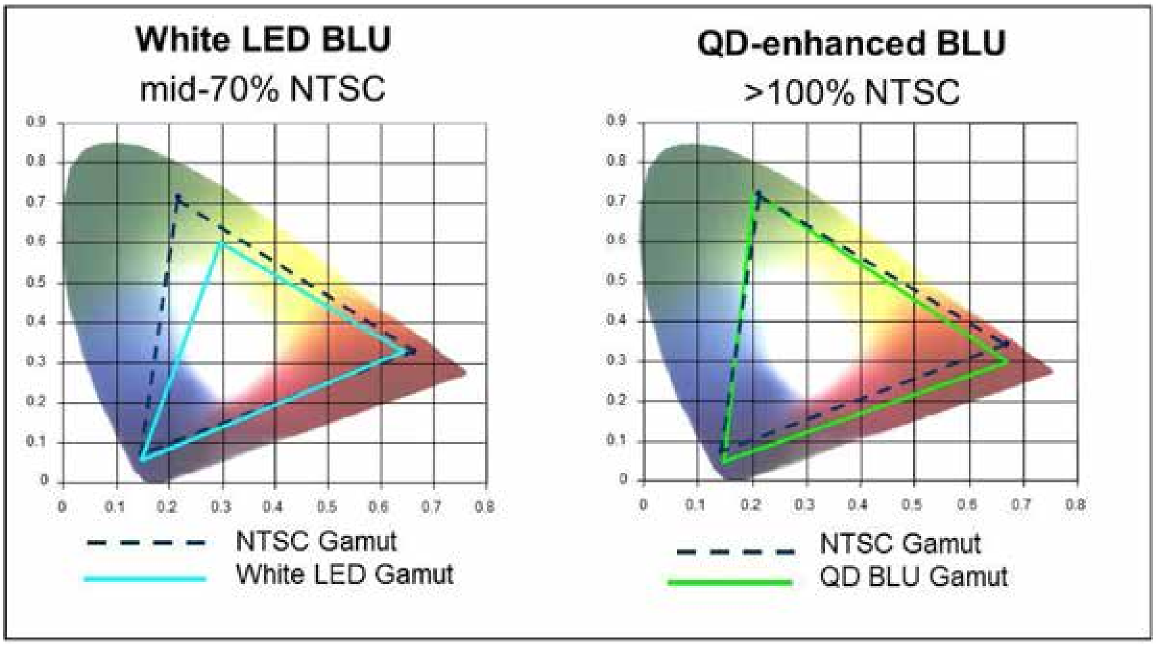
[64] Op. cit. QD Vision (2013a)

2014-2019 time period (Annex 6[65]). This represents an average of 8.8kg per year for this time period…

The … optical component … is incorporated into LED backlight units for displays in TVs, monitors, tablets, laptops, or cell-phones. The same class of optical components is also incorporated into LED light bulbs.

In both cases, the component functions as a "luminescent filter", absorbing some of the higher energy blue light, and down-converting that light to the characteristic colour of the specific II-VI material design. In lighting, red material fills in the missing light spectrum so as to render a more pleasing light than otherwise results, without sacrificing as much efficiency as other materials would lose. In display applications, red and green material is combined, and the resulting red, green, and blue light illuminates the liquid crystal display and gives the Red-Green-Blue components of light that make up the image. This is illustrated below by the CIE diagrams for standard white phosphor-LEDs and QD-enhanced BLUs"[66]

Figure 7-6: CIE Diagrams Which Allow for a 2-Dimensional Projection of all Colours Visible to Humans (horse shoe shape)



Left: colour gamut that can be displayed with LED backlit LCDs utilizing conventional phosphor material for down-conversion, shown relative to the NTSC colour standard; Right: colour gamut that can be displayed with LED backlit LCDs utilizing II-VI down-conversion material containing cadmium, which meets or exceeds the NTSC standard.

Source: QD Vision (2013a)

[65] For more detail, see QD Vision (2013a-1), Annex 6 to QD Visions Application Dossier, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-2/Annex_06_Cd_calculations_summary.pdf

[66] Op. cit. QD Vision (2013a)

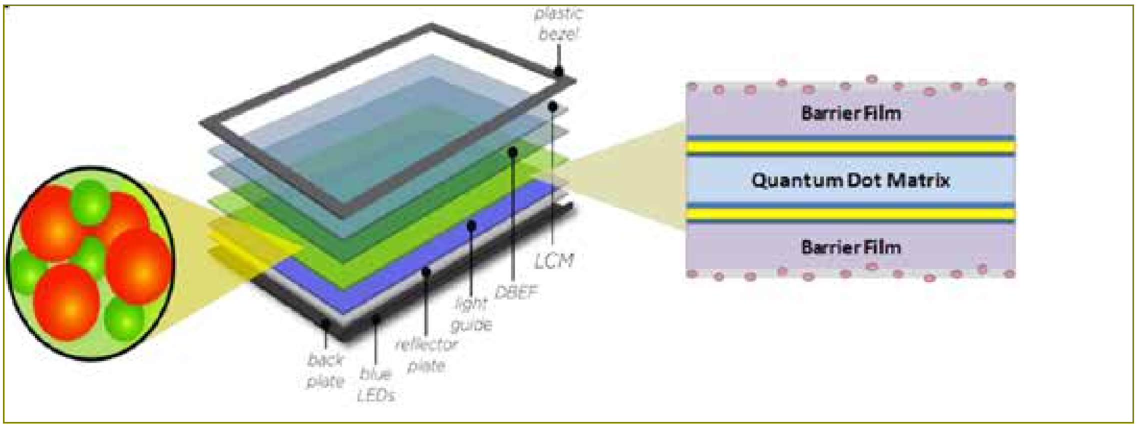
7.3.2 Exemption No. 5

3M[67], the applicant, explains that quantum dot light control films are a new technology that has been developed to enable liquid crystal displays (LCD) to give a technically superior image with a much higher range of colours than is currently possible with other commercially available LCD technologies. Alternative LCD technologies give broader ranges of colours which cannot be tailored to optimum wavelengths. Therefore 3M Optical Systems Division[68] has submitted a request for new exemption:

"Cadmium in LCD Quantum Dot Light Control Films and Components"

3M [69] explains that quantum dot light control films are polymeric films doped with small amounts of quantum dots that result in displays with very high colour quality (high colour gamuts). QD films can provide high efficiency solutions for high quality LCD colour performance that are easily scalable to any size display. When using QD film the only other change to the LCD system that is necessary is to substitute the white LEDs with blue LEDs (nominally by using the same GaN LEDs but without the YAG phosphor). See Figure 7-7 for a representative example of QD film in an LCD system.

Figure 7-7: LCD Assembly Diagram showing the Quantum Dot Film



Source: 3M (2013a)

Two different sized quantum dots, nominally green and red emitting, are incorporated into a polymer film. The smaller (~3nm in size) green dot would have a peak wavelength of approximately 540nm and a FWHM of approximately 30nm. The larger (~7nm in size) red dot would have a peak wavelength of approximately 615nm and a FWHM of approximately 40nm. The QD film would convert some of the blue "pump" light to green and red and allow some of the blue light to leak through unaffected. The spectral output of the blue LED has a FWHM of approximately 15nm and peak

[67] Op. cit. 3M (2013a)

[68] Op. cit. 3M (2013a)

[69] Op. cit. 3M (2013a)

wavelength that ranges from 440nm to 460nm. In this way, narrow red, green and blue spectra of the appropriate peak wavelengths can be generated and high colour gamuts can be achieved.[70]

3M[71] further elaborate that the cadmium is bound to selenium in a core structure, encased within a shell, surrounded by ligands (various amino silicones), which is encapsulated within a matrix material (various polymer materials), and then finally encased between PET (polyethylene terephthalate) films. This QDEF film is then combined with other polymeric material layers within an LCD assembly. 3M claim that an LCD with QD film could easily be disposed of properly, ensuring that the contained cadmium does not contaminate the environment.

The total amount of quantum dots needed, as well as the ratio of green to red dots, depends on a number of factors. These include: the desired colour specifications of the display, the amount of light recycling (number and efficiency of light reflections) in the BLU, and the properties of the colour filters in the panel. The concentration of quantum dots, and therefore, the concentration of cadmium in QD film depend on these factors and the total thickness of the film. However, no more than 20 µg of cadmium/cm^2 of screen area should be used for any application. Typically, only 3 – 5 µg of cadmium/cm^2 of screen area would be used.[72]

7.3.2.1 Applicant's justification for Exemption No. 5

The primary justification for this exemption is that only QD LCDs are able to achieve 100% colour gamut for all screen sizes and a secondary justification is that the potential substitutes have a greater negative environmental impact. [73]

3M[74] explain that QDs used in light control films are cadmium selenide (CdSe)/Zinc sulphide (ZnS) core/shell nanocrystals, optimized to deliver high quantum efficiency[75] as well as to meet the lifetime requirements in display applications. The high quantum efficiency, typically >88%, is necessary for QD film based backlights to deliver higher power efficiency (12%- 45% more energy efficient than traditional LED-LCDs for colour gamut sizes from 70% NTSC to 100% NTSC). QD light control films can have the sole purpose of tailoring the output spectral light distribution for high colour performance or they can have additional optical functionality (i.e., polarization, reflection, refraction, scattering).

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[70] Op. cit. 3M (2013a)

[71] Op. cit. 3M (2013a)

[72] Op. cit. 3M (2013a)

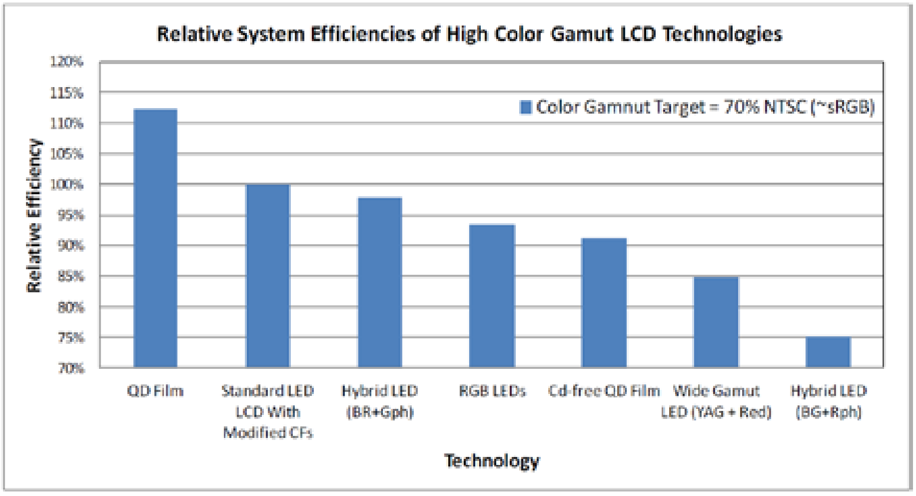
[73] Op. cit. 3M (2013a)

[74] Op. cit. 3M (2013a)

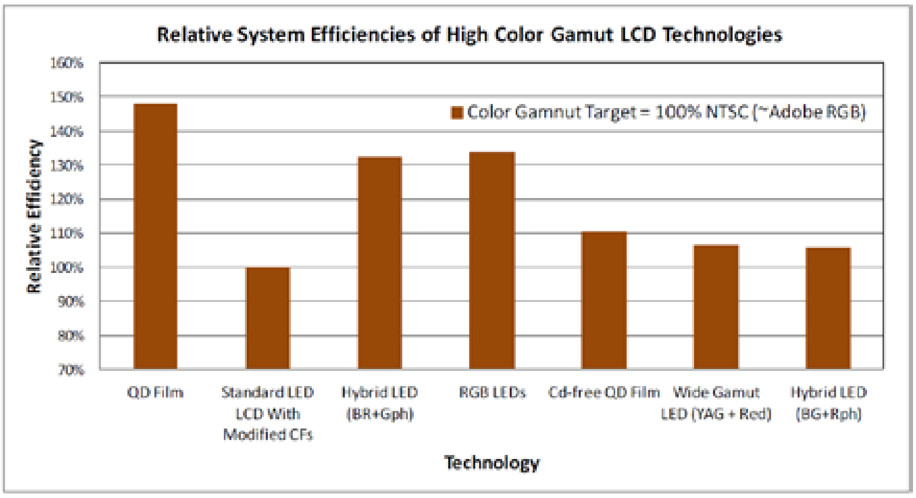
[75] Explained by 3M as *"the quantum efficiency of the dots (how efficiently they convert input photons to output photons)."*

To demonstrate the efficiency of this technology, 3M[76] detail a case study comparing between a 55" LCD TV and a QD film alternative, concluding that QD films result in an average power savings of 46% over existing LCD technologies. Furthermore, a comparison of the relative efficiency[77] modelling of various technology alternatives was included as in Figure 7-8 below.

Figure 7-8: Summary of Relative Efficiency Modelling for Colour Gamut Targets of 70% and 100% NTSC



Note that the relative efficiencies are normalized as a reference to the standard LED-LCD at 100%.



Again, the relative efficiencies are normalized as a reference to the standard LED- LCD at 100%. Also note that this theoretical modelling analysis was performed for illustrative purposes only, currently in practice, only QD film and RGB LED technologies can achieve 100% NTSC colour gamut in LCDs.
Source: 3M (2013a)

[76] Quoted by 3M (2013a) as: Quantum Dot Enhancement Film Cadmium Emissions Analysis, SourceOne, Inc., http://www.sourceone-energy.com/

[77] This reference to efficiency is understood by the consultants to relate to the efficiency of converting light into colour, to achieve the specified colour gamut.

In a later communication 3M[78] explain:

> *"In the context of the diagrams shown, the term efficiency refers to the ratio of electrical power into a display, to the light output from the display. The efficiency value shown in these figures is directly related to energy use. A higher efficiency translates to lower energy use. As an example, for the same light out from a display at ~70% NTSC colour gamut (the first diagram shown) a "Standard LED LCD with Modified CFs" system is approximately 12% less efficient and would therefore consume approximately 12% more energy than the "QD Film solution", assuming all other conditions are equal. The difference in efficiency increases for larger colour gamuts. This is important as the industry is moving to the next generation technical broadcasting TV standards such as Rec. 2020 for ultra high definition (UHD) TV. For the same light out from a display at 100% NTSC colour gamut (the second diagram shown) a "Standard LED LCD with Modified CFs" system would consume approximately 48% more energy than the "QD Film" solution."*

3m[79] estimate that typically 147 kg of cadmium will be placed on the EU market annually by this application (i.e., QD on-surface applications). Table 7-2 outlines the calculations used to develop this estimation. Using the same numbers it is estimated that 565 kg of cadmium will be placed on the global market annually (i.e., the EU has a 26% share of global sales).

Table 7-2: 3M estimation of Cd placed on the EU market through QD applications addressed in Ex. Re. 2013-5. Source: 3M (2013a)

Application	Global Annual LCD Area (1) (m^2)	EU Share of LCD Area (2) (m^2)	% Using QD Film(3)	LCD Area Using QD Film in EU (m^2)	Typical Cd Content per LCD Screen Area (g/m^2)	Total EU Cadmium (kg)
TV	157,333,925	26%	2%	818,136	0.05	41
Monitor	29,365,561	26%	3%	190,876	0.05	10
Notebook/Ultrabook	22,819,763	26%	7%	415,320	0.05	21
Tablets	12,174,293	26%	60%	1,899,190	0.03	57
Small displays (phones, etc.)	12,000,660	26%	20%	624,034	0.03	19
					Total	***147***

1. Based on forecasts from iSuppli in the Q4 2011 LCD Market Tracker Database and the Q4 2011 Small & Medium Display Market Tracker Database
2. Estimated based on EU's share of global GDP
3. Estimates for the potential use of QD film for the various segments

7.3.3 Roadmap for Substitution

Both applicants provide some information as to the time needed before a substitute (assumed to be in the form of a Cd free QD substitute) is assumed to become available in products in the market:

[78] 3M (2014d), Response to 4th round of clarification questions, submitted per email on 17.03.2014

[79] Op. cit. 3M (2013a)

QDVision[80] state that:

> *"The best alternative to cadmium in down-conversion materials for LEDs in display and lighting solutions at this time appears to be the III-V semiconductor down-conversion materials. QD Vision initiated a research effort into this space in 2006... III-V semiconductors (e.g. Indium Phosphide) do not contain cadmium, nor do they contain any of the other RoHS-regulated substances. Since 2006, QD Vision has devoted a considerable amount of funding and effort to creating cadmium-free alternatives... QD Vision continue to believe that such alternatives will indeed be viable one day, however, our increased effort has also lead to an increased understanding of the practical technical difficulties of implementing such a material substitution. Our own research has not yet provided a III-V (Indium Phosphide) semiconductor material which demonstrates performance properties (e.g. efficiency at operating temperature, colour saturation, colour tuning, and stability) that match those of the current II-VI colour converting materials that contain cadmium."*

QD Vision further explains the various steps that need to be undertaken and estimate how much time this would require. The information has been compiled in Table 7-3.

Table 7-3: Compilation of tasks to be performed and cumulative man-hours needed for completion, based on information provided in QD Vision (2013a)

Stage No.	Tasks	Estimated man hours needed
1	Increase in efficiency, approaching market acceptable quantum yields (>90% at operating temperatures); decrease in colour bandwidth (<40nm FWHM), and increase in colour tuneability and reliability.	10,000
2	All technical requirements including reliability might be met for first applications into displays (estimated 90% probability of success at this time).	25,000
3	Design-in and qualification of developed materials.	Time not indicated
4	Manufacturing ramp with supply chain; initial low volume market introduction.	
5	Market ramp.	

3M[81] provides an estimation that the replacement of Cd in commercial applications is to require a minimum of 7 years (by 2021). They explain that the only potential high colour quality substitute that does not have significantly higher energy consumption is Cd-free QD films. 3M estimates that Cd-free QD research (based on InP) shall reach the current colour quality and energy consumption performance with prototypes

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[80] Op. cit. QD Vision (2013a)

[81] Op. cit. 3M (2013a)

becoming available by 2019. Thus they expect full-scale commercialisation by July 2021.

7.3.4 Environmental Arguments

QD Vision[82] has submitted two independent expert statements on LCA (life cycle analysis). QD vision summarises, that the Linnunmaa document concludes that even in the worst case, this exemption renewal could not create any non-negligible environmental effects, while in the best case it may provide large net benefits in terms of reduction in energy usage, carbon dioxide emission, and cadmium waste and air emissions. The ERA Technology (Consultancy) LCA document includes a technology-by-technology comparison, and concludes that II-VI down-conversion technology has an overall less negative environmental and health impact, compared to other available products and technologies.

The Linnunmaa document[83] provides some quantitative information as to general Cd emissions in the EU, originating from various sources. The document also analyses the possibilities for emissions from the Cd in the appliances at various stages of the life cycle, though this is done mainly on a qualitative basis and is thus not further detailed here. A comparison is made between displays using LED backlighting with Cd QDs and displays using LEDs with rare earth metal down-conversion material, with the main difference regarding the energy efficiency of the various components. It is noted that the applicant has estimated that a reduction of energy consumption of up to 20% is possible with Cd QDs, where the display is operated with identical brightness, in comparison to the other technology, however this estimation is not further explained. A further comparison is made between Cd QD based lighting and fluorescent lighting on a qualitative basis. The document shortly mentions the probability of reducing Cd emissions related to electricity production from coal; however this reduction is not quantified.

As a public version of the ERA[84] document was not provided, its contents are not addressed in detail. However the consultants have received permission to cite the following statement, relating to the savings in Cd emissions that are enabled through the use of Cd QDs in displays:

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[82] Op. cit. QD Vision (2013a)

[83] Linnunmaa (2012), Expert statement on LCA of Cd vs. non-Cd options for colour conversion in displays and lighting systems, prepared for QD Vision, available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-2/A11_Linnunmaa_Expert_Statement_on_LCA.pdf

[84] ERA (2012), Review of RoHS exemption request for cadmium in QD lighting and displays – short LCA, submitted by QD Vision with original application for Ex. Re. 2013-2, pg. 6.

"Combustion of coal and oil emit Cd, Hg, Pb, As etc. Emissions from electricity generation are published by the European Environment Agency[85] *and the total EU electricity generated each year is also published by the EU*[86]*. From this data it is possible to calculate that avoiding generation of 1kWh electricity prevents the emission of 3.8Lg Cd.*

***Lighting**: QD Vision estimate that QD lighting consume 0.2W less than other types of lamp so during 50,000 hours in use will save 11.5 kW. Therefore a QD lamp that contains 0.003mg Cd will avoid emission of 0.044mg Cd.*

***Displays**: QD Vision estimate that QD displays consume 16.8W/h less than other types of display so during 30,000 hours in use will save 504 kWh. Therefore a QD display that contains only 1.5mg Cd will avoid emission of 1.9mg Cd."*

QD Vision further provided a socio-economic analysis[87] in which they state that the use of cadmium in II-VI colour converting material in displays can reduce the energy consumption of a TV by approximately 20%. The document estimates that the economic benefits associated with this energy saving are to be around 3 billion euro between 2014-2019, should the requested exemption be granted.

In the preparation of this document, an actual risk of exposure to Cadmium by workers during the recycling activities was assessed using the CHEmical Safety Assessment and Reporting tool (CHESAR) of the European Chemicals Agency (ECHA) and the Advanced REACH Tool (ART) model for estimating inhalation exposure. It is stated that the assessment of the hazards of Cd and the exposure during recycling activities of LCD televisions shows that the risk is controlled, meaning that no effect on the **health of the workers** involved is to be anticipated when taking into account the operational conditions and risk management measures, and the occupational exposure limit of 4 μg Cd/m³ as recommended by the Scientific Committee (SCOEL).

As for **environmental impacts**, the document states that savings in CO_2 emissions are expected in light of the reduction in energy consumption. To demonstrate this, an example is given of a TV using QD technology: "*Coal represents 26% of the total EU production of electricity and 1 kg of coal can generate 3kWh. By using a TV with QD it is possible to save 504kWh. It means that, by using one TV with QD optic, it is possible to save 43.7 kg*[88] *of coal over the lifetime of the television. The content of*

[85] http://www.eea.europa.eu/publications/eu-emission-inventory-report-1990-2010

[86] http://epp.eurostat.ec.europa.eu/statistics_explained/index.php?title=File:Electricity_Statistics,_2011_(in_GWh).png&filetimestamp

=20121128151011

[87] QD Vision (2013b), Socio-Economic Analysis - *Request for a Renewal of Exemption 39 under Directive 2011/65/EU (RoHS II) – Public Version*, submitted during the stakeholder consultation on 06.11.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-2/20131106_QDVision_Socio-Economic_Analysis_exemption_39_Public.pdf

[88] Calculation provided in QD Vision (2013b): (504kWh * 0.26) /3kWh/kg

carbon in coal normally ranges from 60% to 80%[89]*. The estimated reduction in CO_2 emissions over 2014-2019*[90] *has been estimated at 7,095,167 tonnes*." Savings for the environment are quantified using the Social Cost of Carbon (SCC) methodology along with the monetary saving for consumers in light of reduced energy bills and amount to 65,165,348 euro and 2,858,720,924 euro respectively.

3M[91] provide some further information in this regard, quoting:

> "*A case study of 55" LCD TVs has concluded that QD films result in an average power savings of 46% over existing LCD technologies.*[92] *This study also concluded that while the QD film itself contains approximately 39.7 mg of Cadmium per 55" display, the power savings from the QD film results in 149 mg of avoided Cadmium emissions from power plants, which in turn results in 110 mg of net environmental Cadmium avoided per 55" display during a 5.7 year operating lifetime (50,000 hours in use) or 35 mg avoided during a 2.9 year operating lifetime (25,000 hours in use). The EU televisions ecodesign study found that televisions in the EU are used on average 4 hours per day so 50,000 hours is equivalent to a lifetime of 34 years and 25,000 hours is equivalent to 17 years. Furthermore, the cadmium in the QD-LCD can be recovered safely by recycling whereas the cadmium and other toxic metal emissions from power generation contaminate the environment, enter the food chain, etc.*"

3M[93] elaborate on Cd emissions related to electricity generation, explaining that electricity consumption is said to be most significant in the use phase, as demonstrated by the life cycle assessment carried out during the televisions eco-design preparatory study, DG TREN Lot 5 (see http://www.ecotelevision.org/). Cd emissions related to energy production (and consumption) are however related to the energy source, with both the burning of coal and oil emitting Cd emissions. It is explained that coal can contain up to 300 grams per tonne, though most combustion emissions are abated through the use of scrubbers. 3M state that in the UK, in 2009, Cd emissions were still 180 kg, whereas data published for the EU[94] shows that in 2010, ~12 tonnes of cadmium, ~180 tonnes of lead and ~30 tonnes of mercury were emitted from EU energy generation and distribution. 3M then state that:

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[89] Quoted in QD Vision (2013b) as: Energy Information Administration, Quarterly Coal Report (EIA, 1994).

[90] Explained in QD Vision (2013b): Assuming that the carbon content in coal is 70%.

[91] Op. cit. 3M (2013a)

[92] Quoted in 3M (2013a) as: Quantum Dot Enhancement Film Cadmium Emissions Analysis, SourceOne, Inc., http://www.sourceone-energy.com/

[93] Op. cit. 3M (2013a)

[94] Quoted by 3M (2013a) as: http://www.eea.europa.eu/publications/eu-emission-inventory-report-1990-2010

"One source has calculated that for a 55 inch LCD-LED television using QD film, the emissions of cadmium from electricity generation are reduced by 110mg per year as compared to a similar performing standard LED-LCD television without QD film, but this uses data for electricity generated in the USA. Comparable data on cadmium emissions per kWh electricity generated in USA and in Europe exists but the accuracy is uncertain. Emissions will be different due to the different mix of generation sources and emission scrubber efficiencies."

Both 3M and QD Vision were asked to provide further information to clarify the calculations made concerning Cd savings that Cd QD applications enable in light of the significant energy savings associated with the product during the use phase. The data has been compiled into a table format to allow better understanding and comparison of the assumptions made and the information used by each applicant. This information appears in Table 7-6 in Section 7.6.5, followed by its review.

7.4 Availability of Alternatives

7.4.1 Possible Substance Alternatives

The applicants as well as contributing stakeholders have provided information concerning the existence of possible substance alternatives, namely cadmium-free QD technology.

In this regard QD Vision[95] state that:

"the most direct alternative would be cadmium-free quantum dots (CFQDs) which have been proposed and researched by many, including our company. To date, however, these materials do not have sufficient properties (narrowband emission, efficiency, stability under operating conditions) to be a viable technical alternative in the marketplace [see for example Kim et al., Appl. Phys. Lett. 101, 073107(2012); doi: 10.1063/1.4745844; Anc et al., JSS 2 (2) R3071-R3082 (2013) OR Annex 8; AND Yang et al., Adv. Mater. 2012, 24, 4180–4185 – Annex 12]."

As for possible substitutes, it is further explained that:

"*Light emission requires a material with an optically allowed excited state transition. Inorganic materials are to date the only material class that has the reliability to withstand LED operating conditions. Inorganic phosphors are currently in use, but do not have the desirable narrowband emissive properties (in most cases they are three times worse) that lead to LCD displays that can achieve the television colour standards (known as NTSC 1953), nor the optimized lighting efficacy…*
…group IV semiconductors such as Silicon don't generally emit light. To date, III-V semiconductors cannot be made into sufficiently efficient nor narrowband down-conversion materials, and hence do not have any net

[95] Op. cit. QD Vision (2013a)

beneficial properties over conventional phosphor materials. Similarly, the non-cadmium II-VI semiconductors (e.g. ZnS, ZnSe, ZnTe) are better suited for efficient emission outside of the visible spectrum, or have not been shown to be stable enough for commercial use."

In contrast, Nanoco-Dow, one of the contributing stakeholders, provides information concerning a possible Cd free QD substance. Dow Electronic Materials and Nanoco Technologies are working together towards the development and implementation of a Cd free QD technology for display as well as lighting applications. The Nanoco-Dow Cd-free QD material (herein after CFQD™) is said to be a unique, alloyed semiconductor matrix including both indium and phosphor, but different from InP QDs in composition and thus also in its properties. To summarize the information they have provided:[96]

- CFQD™ cadmium-free quantum dots are not made from indium phosphide. Although containing indium, they are made from a unique, alloyed semiconductor matrix with quite different properties.
- Their optical emission performance currently meets the requirements for commercial LCD screens, in terms of enhanced screen colour range and lifetime (at least 30,000 hours).
- The alloyed matrix of elements in CFQD™ quantum dots ensures that both the semiconductor band gap and the strength of the bonding interactions within the nanoparticles can be manipulated, reducing the strength of the quantum confinement effects and thus the range of wavelengths (i.e., the FWHM) emitted by a given size distribution of quantum dots. As a result, a given size distribution of CFQD™ quantum dots exhibits a significantly narrower wavelength distribution than that exhibited by the same size distribution of indium phosphide quantum dots.

Nonoco-Dow[97] provide further information concerning the performance of CFQD™ in on-chip and on-surface geometries. Though the on-chip technology does not exhibit the minimum reliability requirements at present, Nanoco-Dow provide results to show that CFQD™ can be used instead of cadmium QDs to significantly improve the colour gamut with respect to that of a rare-earth phosphor colour-converted TV. They state that:

- In *on-chip* experimentation the colour gamut was increased from 67% to 92% of the area of the United States National Television Systems Committee (NTSC) 1953 colour triangle.
- As for *on-surface geometries*, Nanoco-Dow state that "*CFQD™ have been incorporated into a film displaying 97% NTSC 1953 area (89% NTSC 1953 overlap)... The colour gamut is comparable to that displayed by the commercially available cadmium quantum dot LED TV. Although the colour*

[96] Op. cit. Nanoco-Dow (2013a)

[97] Op. cit. Nanoco-Dow (2013a)

gamut of this TV is reported as 100% of the NTSC 1953 standard, our internal measurements found that the maximum overlap with the NTSC 1953 colour triangle was just 91%...".

- Regarding the use of CFQD™ in *lighting applications*, it is stated that "colour-converted LEDs were prepared… using Nanoco's CFQD™ cadmium-free quantum dot material… Though the luminous efficacy was slightly lower than that for traditional LEDs with a similar CCT (correlated colour temperature), the CRI (colour-rendering index) for the CFQD™ LEDs was comparable or higher.

As for product availability on the market, Nanoco-Dow[98] explains that:

> "*Small-scale manufacture is currently undertaken in the UK and larger scale manufacture is scheduled to be online by mid-2014. A pilot launch of the first TVs using CFQD™ cadmium-free quantum dots is planned for the first half of 2014, with full commercial production expected within the following 12 months… We envisage that CFQD™ quantum dot-containing colour-converted LED lighting (SSL) will be available by the end of 2015.*"

7.4.2 Possible Design Alternatives

The applicants as well as contributing stakeholders have provided information regarding a number of substitutes, including:

- Compact Fluorescent (CFL) bulbs;
- Traditional LED LCDs with More Absorptive Colour Filters;
- RGB LEDs;
- Hybrid LEDs;
- OLED technology;
- Plasma technology.

Table 7-4 details some of the aspects mentioned regarding these possible alternatives by the different stakeholders. The various sources can be viewed for more detailed information.

[98] Op. cit. Nanoco-Dow (2013a)

Table 7-4: Comparison of Key Qualities and Performance of Possible Alternative Technologies

Technology	RoHS compliance	Energy efficiency	Colour performance	Additional comments
CFLs[99]	Contain Hg (1mg vs ~20ug in comparison with CdQDs*) **not clear what geometry and product category would be covered with the ~20ug estimation*	CFLs are also less than half as efficient as today's LED bulbs, and thus even less efficient in comparison with Cd QD technologies	-	Where Hg is used in vapour state, emissions can occur during use in case of breakage
Traditional LEDs with more absorptive colours[100]		The lower light transmission through the filters leads to higher device energy consumption – inefficiency is said to increase with high colour gamut targets.	Colour gamut target of ~70% NTSC leads to system efficiency reduction above 12%. Colour gamut target of ~100% NTSC, leads to system efficiency reduction above 45%	Highly absorptive colour filters are explained to be difficult to manufacture and are not scalable to all LCD applications (less suitable for smaller displays)
RGB LEDs[101]		Approximately 19% less efficient for a 70% NTSC colour gamut target and approximately 14% less efficient for a 100% NTSC target		Relevant for larger sized LCDs (typically notebooks and larger). Temperature and age stability are also mentioned to be problematic areas.
Hybrid LEDs	Currently not used in LCD backlight and so could only be relevant as an alternative in the future.			

[99] Op. cit. QD Vision (2013a)

[100] Op. cit. 3M (2013a)

[101] Op. cit. 3M (2013a)

Technology	RoHS compliance	Energy efficiency	Colour performance	Additional comments
OLED[102]		The energy consumption of an OLED display is estimated to be significantly higher than quantum dot film LCDs. This view is also supported by the stakeholders Touch Display[103] and Nanoco-Dow[104] for the products currently available on the market. However, Nanoco-Dow explain energy efficiency is linked with the image produced (predominant white/ black colour) being 3 times higher than that of a CdQD LCD (white) or consuming very little energy (black)	Ability to produce a high colour gamut area, even above 100% NTSC.	OLEDs directly convert electricity to light and can be patterned into red, green & blue addressable sub-pixels. BLU's and colour filters are thus not needed. Used mainly for small-size screens of smart phones, etc. - manufacture of larger size displays considered technically challenging at present
Plasma[105]		Consume significantly more power than do LCD displays for the same luminance (~ 2-4 times as much power)		Relatively thick and heavy and thus currently only available in sizes of ~ 40" (102cm) diagonal & above

Note: Reference to source applies to information provided for technology, as long as no further source is given.

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[102] Op. cit. 3M (2013a)

[103] Touch Display Research (2013), Contribution by Touch Display Research Inc. to stakeholder consultation, submitted 21.09.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-2/20130921_Colegrove_stakeholder_contribution_Re_2_5_OLED_TVs_are_high_power-final.pdf and http://touchdisplayresearch.com/?page_id=447

[104] Nanoco-Dow (2013b), Contribution made concerning Ex. Re. 2013-5 – answers to RoHS Consultation Questionaire, submitted by Nanoco Technologies Limited & Dow Electronic Materials on 06.11.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-5/20131106_Nonoco_Dow_Contribution_Ex_2013-5_Response_to_RoHS_Questionnaire.pdf

[105] 3M (2013a) quote the following sources regarding this statement: http://en.wikipedia.org/wiki/Plasma_display ; http://www.energystar.gov/index.cfm?fuseaction=find_a_product.showProductGroup&pgw_code=TV ; and http://www.displaymate.com/shootout.html#series1

7.5 Stakeholders' Contributions

During the stakeholder consultation, various stakeholders contributed information. As most contributions have been made regarding both exemption requests, the main aspects are detailed shortly below and regard both requests unless otherwise stated. Furthermore, both applicants submitted contributions in support of the other request. As most of the supporting information is reflected in the information provided in the sections above, such information is not further detailed below.

Touch Display Research Inc.[106] has submitted a contribution with some data as to the performance of OLED displays. In short it is explained that, at present, the OLED TVs which are currently on the market consume considerably more power than the equivalent LCDs. It is stressed, however that it should not be concluded from this statement that OLEDs won't succeed once further developed.

Nanoco Technologies Limited and Dow Electronic Materials have made a few contributions, objecting to both requests and providing information as to Cd free QDs as well as general information to QD technology and to possible lighting alternatives for displays. The key aspects are conveyed in the various sections above.

Merck[107] provides a contribution, explaining that they also manufacture displays and develop various materials and applications for display lighting. They claim worldwide recognition as a leading company for developing high end materials for future and current display technologies, working among others on a complete portfolio of materials for OLED displays. To clarify that the exemption is relevant for more than just the two applicants, they state that many other companies are developing applications similar to the CdQD applications described in the requests and that further product launches are expected soon. The use of quantum materials is said to be the only way at present to provide "*high-performance colour LCDs, which offer low power consumption compared to standard LCDs (approximately by a factor of two). Displays can be made with a power consumption which is by a factor of three less than the current OLED displays in the market with a comparable colour performance...this situation will not change at least until 2020*." Merck support both of the requests.

Nanosys Inc. Have submitted a letter of support and later also took part in a targeted stakeholder consultation in light of their being a technology partner of 3M. Parts of the information they have contributed are quoted above, and also reflected in the information provided in the above sections. Thus the key issue are not further detailed here.

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[106] Op. cit. Touch Display Research (2013)

[107] Merck (2013), contribution submitted by Merck in the stakeholder Consultation, regarding exemption requests 2013-2 and 2013-5, submitted on the 07.11.2013 and available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-2/20131107_MERCK_ContributionEx_Re_2013-2_and_2013-5_QD_RoHS.pdf

Blubox Trading AG[108] has made a contribution providing information about the technology they represent for integrated plants for recycling of mixed lamps and flat screens. Their contribution is meant to support that products containing the QD Vision technologies they claim can be safely and securely handled at end-of-life by the Blubox technology as required in the various EC rules and regulations. This technology is said to be installed in 3 locations across Europe and is fully contained, does not produce emissions, is safe to operate and almost fully automated and therefor cost-effective. Blubox was asked by QD Vision to conduct a series of tests which included processing the company's components through the Blubox system, to see how effective the handling of the components is. It was concluded that "*The components can be handled safely by the system operators and processed efficiently within the Blubox system. The dismantling of flat screens containing QD Vision's components is not required prior to processing and the potentially hazardous components...(Cd) are separated and accumulated in the fraction of fine particles in very small amounts, which can then be recycled or disposed of safely and securely...*".

Crytalpex Corporation; Ocean Nano Tech LLC; QLight Nonaotech LTd.; Pacific Light Technologies; Voxtel Inc.; and Navillum Nano Technologies[109] have submitted a general letter of support. The letter briefly reiterates that the exemptions are relevant for additional stakeholders involved in the development and manufacture of QDs as well as in the implementation of such technologies in lighting and displays. Further reference is made to the advantages afforded by QD technologies in solid state lighting applications in terms of energy efficiency and the respective emission reduction.

Lighting Europe[110] has submitted a contribution supporting the two requests. It states that *"...the main focus of the lighting industry is on developing energy efficient lighting with a high quality colour spectrum...",* and *"energy use is the main environmental impact of the product which takes approximately 90% share from the total negative lifecycle impact. The environmental advantage due to energy efficiency outweighs by far the much smaller impact of the materials used in the product. Therefore, LightingEurope strongly supports the use of innovative materials to increase efficiency and improve colour quality of lighting... LightingEurope members*

[108] Blubox Trading AG (2013), Blubox Trading AG Contribution submitted in the Stakeholder Consultation", submitted on 07.11.2013 and available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-2/20131107_Blubox_Contribution_Ex-Re-2013-2_QD_Vision_Letter_110513.pdf

[109] Crytalex et al. (2013), Support Letter Sighned and submitted in the Stakeholder Consultation by Crytalpex Corporation; Ocean Nano Tech LLC; QLight Nonaotech LTd.; Pacific Light Technologies; Voxtel Inc.; and Navillum Nano Technologies Concerning Requests 2013-2 and 2013-5, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-2/20131111_Ex_Re_2013-2_5_6_Support_Letters.pdf

[110] Lighting Europe (2013), Lighting Europe Contribution submitted in the Stakeholder Consultation", submitted on 11.11.2013 and available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-2/20131111_Lighting_Europe_WG_Material_support_letter_RoHSexemption39_Ex_Re_2013-2-5_final.pdf

have extensive expertise in the field of phosphor materials and lighting products and our experience is that the use of Cadmium II-VI colour converting materials will lead to improved colour rendering (CRI > 90), luminous efficacy (improvements over 20%) and lower overall system cost for LED lamps and luminaires… For general lighting applications, an alternative to Cadmium II-VI colour converting materials is the current use of AlInGaP red LEDs… Unfortunately, the red LEDs suffer from severe efficiency loss as the temperature increases. This limits the applications for use and increases the total cost as expensive drivers and heat sinks are necessary to correct for these ill-effects. In the display market, the green InGaN LED is insufficient to meet the efficiency requirements. Cost and complexity also negate the practical use of RGB LEDs in comparison to a colour converting material that can provide the same colour output."

Lighting Europe further raise a few questions regarding the market surveillance and the compatibility of an exemption wording to the capabilities of market surveillance operations:

- They raise concern as to which part of the LED is to be considered as a homogeneous material; and
- As to the experience of market surveillance authorities with regard to testing of LEDs, and complying exemption related allowances.

Lighting Europe further explains that setting a maximum cadmium content level for the exemption may result in additional administrative costs for industry and market surveillance authorities. They believe the environmental advantage of such an allowance to be questionable.

LightingEurope is asking *"whether it would be a better solution not to have limit value. As mentioned above, a threshold would create legal uncertainty due to uncertainties in interpretation of homogeneous material samples and also for variations in measurements of cadmium content using state of the art measuring and mechanical disjointing techniques."*

The **Swedish Ministry of Environment**[111] has submitted short statements for each of the requests. Concerning Ex. Re 2013-2, it states that *"The exemption applies to a use that was not available on the EU market when the previous exemption was approved. According to the description in the request for renewal of the exemption, the referred use is still not applied to any products on the EU market, why an exemption does not seem justified.*" As for Ex. Re. 2013-5, it emphasizes that "*In our opinion, the exemption should be specified more clearly, to avoid that it may be applied to uses in other screens than intended. We suggest that the specification should include a clear technical description of the type of screen referred to in the request*."

[111] Swedish Ministry of Environment (2013), Contribution to RoHS Stakholder 2013 Consultation 1, submitted 11.11.2013, available under http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/SE_Comments_on_stakeholder_consultation_RoHS_Aug_Nov_2013.pdf

7.6 Critical Review

7.6.1 REACH Compliance - Relation to the REACH Regulation

Chapter 5.0 of this report lists entry 23 restricting the use of Cd and its compounds in Annex XVII of the REACH Regulation. This entry restricts the use of Cd in mixtures and articles produced from a number of synthetic organic polymers referred to as plastic materials. Mixtures and articles produced from the named plastic materials shall not be placed on the market if the concentration of Cd (expressed as Cd metal) is equal to or greater than 0.01% by weight of the plastic material. Among others this list refers to PET which has been mentioned by 3M as the sheet material used to encapsulate the matrix in which the Cd QDs are present. From the explanations provided by 3M, the Cd in QD film applications is present only within the QDs contained within the matrix material and Cd is thus understood not to be present in the PET sheets in between which it is encapsulated.

In the context of the RoHS Directive, the important factor would be to understand if within the end product component, the two layers can be separated in order to understand if PET and Cd are in the same homogenous material or not. However to the consultants understanding the homogenous definition does not apply to the term used in Article 32 (the plastic material), nor is it generally applied in the REACH context. Thus, in the consultants' understanding, entry 32 of Annex XVII does not apply to the referred uses of Cd in QD films used for solid state lighting and display lighting applications.

Various Cd compounds are also specified for entries 28 – 30, which restrict the placing on the market of these compounds as substances and in mixtures. As the use of Cd in the relevant applications results in its presence in a component present within a product to be placed on the market and not a substance or mixture, these restrictions would not apply.

The consultants conclude that the use of Cd in QD films used for solid state lighting and display lighting applications, would thus not weaken the environmental and health protection afforded by the REACH Regulation. The same holds true for potential substitutes, namely Cd free QDs based on InP, which may apply as a substance alternative, as this substance is currently not specified in the REACH legal text. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

7.6.2 Scientific and Technical Practicability of Substitution

7.6.2.1 Elimination

In the consultants view, the information submitted, sufficiently demonstrates that where non-QD alternatives are concerned, there is a trade-off between the ability to achieve high colour performance (i.e., colour gamut) and the final energy efficiency of the product. This is understood to be the reason why application of alternatives with a wider band-width in products, results in either lower colour quality or higher energy consumptions. In some cases, additional obstacles for implementation may exist, the most relevant for substitution being the limited scalability of some of the alternative technologies, to allow covering the full product range. Though the estimations made by the applicants concerning differences above 10% energy efficiency in the comparison of Cd QD technologies with alternatives may be questioned, the information submitted by other stakeholders does not suffice to negate this claim:

- Some of the contributing stakeholders have provided their support to this point in general (e.g., Lighting Europe, Merk – see Section 7.4.2 for further information)
- The contribution of Nonoco-Dow, which do not support the requested exemptions, states that the "*current power consumption for OLED TVs is higher than for LCD TVs because it is not yet fully optimised. As the technology stabilises for mass production, power consumption is expected to improve dramatically, towards that of an LCD*." Though it can be understood that the development and optimisation of OLED technology may provide a sufficient alternative to Cd based QD technology, it also clarifies that the current state of technology is still insufficient in this regard. Touch Display Research Inc. has also referred to this point concerning the OLED used in displays already on the market.

Though OLED technology could further develop and become comparable in terms of both colour and energy efficiency with Cd QD technology, information is lacking as to how long this may take. It can thus not be concluded that OLED provides a practical alternative at present, neither can it be assumed at what time in the near future this may change.

It is further concluded that even if there are some specific applications where the QD advantages are less prominent than suggested, for the majority of the product range, the use of Cd based technology would provide end-products with qualities that are to be considered beneficial in comparison with other displays in terms of colour and energy performance. Based on the information made available CdQD technologies are understood to be at least 10% more efficient than the alternative technologies, in converting light photons into colour photons, in most cases showing a higher efficiency (cf. Figure 7-8 for further detail). This efficiency is understood to translate into energy efficiency, in cases where the same colour performance can be achieved, as with QDs the narrow band spectrum allows for more light photons to be translated into the image. Further information links energy savings with a reduction in Cd emissions, related to the reduction associated with producing energy from coal – this is further discussed in Section 7.6.5 below.

7.6.2.2 Substitution

From the information provided by the applicants as well as some stakeholders, it can be understood that substance alternatives, in the form of Cd-free QDs could in general be applied in displays in the same way that Cd based QDs are applied. Concluding as to the applicability of substance alternatives thus requires:

- Ensuring that alternative QD materials can provide at least comparable properties; and
- Clarifying that they are already available on the market and provide a comparable reliability to Cd based QD technology.

QD Vision[112] state that *"Reliability has been a major impediment to the inclusion of new light emissive materials in electronic equipment in general, and to date the reliability of cadmium-free alternatives is far from sufficient to meet the requirements of consumer electronic and lighting devices. However, given the lack of market acceptable cadmium-free alternatives, there is also a complete lack of publicly available reliability data on such material alternatives"*.

Nanoco-Dow have provided information as to a promising Cd-free QD material that is scheduled to come on to the market shortly, however as long as products are not commercially available, such alternatives could not yet be regarded as an available substitute, nor could the comparable properties and reliability be confirmed.

It should however be noted in this regard, that according to Nonoco-Dow and the applicants, once a Cd-free QD material is established in terms of its colour spectra, performance and reliability under the application conditions, its implementation into end-products is to be very similar to that of the present Cd-QD based products. In this regard, similar products, using the same QD geometry are understood to require the same resources in terms of production. Assuming it provides comparable properties, a RoHS compliant QD Cd free material would thus be understood to have an advantage as products should otherwise also be comparable. Furthermore, even if such products may result in a certain decrease in performance (colour gamut; energy efficiency) as soon as this alternative is viewed to be available, it should be considered if a certain level of lesser performance would be acceptable, to allow the elimination of a RoHS regulated hazardous substance.

7.6.3 Cadmium Reduction

The information provided by the applicants has been compared to determine the relative amounts of Cd required for different products, based on the various geometries. Table 7-5 is a compilation of this information to that end. It should be noted that the current Ex. 39 permits the use of 10 µg Cd per mm^2. As this allowance does not provide a further limitation on the thickness of the colour converting material, in practice, a range of concentrations may be applied.

[112] Op. cit. QD Vision (2013a)

Table 7-5: Comparative Cd Concentration and Quantities in Various Applications, Based on Applied QD Configuration – Compiled by consultants based on data provided by applicants in Annex 6 to QD Vision (2013a) and in 3M[113] (2014b)

Product	Required Cd concentration in the homogenous material		Resulting Cd amount in product		Comments
	On Edge (QD Vision)	On Surface (3M)	On Edge (QD Vision)	On Surface (3M)	
Large Display	1200ppm	90 - 145 ppm yellowish / low efficiency: 600 ppm (Approximate film thickness: 400 µm)	1.5mg (1500 µg)	TVs: 8.5-40.4 mg yellowish / low efficiency: 162 mg	TVs: Display sizes from 32" - 60"+ diagonal
Medium display	2000ppm	150 - 250 ppm (Approximate film thickness: 200 µm)	0.2mg (200 µg)	Monitors: 2.4 - 14.1 mg: Notebooks: 0.8 - 4.0 mg: Tablets: 0.07 - 1.4 mg:	Mid-size monitors, laptops, tablets Display size from 10-32" diagonal
Small display	3000 ppm	205 - 340 ppm (Approximate film thickness: 100 µm)	10ug	Mobile phones: 0.07-1.4 mg;	Smart-phones Display size around 3" diagonal
Lighting	Wide range of values: several thousand ppm	No information provided - 3M's focus has been on on-surface QD technology for display applications	20ug	No information provided - 3M's focus has been on on-surface QD technology for display applications	

The compiled information clarifies the complexity of addressing both on-edge and on-surface configurations with a single threshold limit. Though on-surface configurations use significantly lower concentrations, they result in a larger total Cd quantity in the final product. In contrast, using a quantified threshold would require specifying quantities for a large number of sub-product groups. This may also result in less motivation of industry towards further reductions where such thresholds are already met in specific end-products.

To add to that, as on-edge technologies exhibit an advantage in terms of the total Cd present in the end-product, the applicants were asked as to the ability of this technology to cover the full product range.

[113] Op. cit 3M (2014b)

A few limitations have been named in this regard:

- **Lifetime and Reliability** – Though 3M[114] state that"*…In contrast, the on-surface approach has the QDs remote to the LEDs, greatly reducing temperature and flux exposure. Therefore, the on-surface geometry has a significant advantage that results in increased system lifetimes that can be on the order of 4 orders of magnitude*"[115], the more important question here is if a minimum reliability is ensured. As QD Vision (2013a) refers to a *"lifetime of 30,000 operating hours"* for current products using its applied on-edge technology, translating to a 20 year service life if the product is to be used for 4 hours per day.

- **Form Factor and Bezel Size** – The on-edge geometry is not scalable to all display sizes. The fact that a QD element (a glass tube filled with a QD matrix material) has to be inserted into a device between the LEDs and the light guide plate (LGP) simply does not match with the slim, narrow form factors of many smaller LCD devices, particularly those of a 14" diagonal and less. Also some larger edge-lit TV's won't be able to incorporate quantum rails, as bezel design considerations would not allow for the extra space required. [116]

  Though the suggested 14" threshold may not be exact, the various information provided by QD vision in various documents supports that on-edge configurations cannot be applied at present in all displays in light of insufficient space. Though this aspect is not exclusive to the smaller displays, it is also clear that in such displays this is indeed more of an issue than in the larger ones.

- **Direct-Lit LCD Systems** – 3M[117] explain that one of the major drawbacks to the on-edge approach is that it only works in systems that use an edge lighting approach. In this regard QD Vision[118] states that *"Placing the QDs on the edge of a display is only useful if the LEDs are on the edge. Edge-lit design is implemented in essentially all mobile phones, tablets, and notebooks, but one can find some products that are not backlit this way in segments of monitors, all-in-one computers, TVs, and signage. Usually the industry uses the terms 'edge-lit' vs 'direct-lit' to make this distinction…We do anticipate that future developments in QDs will enable more efficient material usage in direct-lit designs than the current generation of on-surface technology. However, we would not characterize those potential future solutions as on-edge technology, but rather something that is much closer to on-chip technologies… On-chip configurations may impact both edge-lit and direct-lit backlighting approaches*

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114 Op. cit. 3M (2014b),

115 Quoted in 3M (2014b) as Coe-Sullivan, et al., JSS 2 (2) R3026-R3030 (2013)

116 Op. cit. 3M (2014b),

117 Op. cit. 3M (2014b),

118 QD Vision (2014b), Response to 3rd round of clarification questions, submitted per email on 24.02.2014

in the future. Again we emphasize that such solutions are not market-ready today."

It should thus be noted that a possible shift away from the direct-lit approach could have an impact on the application of on-chip developments as well as on that of other technologies used in such displays, including Cd-free QD applications.

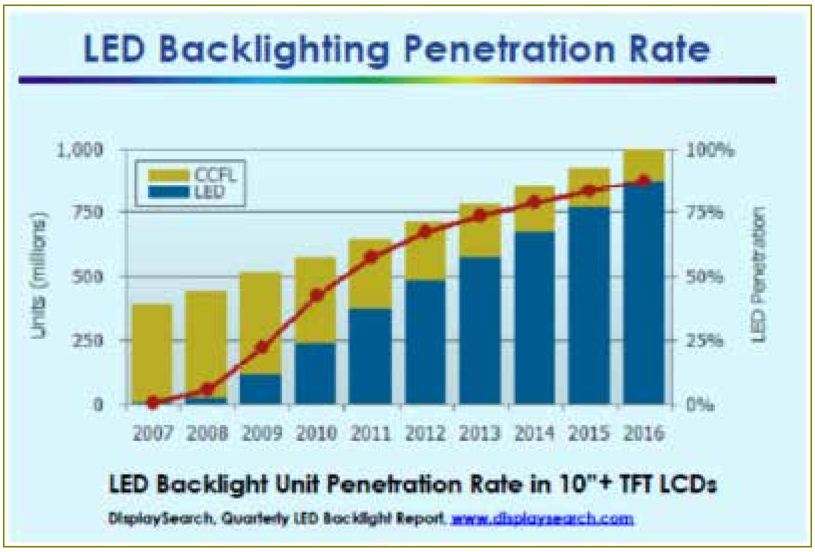
7.6.4 Market Aspects

Though it has not been discussed in detail by the various actors, it is understood that the future of the display lighting industry is to be significantly impacted, following the EU COMs ruling if to grant an exemption or not. The range of impacts may also vary as a result of the possible wording that such an exemption may have, and the range of products that would be respectively addressed.

In this context, an important aspect is to understand what part of the display market, the Cd QD technology displays are expected to represent in the coming years.

3M[119] have stated in this regard that they assume *"QDs to penetrate the display market in a similar manner to how other new technology introductions have gone within this industry."* To illustrate this comparison they provide Figure 7-9 to show *"how LED backlight technology is currently completing its penetration into the LCD industry, displacing CCFL*[cold cathode fluorescent] *backlight units. QD penetration into the LED backlit LCD industry in 2013 is best compared to the LED penetration rate (from the graph, above) as of 2007, and so perhaps we are 3-4 years from a 50% penetration rate."*

Figure 7-9: LED Backlight Technology Penetration in the LCD Industry



Source: 3M (2014a)

[119] 3M (2014a), Information provided to clarify open issues specified at a targeted stakeholder meeting held on 13.12.2013", submitted by the applicant on 17.01.2014

QD Vision has also provided the diagram above and a similar statement as to the possible penetration of Cd QD display applications on the market.[120]

To summarize, the provided information suggests that the penetration over the next 3-5 years could be in the range of 20-50% of the LCD market. As it is clear that such market penetration would have a significant impact on the use of alternative technologies being implemented in display products, it raises a question as to the severity of this impact on other segments of the lighting industry. As this point has not been raised by stakeholders, data is insufficient to go beyond raising the general concern in this regard.

Concerning CD QD in solid state lighting applications, QD Vision[121] state that "While QD Vision has several active collaborations with companies targeting lighting applications with our materials, we don't view it as likely that 2014 will see new product launches. 2015 and 2016 will likely be when QDs in this application and industry are again ready for introduction, with typical market growth expected thereafter." Further information does not allow concluding as to expected penetration of Cd QD technologies in the solid state lighting market – neither in terms of types of lighting applications, nor in terms of possible trends in market share.

7.6.5 Environmental Arguments

Information has been included by applicants as to the various environmental impacts.

Various comparisons of Cd QD technologies with other technologies have been submitted, including quantitative information and qualitative information. However, the detail of submitted data does not allow a full understanding of all aspects. Quantitative information usually regards a specific device, where as it is difficult to deduce from one device to the full range of application (e.g. from a large display to all displays etc.). It can be followed that when comparing devices with comparable colour performance certain benefits occur, especially regarding energy consumption. However, the detail of information does not allow concluding as to the range and significance of such benefits regarding the full product range.

Information was also provided related to the reduced Cd emissions that are enabled through the use of the Cd QD technology, in light of the reduced energy consumption attributed to such products. Both 3M and QD Vision clarify a reduction of Cd emissions to be expected, related to a decrease in manufacture of energy from coal. Coal combustion is explained to be a source of emissions of Cd, Hg, Pb and As, that cannot be completely abated. Both QD vision and 3M provide results of an example calculation of such savings as related to a TV:

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[120] QD Vision (2014a), Response to open issues highlighted during the targeted stakeholder consultation held on 13.12.2013, sent on 17.01.2014

[121] Op. cit. QD Vision (2014a)

- The 3M information refers to a savings of 149 mg Cd over 50,000 hrs of operation in comparison with 39.7 mg of Cd used within the display, i.e, a net benefit of 110 mg of Cd avoided. This is further demonstrated with a lifetime of 25,000 hrs for which the net benefit is estimated to be 25 mg avoided Cd.
- The QD Vision information refers to a savings of 1.9 mg Cd over 30,000 hrs of operation in comparison with 1.5 mg of Cd used within the display i.e., a net benefit of 0.4 mg of Cd avoided

The calculations resulting in these numbers, along with various explanations and references appear in Table 7-6 below.

Table 7-6: Calculation of Cd Savings from Reduced Energy Consumption through Product Use Phase. Compiled by consultants based on data from the following sources: Source One Energy Solutions (2011)[122], QD Vision (2014c)

QD Vision calculations			
	Unit	**Value**	**Notes and references**
Typical power consumption of 42" TV with QD Optic	W	67.2	20% reduction due to QD benefits
Typical power consumption of 42" TV with LED only	W	84	RG Phosphor is next best alternative
			20% power difference is conservative at NTSC spec
Basis	1 TV		
Lifetime of a TV	hours	30,000	Rated lifetime of our components
Power consumed by TV with QD optic	W	67.2	
Power consumed by TV w/o QD optic	W	84	
Savings with QD optic	W	16.8	84 – 67.2
Total energy saved over lifetime	kW-hr	504	(C13*C8)/1000
Cd content in TV Optic	mg	1.5	Conservative estimate for either 1H or 2V configuration of 42" TV
EU cadmium AIR emissions from	tonnes	12,228	http://www.eea.europa.eu//publications/eu-emission-

3M - based on Nanosys calculations for one source report, dated 2011			
	Unit	**Value**	**Notes and references**
Typical power consumption of 55" TV with QD Optic	W	129.46	
Typical power consumption of 55" TV - "current models"	W	239.83	
Basis	1 TV		
Lifetime of a TV	hours	50,000	
Power consumed by TV with QD optic	W	129.46	
Power consumed by TV w/o QD optic	W	239.83	
Savings with QD optic	W	110.4	
Total internal energy saved over lifetime	kW-hr	55185	
Electric T&D losses between the power plan and the TV	rate	6.14%	Average energy losses across the US - EIA, State Electricity Profiles 2008, DOE/EIA-0348(01)/2
Electric T&D losses between the power plan and the TV -	kW-hr	338.8359	Lifetime energy savings* electric T&D losses:

[122] Source One Energy Solutions (2011), Quantum Dot Enhancement Film Cadmium Emissions Analysis, prepared for Nanosys

QD Vision calculations			
	Unit	**Value**	**Notes and references**
electricity generation (2010)			inventory-report-1990-2010
Electricity generation by EU27 2010	TWh	3,181	http://epp.eurostat.ec.europa.eu/statistics_explained/index.php?title=File:Electricity_Statistics,_2011_(in_GWh).png&filetimestamp=20121128151011
EU Cd emissions per kWh of electricity generation	ug/kWh	3.8	C17/C18
Cd saved during display lifetime	mg	1.9152	C19*C15/1000
	Note: Savings estimated here across the TV's life time exceed the 1.5mg of Cd in a QD TV		

3M - based on Nanosys calculations for one source report, dated 2011			
	Unit	**Value**	**Notes and references**
calculated			**calculation added by consultant to check results**
Total electricity generation savings	kW-hr	5,857.3	
US - Grams Cd per KWh - emissions factor	g/kWh	5.56E-05	
US - Coal electricity Cd emissions	µg/kWh	55.58	According to the EIAf, over the last three years coal was used to generate 45.88% of the electricity in the United States.
US - Coal electricity Cd emissions	mg/kWh	0.0556	Unit conversion added by consultant to check results
US - Grid electricity Cd emissions	µg/kWh	25,5	For US
US - Grid electricity Cd emissions	mg/kWh	0.0255	Unit conversion added by consultant to check results
Cadmium emissions avoided per 55" QDEF TV	mg	149.38	Total energy savings* Cd emissions per kWh
Cadmium content of 55" QD Enhancement film	mg	39.70	
NET Savings	mg	109.68	

Though the numbers differ significantly in each case, it can be followed that products that consume less energy may contribute to the environment in light of the benefits derived from a lower demand for electricity. However, the information provided by the applicants does not allow concluding if this benefit would indeed justify the use of Cd in the application for a number of reasons:

- The applicants base their estimations for Cd emissions savings on the operation of the TV for a stated service life of 25,000 to 50,000 hrs. As the 3M information states, the EU ecodesign study found that televisions in the EU are used on average 4 hours per day. Though 3M continue to calculate that the service life of the TV would thus be between 17 and 34 years, the consultants cannot follow this logic. Regardless of the calculation itself, in the current society, it is doubtful if the average private consumer would indeed use the same TV for such long periods, especially if one assumes that image quality, energy efficiency and other parameters shall continue to develop tempting consumers to purchase new appliances. In this sense, it is concluded that only a portion of the related benefit could be considered to accumulate during the actual service time of the product.
- The calculations of Cd savings in both cases are based on the Cd emission factor that is associated with the production of electricity in the EU (3.8 ug/kWh as stated by QD Vision) or in the US (25.5 ug/kWh as explained in the calculation referred to by 3M). The Cd emission factors, for the most part, are the result of the rate of energy produced from coal, estimated to be 26% and over 50% for the EU and the US respectively. However, the factor 2 difference in the share of coal combustion from the energy mix does not suffice to explain the larger difference between the Cd emissions factors used. Cd emissions resulting from energy production depend on a few factors, including:
    - The Cd content of the coal being used (tied to the type and origin of the coal);
    - The retention of Cd in flue gas abatement technologies applied at the power plant (i.e., how much Cd remains in unavoidable emissions) as well as respective emissions that cannot be avoided to air as well as other media; and
    - The share of coal based energy production in the general energy mix.

  Therefore conclusions on Cd savings tied to Cd emissions from electricity production are complex and do not generally allow deducing the significance of environmental benefits.
- Another aspect of concern is the dependence of this estimation on a certain energy mix relevant for the EU. It is assumed that this mix shall not remain unchanged over the next 20 years or even over the next 10 years. This is further supported by information that both applicants provide to show that Cd emissions from electricity production have substantially decreased in the EU in the last decades. It is thus concluded that the estimations would need to assume a certain change in the energy mix over time which would likewise mean that annual benefits would change over time.

- It can be followed that from the alternative technologies, some are more efficient than others. A benefit related to lower energy consumption could also be calculated for other technologies and it is understood that some would also allow a certain degree of Cd savings. In this sense it remains unclear what portion of the Cd savings could only be achieved through the Cd based technology and what portion could be achieved through other technologies.

In general, though the consultants can follow that benefits, in terms of emission reductions and benefits derived from lower energy consumption during use, might be possible for the Cd QD technologies, the provided information from both sources does not allow quantifying the degree of this benefit, nor comparing it with the respective benefit that is relevant for other display technologies.

7.6.6 Legal Aspects

A number of stakeholders, as well as one of the applicants, have provided information concerning the applicability of the current exemption 39 (which QD Vision have requested to be renewed) to the various applications for which an exemption is being discussed. The current Ex. 39 reads:

> *"CADMIUM in colour converting II-VI LEDs (< 10 μg Cd per mm^2 of light-emitting area) for use in solid state illumination or display systems*
> *Expires on 1 July 2014"*

The current Ex. 13(b) has also been cited in this regard and is formulated in Annex III of RoHS as:

> *Ex. 13(b): "Cadmium and lead in filter glasses and glasses used for reflectance standards"*

A main concern that has been raised regards the applicability of these exemptions to the use of Cd in products already available on the EU market. In this context, it should be noted that the legal aspects of how stakeholders choose to interpret the various exemption wordings, and what products are as a result placed on the market, is beyond the mandate of the consultants. Though the consultants aim at providing a wording formulation that is clear and that limits use only to areas where this is understood not to be avoidable, what is later done in practice falls beyond the scope of this project. The importance of this issue thus regards the various considerations tied to the formulation of an exemption, should it be decided to grant a new exemption or to extend and or adjust the current one.

Furthermore, the possibility that the scope of Ex. 13(b) includes the use of Cd in QD applications has been raised, the main concern being that it provides no limitation for the use of Cd and could thus be interpreted by manufacturers as permission to use more Cd in QD applications as compared to the allowances prescribed in Ex. 39. Though it may be argued, how the Ex. 13(b) wording formulation is to be understood, the fact remains that this exemption existed in the RoHS 1 legal text with an even wider scope, at the time that the request leading to the current Ex. 39 was submitted and evaluated. The original formulation "Ex. 13: *Lead and cadmium in optical and* *filter glass*" still existed in the RoHS 1 consolidated version[123] of 26.02.2010 (as well as before) in which the original Ex. 39 makes its first appearance and the current narrower scope was only updated at a later time. It is thus understood that neither 3M nor the evaluating consultant assumed at the time that the applications mentioned were covered by an existing exemption, as a new exemption would otherwise not be needed. Though it could be that the existing formulation was not taken under consideration in the course of the review, the fact that a specific exemption was granted should clarify that the areas of application in which such materials were permitted for use fall under the scope of Ex. 39 and would thus not fall under the scope of other exemptions. As the scope of Ex 13(b) is narrower in relation to the earlier Ex. 13, the same logic should apply concerning the scope of the current Ex. 13(b), thus also not to be understood to cover Cd QD applications in displays and lighting.

A further area of concern, raised by Lighting Europe, regards the capability of market surveillance operations to sample the related homogeneous material, and to conclude unambiguously from measurement results if the Ex. is misused or not. This could also be relevant in the understanding of what component is understood to be the homogenous material in the various Cd QD applications. Regarding the first questions, in Annex 6 to their original application, QD Vision[124] mention *"direct elemental analysis (ICP-MS) of prototype products after dissolution in HF[*hydrogen fluoride]*"* as the method used to establish the actual quantities of Cd in prototype applications. Nanoco-Dow[125], in their original contribution, have referred to "...analysis of the resin by inductively coupled plasma mass spectrometry (ICP-MS)", which is understood to be the same method used by QD Vision. The US EPA refers to a detection threshold of 0.0001 mg/l for Cd in ICP analysis[126]. The consultants thus understand an analysis method to be available.

7.6.7 Possible Wording Formulation of an Exemption

Under certain assumptions, the EU COM may see an exemption as relevant. This section thus shortly discusses how such an exemption could be formulated.

As has been explained shortly above, specifying a threshold that would address both on–edge and on-surface configurations is a complex task. Prescribing a concentration would give preference to on-surface configurations, though these generally result in more Cd per end product. Prescribing a quantity limit would need to be compatible for a range of products, as within a product group, quantities depend not only on size but also on other provided properties such as colour spectra (e.g., white light versus warm yellow light). This shall require addressing a number of product groups and shall

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[123] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002L0095:20100226:EN:PDF

[124] Op. cit. QD Vision (2013a-1)

[125] Op. Cit. Nanoco-Dow (2013a)

[126] See "U.S. EPA's Methods and Minimum Detection Limits - List taken from the 2007 version of 40 CFR 141.23 to 141.25" at http://www.epa.gov/ogwdw000/ccr/pdfs/list_ccr_mdl_and_methods.pdf, last viewed 17.2.2013

result in a "split-exemption". Such a split could make future reviews of an exemption more complex, as has occurred in the case of the CFL exemptions. It should also be said in this regard, that at present a quantity threshold is preferable for on-edge applications, and could also result in a shift away from the backlight approach in displays in general. It is unclear if this shift is beneficial in the long term, despite its appeal in the Cd amount context in the short term.

The consultants understand the industry to be moving towards a reduction in the total amounts of Cd that need be applied in end-products. Both applicants have attested to their own research into Cd-free QD alternatives and it is also clear that research is still underway in the hope of delivering an on-chip geometry, providing the minimum reliability requirements of possible end-products. The application of Cd QD in displays has made its first day-view on the market (currently in a number of TV's and in a number of tablet applications) and is further expected to mature and develop with time. As with any technology, it can be assumed that this will lead to higher efficiencies, probably also in terms of the amounts of Cd that are to be applied. To further promote this direction, the consultants feel that if an exemption is to be granted, at present, it would be preferable to provide a simple formulation, allowing more room for development of the market in the near future.

The wordings listed in Table 7-7 have been mentioned in the context of these requests for exemption:

Table 7-7: Possible wordings proposed for Ex. Re. 2013-2 and Ex. Re. 2013-5

No.	Proposed by	Wording
1	Original Ex. 39 wording	*CADMIUM in colour converting II-VI LEDs (< 10 µg Cd per mm² of light-emitting area) for use in solid state illumination or display systems*
2	QD Vision – proposed change	Cadmium in II-VI colour converting material (< 10 µg Cd per mm² of light-emitting area) for LEDs for use in solid state illumination or display systems
3	3M – request for new exemption	*Cadmium in LCD Quantum Dot Light Control Films and Components*
4	Lighting Europe – proposed merge of requests	Cadmium in light control materials used for lighting- and display devices

As has been raised by some of the actors, the initial formulation of Ex. 39 (No. 1 in Table 7-7) is ambiguous and open to interpretation as to how Cd may be used in colour converting II-VI LEDs (i.e., it remains unclear if this formulation indeed covers the three possible configurations or if it regards only the direct use of Cd Qds in a layer applied directly to the LED as is the case in on-chip configurations). The No. 2 suggestion is also ambiguous, as *"colour converting materials for LEDs"* could still be interpreted to mean materials to be used in the LED component, where as in some cases the configuration makes use of the material in the proximity of the LED. The No. 3 suggestion only addresses on-surface configurations, though clearly, where other configurations can be used, this would result in the use of less Cd per product.

The No. 4 suggestion on the other hand allows the use of Cadmium in all light control materials. The main concern in this regard, is that the exemption could be used for an application that is not defined as a quantum dot application, consequently resulting in an extreme increase of Cd. This formulation would thus not serve the purpose of limiting the use of the exemption to a clear and limited area of application.

The consultants contacted both applicants to clarify the significance of various terms to the formulation of a possible exemption.

QD Vision[127] have proposed the following formulation: *"Cadmium in components for lighting and display applications containing downshifting cadmium based semiconductor nanocrystal quantum dots, where for display applications the cadmium per display screen area is limited to less than 20 ug/cm²"*, noting that *"the term "downshifting" as being the most specific and scientifically accurate term of art to describe the process of absorbing high energy photons and emitting somewhat lower energy photons. The term "down-conversion" is used in the scientific literature sometimes to describe processes wherein one photon is absorbed and two photons are emitted (not the case in the QDs considered in this consultation), and hence could cause some confusion. The term "colour converting" to our knowledge is not well-defined in the scientific literature, and hence has the potential to cause confusion with, for example, simple absorptive filter materials."*

3M propose[128] the formulation "*Cadmium in light control materials used for lighting and display devices*" explaining that "*The term "light control materials" would include both on-surface film (QD Film) and on-edge structure applications. An alternative acceptable term for "light control materials" would be "light converting materials". The term "light converting materials" also describes both on-surface and on-edge structure applications.*" In reference to a practical threshold for the use of Cd, they further explain that "*The lowest maximum concentration value appropriate for the on surface film application is 0.2 µg Cd per mm² (accordingly, a maximum would be expressed as <0.2 µg Cd per mm² of light emitting or light converting area in light control films for use in display systems)...For on-surface applications, it is essential that concentrations be stated in unit area, for example: "µg Cd per mm² of light emitting or light converting area*"

In the consultant's understanding, the threshold of 0.2 µg Cd per mm² (or *20 ug/cm²)* is acceptable by both applicants. As this threshold is a substantial reduction as compared to the current 10 µg/mm2, it would in any case be recommended that should an exemption be granted, this threshold be adopted. The wording that QD Vision propose is understood to address the various uses of cadmium in QD Dots for which the exemptions have been requested more precisely – "*downshifting cadmium based semiconductor nanocrystal quantum dots*" – and would thus allow limiting the scope of a possible exemption to the use of Cd in specific materials used for specific applications. The consultants see a further limitation of the use to components for use in the lighting of displays as beneficial.

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[127] Op. Cit. QD Vision (2014b)

[128] 3M (2014c), Response to 3rd round of clarification questions, submitted per email on 24.02.2014

As is explained below, the consultants would not recommend at present that an exemption be granted allowing the use of the discussed technologies in solid state lighting.

The following formulation is thus assumed to cover the various applications in display lighting and should be considered should an exemption be considered:

> *Cadmium in components for display lighting applications, containing downshifting cadmium based semiconductor nanocrystal quantum dots, where the cadmium per display screen area is limited to less than 0.2 ug/mm²*

Both applicants have been consulted as to the suggested wording to ensure that the Cd threshold still allows manufacturing display applications with both on-surface as well as on-edge QD configurations.

QD Vision[129] have raised a few points concerning the various adjustments made to earlier proposals, which in the consultants opinion are worth noting to enable better understanding of the new proposal:

- *"Specifying display applications as 'display lighting applications' – we would interpret this as inclusive of all formats of display backlight units, whether direct or edge-lit, and hence inclusive of our applications.*
- *Changing units to ug/mm2 from ug/cm2 – we assume it is desirable to utilize the same units as the original exemption 39, and hence this change is also not meant to change scope, but rather make the exemption changes easier to understand. The unit conversion is correct, and hence there is no change of scope and our applications remain covered by the proposed new language."*

It should be noted that further stakeholders were not consulted as to the applicability of this formulation, and more specifically of the threshold. From the information made available through the consultation process and by the applicants, it is understood that though other manufacturers may be active in the development of Cd Qd applications for display lighting, none of these have matured into actual products available on the market at present. Furthermore, as it is understood from both applicants that the proposed threshold is sufficient to allow development of the various configurations, other manufacturers would be expected to develop further applications complying with this threshold.

It is apparent that the application of QDs in display lighting is developing, both in the direction of further reductions that may be possible through on-chip configurations and through the possible application of Cd-free QDs. In the consultants view the availability of the exemption is thus to be reconsidered in the short term to ensure that the reduction of Cd is still motivated and/or that the use of Cd QDs is indeed still unavoidable. The duration of the exemption should be sufficient to provide the applicants with sufficient time to: research and prepare a comprehensive strategy for the reduction of Cd quantities/ its substitution, in the relevant applications, as well as to submit an application for exemption renewal should this remain relevant (at least

[129] Op. cit. QD Vision (2014c)

18 months before expiration). To accommodate the applicants with sufficient time in this regard, the consultants recommend a duration of 3 years.

7.6.8 Conclusions

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

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

Concerning elimination, it is understood that various alternatives exist, many of these already in use in display and lighting applications currently on the market. However, most of these alternatives are said not to provide comparable colour gamut performance as is possible with Cd QD products, or otherwise to result in significantly higher energy consumption. Though the colour aspect could be seen as an aesthetic aspect, the applicants have provided quantifications of this quality that allow it to be addressed on a comparative and thus technical basis. In this sense, if the colour gamut aspect is to be understood to suffice, alternatives could be understood to provide performance inferior to that of the Cd QD applications, thus meaning that elimination is not possible on the grounds that substitutes are not practical as the colour gamut provided would be significantly inferior to that of the discussed applications. The only alternative that is understood to provide comparable colour performance (e.g., OLED) is said at present to exhibit substantially higher energy consumption in comparison with that of the technologies at hand, and would thus be understood to be impractical on this level. As for substitution, the current research into alternatives relevant as a substitute in quantum dots used in lighting applications has not sufficiently matured in terms of implementation in products which are currently available on the market. Though the information provided by Nanoco-Dow is promising in terms of the launch of first products on the market in the coming year, as long as such a counter product is not available, a comparison would not be allowed. As a forecast is always liable to change, it remains to be seen at what time such alternatives shall become available in products on the market. At that time, concluding as to the comparable reliability shall also become possible. It should however be noted that if such products are indeed to come onto the market in the coming months, in light of the time needed for the final stages of granting an exemption, it could be that the fulfilment of this criterion shall change.

If to return to the alternatives relevant for elimination, the applicants, as well as a number of the stakeholders claim that CdQDs used in displays provide better performance in terms of energy efficiency when in operation. The low range of energy efficiency cited is above 10%, rising considerably in the comparison with most of the alternative technologies or in relation to the display size. In this regard, it is understood that the negative environmental impacts tied with the available alternatives would be higher than the positive ones in terms of energy consumption, though the range of difference is not clear. As other environmental aspects could change this balance (e.g. consumption of energy, raw materials and water in production), it cannot be concluded if and to what degree the third criterion is fulfilled. However in light of the colour gamut aspect highlighted above, the consultants understand at least one of the criterions to be fulfilled.

As for possible impacts on the lighting industry in light of significant penetration of Cd-QD technologies into the relevant product market range, applicant information suggests a penetration of 20–50% over the next 5 years. As data is lacking to confirm this estimation as well as to conclude as to the impact that this may have on the rest of the lighting industry, the consultants could not further conclude as to this aspect. That said, in light of the presence of Cd, a RoHS regulated substance in the relevant product, the swift penetration of the various CFL applications is to be kept in mind in this regard. An example of a product providing energy saving benefits as well as low costs, CFLs quickly dominated the lighting market in various areas. This aspect is understood to have provided industry with a strong market related argument concerning the applicability of substitution with Hg-free products, as is at least in part represented in the numerous exemptions listed in Annex III of the RoHS Directive to date.

Concerning Cd QD applications in solid state lighting applications, it should be emphasized that little information has been provided by the applicants in reference to such applications. Even more-so in terms of understanding how possible lighting applications may compare with other alternatives, for which the market provides a wide range of solutions. If in display lighting applications, colour gamut is understood to be a significant parameter for image quality, in lighting applications, other parameters are also of importance. The consultants do not feel that the provided information allows a comprehensive understanding of the various aspects, nor of the lighting areas for which applications are to be manufactured with Cd QD technology (consumer products, industrial lighting, long-life lamps etc.). Furthermore, it is understood that such products are only expected to become available on the market in the future, thus meaning that it is still difficult to state what part of the market range would be covered and what actual properties the Cd QD technology could provide that are not already provided with other technologies. In some cases, it would be relevant to shed light on the benefits of a new application in comparison with similar applications on the market (i.e., demonstrate to what degree such benefits justify the use of a RoHS regulated substance). However, the current information suggests that the use of Cd QDs in lighting applications is still in development and would not allow a sufficient comparison – either in light of the development which is still forthcoming or in light of the confidentiality tied to products still not on the market[130].

[130] As the RoHS exemption evaluation process is a transparent one, confidential information may not be used to support argumentation, either in support or in oposition of a request.

7.7 Recommendation

Concerning the use of Cd QDs in solid state lighting, the information provided does not allow a conclusion that such an exemption would be justified at present. The consultants therefore recommend not granting an exemption for Cd in QD applications to be used in solid state lighting. It should however be noted that such an exemption may be regarded as relevant within the next few years. This recommendation is thus made in light of the current limitations to clarifying the necessity of such an exemption and is not to be understood as the consultants support or objection to future requests.

For the application of Cd QDs in displays, the consultants recommend granting an exemption with the following wording:

> *Cadmium in components for display lighting applications, containing downshifting cadmium based semiconductor nanocrystal quantum dots, where the cadmium per display screen area is limited to less than 0.2 ug/mm²*
>
> *To expire 01.07.2017*

This exemption is recommended for a shorter period than that applied for, in light of the understanding that applications resulting in reduction of Cd quantities as well as Cd free substitutes are in final stages of research.

7.8 References Exemption Request 2013-2 and 2013-5

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3M (2014d), Response to 4th round of clarification questions, submitted per e-mail on 14.03.2014

8.0 Exemption Request 2013-3 “Lead in solders used in boards of heart-lung machines”

Abbreviations

CP centrifugal pump

HLM heart-lung machine

Declaration

The phrasings and wordings of stakeholders’ explanations and arguments have been taken directly from the documents provided by the applicant and other stakeholders as far as possible. They have been altered in cases where it was necessary to maintain the readability and comprehensibility of the text.

8.1 Description of Requested Exemption

Sections 8.1 through 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 Exemption Scope and Wording

MAQUET[131] (2013a) Cardiopulmonary AG requests an exemption for

> *“Lead in solders used in boards of heart-lung machines*
> *The exemption shall expire in 2017”*

Prior to the stakeholder consultation, the request was subject to a first plausibility check. Maquet[132] (2013a) addresses heart lung machines (HLM) and centrifugal pumps (CP) in its original exemption request, and requests two different expiry dates – December 2015 for the HLM, and December 2017 for the CP. As the scope of the proposed wording does not reflect these aspects, the consultants proposed the applicant to modify the wording for the requested exemption to match it with the scope and the requested expiry dates in the exemption request. Maquet[133] agreed to the following modified scope and wording:

> *“Lead in solders of printed circuit boards for:*
>
> *a) heart-lung machines, exemption to expire in December 2015*

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[131] MAQUET (2013a), document “EU-Commission-120122.pdf”, submitted by the Maquet Group, retrieved from http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-3/EU-Commission-120122.pdf; last accessed 30.12.2013

[132] Op. cit. MAQUET (2013a)

[133] MAQUET (2013b), document “Maquet_Confirmation-Exemption-Wording.pdf”, submitted by Rudi Kober, MAQUET Cardiopulmonary AG, via e-mail to Otmar Deubzer, Fraunhofer IZM, on 16.08.2013

b) centrifugal pumps that can be used as components of heart-lung-machines as well as stand-alone devices; exemption to expire in December 2017"

This wording was adopted for the stakeholder consultation.

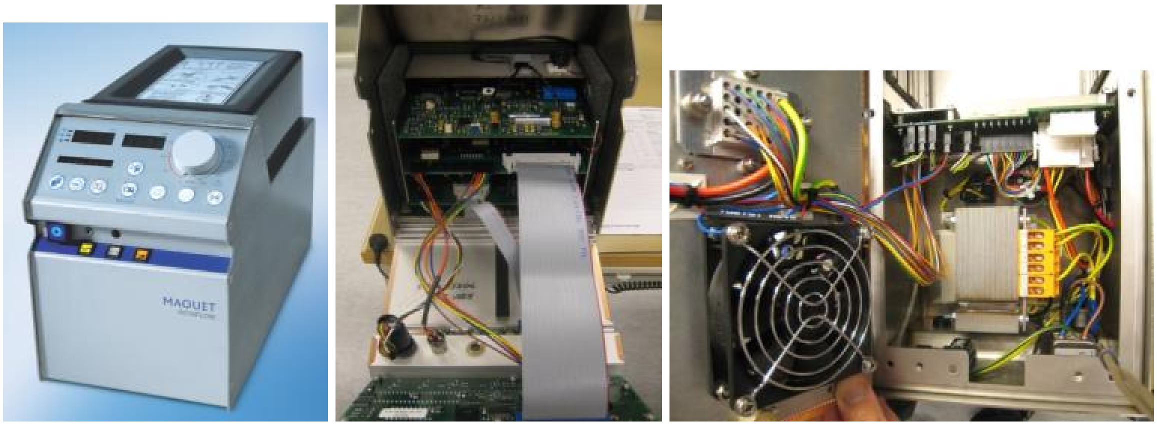
8.1.2 Technical Background of the Exemption

According to Maquet[134], the Maquet heart-lung machine (HLM) "HL20" and the centrifugal pump (CP) "Rotaflow" use a solder on printed wiring boards with 40% of lead content.

Figure 8-1: Heart-lung-machine

Source: Maquet (2013a)

Figure 8-2: Centrifugal pump



Source: Maquet (2013a)

[134] Op. cit. MAQUET (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.

The redesign of these devices in order to substitute the lead in the solder cannot be achieved until July 2014, and the exemption is therefore required until 2015 for the heart-lung machine and until 2017 for the centrifugal pumps.

8.2 Stakeholders' Justification for Exemption

Maquet[135] had submitted the exemption request in early 2013. The evaluation of the exemption request was started after the end of the consultation in November 2013. On 9 January 2014, the new exemption 33 was officially published[136] as amendment of RoHS Annex IV with the following wording:

> *"Lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators. Expires on 30 June 2016 for class IIa and on 31 December 2020 for class IIb"*

Maquet[137] thereupon officially withdrew the exemption request as the applicant interpreted the requested exemption to already be covered by the above new Exemption 33 in Annex IV.

8.3 Recommendation

The exemption is not required.

The applicant understands its exemption request to be already covered by Exemption 33 in RoHS Annex IV and therefore has withdrawn the exemption request.

8.4 References Exemption Request 2013-3

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[135] Op. cit. MAQUET (2013a)

[136] For the amendment, see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:004:0069:0070:EN:PDF; last accessed 7 March 2014

[137] MAQUET (2014), document "Maquet_Exemption-Withdrawal.pdf", sent via e-mail by Rudi Kober, Maquet, to Otmar Deubzer, Fraunhofer IZM, on 7.3.2014

9.0 Exemption Request No. 2013-4 “Mercury components used in high operating frequency (>50MHz) Intravascular Ultrasound Imaging Systems”

Abbreviations

ACIST	ACIST Medical Systems - Manufacturer of advanced contrast injection technologies for the cardiac cath-lab, hybrid operating room and radiology suite
ERC	Electric Rotating Connector
Hg	Mercury
IVUS	Intravascular ultrasound imaging system

9.1 Description of Requested Exemption

Sections 9.1 through 9.3 are heavily based on information provided by the applicant and other stakeholders and do not necessarily reflect the view of the consultants.

ACIST[138] has applied for an exemption for:

> “Mercury components used in high operating frequency (>50MHz) Intravascular Ultrasound Imaging Systems”

The applicant has explained that mercury is applied in an electro-mechanical component – electric rotating connectors (ERC) - used in medical device applications for intravascular ultrasound imaging[139]. In such systems, an intravascular ultrasound imaging system (IVUS) catheter is inserted into a patient’s coronary artery via the circulatory system during percutaneous coronary interventions. From within the coronary artery, the transducer within the catheter must be rotated 360 degrees in order to scan around the entire artery. [140]

The ACIST HD-IVUS system is a high gain (+60dB) wide band (60% fractional bandwidth) system that is extremely susceptible to noise sources. The use of mercury

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[138] ACIST (2013a), Original Request for Exemption from the RoHS 2 Directive, submitted by the applicant 26.04.13, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/ACIST_Medical_Systems_Exemption_Application__Directive_2011-65-EU__4-26-13.pdf

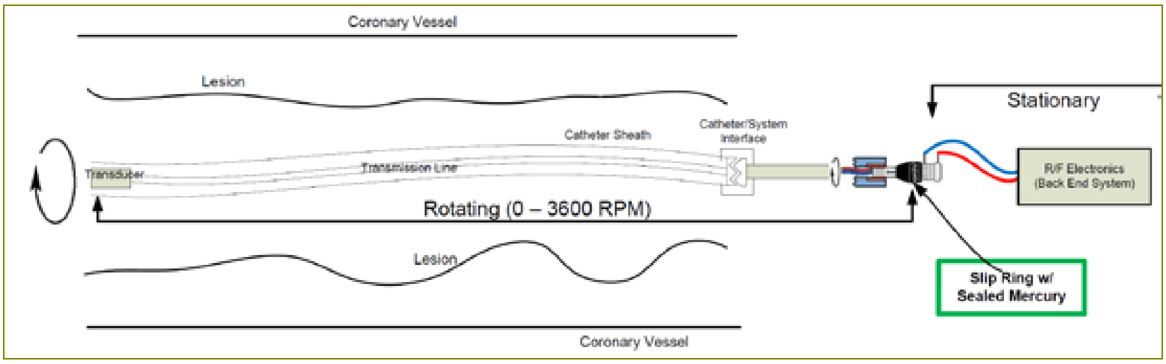
[139] Op. cit. ACIST (2013a)

[140] ACIST (2013b), Answers to First Clarification Questions , submitted by the applicant 31.07.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20130731_ACIST_Medical_Systems_Response.pdf

in the slip rings[141] (i.e., the ERC) virtually eliminates the RF noise generated by typical metal on metal slip rings as the metal contacts vibrate under rotation. The use of mercury in the slip ring also increases the contact area of the liquid metal on solid metal contacts thereby supporting the high peak power requirements of the ACIST HD-IVUS system. [142]

The use of the mercury for the conduction path provides a virtually noise free signal between a mechanically rotating ultrasound element (transducer) and stationary electronics. This connection transmits both a high voltage RF signal at specific frequencies and a low voltage RF reflected ultrasound signal at specific frequencies. This connection is maintained as the transducer is rotated at varying rotational speeds (0 – 3600 RPM). See Figure 9-1 below for illustration.[143]

Figure 9-1: System block diagram, indicating critical function performed by mercury based electric rotating connector



Source: ACIST (2013a)

ACIST further, state that devices using the mercury based slip rings, prevent significant electrical noise which would impact the image quality, possibly having consequences for patients. It is elaborated that they operate with higher pull back speeds, reducing catheter in-situ dwell times, which in turn reduce the risk of catheter induced ischemia.[144]

In a later communication, ACIST[145] explains that at present the ACIST IVUS HDi/Kodama is the only IVUS system that can operate at both the 40 and the 60 MHz frequencies. ACIST provides a comparison of system properties with IVUS models of other manufacturers (see Table 9-1 below). The higher frequency operation is

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141 ACIST (2013b) stated that to their knowledge, “the mercury slip ring component is not currently used with any other intravascular ultrasound imaging system (IVUS). All currently marketed IVUS systems utilize rotary inductive couplers (rotating transformers)”

142 Op. cit. ACIST (2013b)

143 Op. cit. ACIST (2013a)

144 Op. cit. ACIST (2013b)

145 ACIST (2014), ACIST Response to 2nd Round of Clarification Questions, submitted per email on 01.02.2014.

understood to allow obtaining higher resolution imaging beneficial for patients. Furthermore, system pullback speeds for the ACIST IVUS HDi, specified at 0.5, 1.0, 2.5, 5.0 or 10.0 mm/s. are explained to allow a range of dwell times between 130 to 16 seconds whereas other IVUS devices will have dwell times in the range of 130-70 seconds, depending on the applied pullback speed. ACIST reference two angioplasty studies indicating that ischemia generally occurs in patients undergoing balloon inflations in 30 to 60 seconds. This is to show that the possible reduced dwell times can assist in reducing the risk of catheter induced ischemia.

Table 9-1: Comparison of IVUS Manufacturers, Source: ACIST (2014)

Feature	ACIST HDi/Kodama	ACIST HDi/Kodama	BSC iLab /SR Pro	Volcano s5 / Revolution	SJM Ilumien / Dragonfly
Frequency / Wavelength	60 MHz	40 MHz	40 MHz	45 MHz	1300 nm
Energy Source	Ultrasound	Ultrasound	Ultrasound	Ultrasound	NIR Light
Axial Resolution	0.04 mm	0.06 mm	0.09 mm	0.100 mm	0.015 mm
Lateral Resolution	0.09 mm	0.14 mm	0.48 mm	0.620 mm	0.04 mm
Soft Tissue Penetration	> 2.5 mm	> 3.0 mm	> 3.0 mm	> 3.0 mm	> 0.8 mm *
Blood Penetration	> 3.4 mm	> 4.0 mm	> 4.0 mm	> 4.0 mm	< 1.2 mm
Frame Rate(s)	30 or 60 fps	30 or 60 fps	30 fps	30 fps	100 fps
Pullback Speed(s)	0.5, 1.0, 2.5, 5.0 or 10.0 mm/s	0.5, 1.0, 2.5, 5.0 or 10.0 mm/s	0.5 & 1.0 mm/s	0.5 & 1.0 mm/s	10 or 20 mm/s
Calibrated Frame Spacing(s) Available	0.02, 0.03, 0.04, 0.09, or 0.017 mm	0.02, 0.03, 0.04, 0.09, or 0.017 mm	0.02 or 0.03 mm	0.02 or 0.03 mm	0.1 or 0.2 mm
Calibrated Pullback Length	120 mm	120 mm	100 mm	100 mm	75 mm

· Soft Tissue Penetration with contrast injection (blood clearing)

*Sections 9.1 through 9.3 are heavily based on information provided by the applicant and other stakeholders. Alterations have been made mainly to ensure comprehension and to avoid repetition.

9.2 Applicant's Justification for Exemption

The applicant refers to www.mercotac.com, for further detail as to the properties of these components. In short the following points are explained:

The Mercotac[146] ERC uses *"a unique design principle unlike the sliding, brush contact of a slip ring. The connection is made through a pool of liquid metal molecularly bonded to the contact, which provides a low-resistance, stable connection. During rotation, the fluid maintains the electrical connection between the contacts without any wear."* The Mercotac connector is said to have the following benefits:

- Ø Unlike a slip ring, Mercotac connectors produce near zero electrical noise due to their unique design. The connectors do not degrade the signal over time;
- Ø Resistance through the rotating contact is less than one milliohm;
- Ø The connectors are maintenance free;
- Ø The connectors are more compact and cost far less than slip rings of equal capacity; and
- Ø Both current power and instrumentation signals can be sent through a single, compact connector.

ACIST[147] states that the manufacturer of the slip ring has completed reliability testing and recorded an average life of 828 days and over 2 million cycles before failure. For safety the device is designed to accumulate the mercury at the end of life in a containment area inside the body. In addition there are redundant sealing mechanisms to prevent external mercury leakage.

According to the applicant[148], the primary function of this electro-mechanical component is to provide transmission of radio-frequency energy through a mechanically rotating shaft to a non-rotating connector within the system. The slip ring is primarily designed to maintain signal integrity across the rotating boundary. The use of mercury within the slip ring increases the components current handling ability while reducing the contact noise that is normally present on non-mercury wetted sip rings. Prevention of friction is therefore an important attribute of the mercury slip ring because friction leads to wear and electrical noise which degrades the signal transmission properties of the component. The conductive liquid Mercury within the slip ring provides for lower friction than any solid-to-solid contact.

ACIST[149] details "the key clinical advantages that are enabled by the use of the mercury wetted slip rings within the ACIST HD-IVUS system are:

[146] See www.mercotac.com; last accessed 14.01.14

[147] Op. cit. ACIST (2013a)

[148] Op. cit. ACIST (2013b)

[149] Op. cit. ACIST (2013b)

- *The wide band width of the mercury wetted slip rings enables the ACIST HD-IVUS system to operate at both 40 MHz (which is used by current IVUS systems) and 60MHz on the same catheter.*
- *The 3600 rpm rotational speed of the mercury wetted slip rings enables high rotational speeds (60 frames per second), which enables high speed pullback, which reduces the risk to the patient of catheter induced ischemia and extends*[150] *procedure times.*
- *The low noise and low insertion loss of the mercury wetted slip rings, enables 60MHz imaging.*
- *The high power handling capabilities of the mercury wetted slip ring enables 8X oversampling and averaging to improve the overall system's signal to noise ratio by 9dB.*
- *Operation at higher imaging frequency allows higher spatial resolution with good signal-to-noise ratio. Better resolution images support better assessments of the vessel structure, thus potentially improving the treatment of the patient...* [and preventing] *incorrect placement of the stent, vessel dissection, perforation or stent stenosis...*
- *In addition... it is desirable to scan the entire length of the artery. This is accomplished by using a motorized system that mechanically pulls back the transducer inside the catheter at a controlled speed. As the speed of the pullback is increased, the rotational speed is also increased* [respectively]*...*
- *... higher pull back speeds reduce catheter in-situ dwell times, which reduces the risk of catheter induced ischemia. Catheter induced ischemia occurs when the presence of the catheter within a diseased artery reduces the blood flow sufficiently to the heart tissues...*

Therefore, the HD-IVUS system has been designed to acquire images at a high frame rate (60 frames per second), which requires a rotation speed of 3600 RPM. This frame rate allows pullback rates of up to 10 mm/sec. At lower pullback rates, a lower frame rate of 30 frames per second is adequate, corresponding to 1800 RPM...

The RF signal received from the transducer ranges from a maximum of 7 millivolts peak to peak (-40dBm) to about 0.20 millivolts peak to peak (-90dBm). The high end of this range (7 mV) is the bright reflection represented by metal such as stents deployed to provide support struts to prop open a diseased section of a blood vessel. The low end of this range (0.20 mV) represents the ultrasound reflection from soft tissue through the blood within vessel, and therefore, represents the typical reading for an intravascular ultrasound imaging system.

Impairment of ultrasound images begins when the noise source exceeds the noise floor of the system. The noise floor of the system, prior to signal averaging, is 0.20

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[150] In light of the duration quantifications later provided, the consultant assumes this mean that an extended procedure (imaged length) can be performed at a duration, in which similar devices would only be able to scan a shorter section of the artery.

millivolts peak to peak or about -90dBm. The noise from the mercury wetted slip ring contributes to the overall noise source of the system and is therefore less than 0.20 millivolts peak to peak. Noise from a non-mercury wetted slip ring is reasonably anticipated to be in the range of tens to hundreds of millivolts."

ACIST[151] explains that the component lifetime is compatible with the device lifetime. The slip ring is provided in a completely sealed housing and requires no maintenance. This component is designed to last well beyond the expected lifetime of the overall system and is therefore not designed to be replaced.

According to the applicant[152], the ACIST HD IVUS system is not currently marketed in Europe. The company estimates that less than an average of 75 components would be placed on the EU market through this application per year for the next 5 years, with each component containing 450 mg of mercury. Therefore, on an annual basis, the total amount of mercury placed on the EU market will not exceed 34 grams. All of this mercury is contained within the system, fully retrievable, and not emitted from the system.

9.2.1 Possible Substitute Alternatives

The applicant[153] claims that *"based on current technology, substitution of any other material for mercury within the slip ring is not possible because Mercury is the only conductive metal which is a liquid at room temperature. Use of any type of solid contact increases electrical resistance, decreases life through temperature build up and wear, introduces electrical noise through variation in resistance via mechanical non-uniformities, decreases bandwidth through introduction of resistance and limits power handling through the need to reduce surface area of the contact..."*

9.2.2 Possible Design Alternatives

In the information submitted by ACIST, a few design alternatives are mentioned, that could be relevant for eliminating the need for mercury in such applications:

- The use of silver graphite brush slip-rings
- The use of rotary inductive couplers (rotating transformers), which is practiced in other IVUS.

In short, the applicant[154] states that *"There is no viable alternative. Rotary capacitive couplers are not practical because of the high capacitive coupling required... they do not provide adequate bandwidth, power handling capability, low insertion loss and frequency response. Non-mercury wetted slip rings are not practical because they cannot handle the high peak current and they generate electrical noise that impacts the performance of the system."*

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[151] Op. cit. ACIST (2013b)

[152] Op. cit. ACIST (2013b)

[153] Op. cit. ACIST (2013b)

[154] Op. cit. ACIST (2013b)

The applicant[155] provides information concerning silver-graphite brush slip-rings, a possible design alternative to the mercury based electric rotating connectors. ACIST explains that:

> *"Typical silver-graphite brush slip rings exist in industrial and commercial use. They are used to transfer power, control circuits, analog or digital signals including data and electrical signals from a stationary to a rotating structure. Examples include generators, motors, alternators, wind turbines, and radio telescopes.*
>
> *A silver graphite brush slip ring introduces noise to the signal being transmitted for processing. In the application in question the signal generated must be virtually noise free to insure the equipment operates properly and provides an accurate picture of the area being imaged... Alternative design is not feasible that supports current system performance requirements for a low-noise, high-voltage transmit, and a low-voltage receive transmission at high rotational speed... Resistance through a typical slip ring is 10 - 20 milliohms. This design is incapable of providing a noise free signal that is required for the system to perform properly. Noise introduced into the system in this matter would be indistinguishable from actual reflected ultrasound signal, rendering the image produced unusable for medical imaging".*

As for rotary inductive couplers (rotating transformers), used in other IVUS, ACIST[156] asserts that compared to mercury based ERC, couplers have the following limitations (see source for further detail):

- "*Reduced bandwidth;*
- *Reduced peak power handling due to magnetic core saturation;*
- *Reduced high frequency performance due to available ferrite materials; and*
- *Higher insertion losses (-3dB of insertion loss at 47MHz with increasing loss above this cut off frequency; Insertion loss is more critical when imaging at 60MHz because of increased tissue attenuation at the higher operating frequency).*

The above limitations are extremely relevant to the ACIST HD-IVUS system due to system operation at both the 40MHz and the 60MHz bands, necessary to provide higher resolution IVUS imaging. In order to pass both frequency spectrums, the minimum bandwidth requirement for the system's rotating coupler is 30-74 MHz, assuming a 60% fractional bandwidth. The unique design advantages provided by the mercury wetted slip ring of high bandwidth (DC-200MHz), high power handling ability (3.0A), low noise, and low insertion loss (<-1dB) are critical to the ACIST imaging system design."

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

[156] Op. cit. ACIST (2013b)

Further alternatives have been named in a contribution made by Moog Components Group[157] (hereafter MOOG), including:

- Fibre brush technology;
- Composite brush technology (including but not limited to silver-graphite slip rings mentioned above); and
- Nobel metal monofilament brushes (gold / silver / palladium alloy based brushes).

From an application note[158] made by MOOG, it can be understood that besides the fibre brush technology, the various alternatives all have various limitations that would not allow them to be practical for use in the ACIST IVUS HDi. Fibre Brush technology is explained to "*feature a brush design composed of multiple small "fibres", or wires, culminated into a bundle that provide intimate ring contact, low brush force, low torque, and excellent conductive properties. The multiple fingers allow low contact force and subsequently low friction and very low wear rate. The multiple contacts also provide good current density properties for high current. These contacts are well suited for low noise and high current hybrid applications. Evaluation of this technology is certainly warranted in intravascular ultrasound imaging and fibre brushes are actually being used in similar applications... Advantageous features of this technology are very low electrical noise, excellent conductivity, and very long life*." Further details are available in the submitted documents.

ACIST[159] was thus asked to explain if this technology could provide a practical alternative for the ERC, eliminating the need for Hg in this application. They stated that:

"An analysis was performed on the Moog Product Catalogue for Slip Rings. All products were filtered for acceptability based on the following minimum performance requirements.

- *3A current rating;*
- *80V voltage rating;*
- *3600 rpm speed rating.*

Only the EC3848-6 meets the voltage and speed requirements and may be configured using multiple contacts to meet the current requirement, but the following specific concerns with the EC3848-6 arose during the assessment:

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[157] Moog (2013a), Contribution to RoHS Stakeholder 2013 Consultation 1 – Answers to Questionnaire, submitted 02.10.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20131002_Moog_Contribution_RoHS_Ex_Re2013-4_mercury_slip_ring_response.pdf

[158] MOOG (2013b), Application note sumitted by MOOG during the 2013 Stakeholder Consultation 1: Fibre Brushes – The Low Maintenance, Long Life, High Power Contact Slip Ring Material ", available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20131003_Moog_App_note_207_long_life_contacts.pdf

[159] ACIST (2014)

- *The published EC3848-6 spec sheets provide little data regarding RF performance. Only one parameter is listed that is of interest to an RF application. The 20 milliohms specification does not provide a complete picture due to being limited to the 5 rpm speed. This would have to be measured at operating speed, then the results would have to be shown in relation to frequency.*
- *Other missing information that would be required to characterize an inline RF device includes: Return loss vs frequency; Loss vs frequency; and Noise vs frequency.*
- *The EC3848-6 does not have a 3 amp per channel capability (rated at 1 amp per channel). It would require three contacts for each leg of our signal path to handle our 3 amp signal. This would impact noise susceptibility due to the transmission line differences between the Mercotac coax transmission line and the Moog solid wire flying lead and solder terminal design. To accommodate this difference, a complete redesign of the electronics would be required, and the make-and-break electrical contacts would still be subject to pitting and the reliability issues mentioned above.*
- *Routing the signal path through 6 individual slip rings will not only upset the critical balance of the catheter connection, but also expose the signal path to interference from the motor driver circuitry as well as the digital circuit boards inside the PIM. The motor and digital circuit boards are located within millimetres of the slip ring.*

Due to the above concerns and analysis, ACIST Medical Systems, Inc. does not find any Moog slip ring to be a candidate to replace the Mercotac slip ring."

9.2.3 Environmental Arguments

ACIST[160] claim there is negligible risk of mercury emissions that apply to the component at end of life. End of life for the component is defined as either when the component or the sub-system which contains the component fails, or when the system is taken out of use by the customer. The risk of any emissions is mitigated through ACIST Medical System's policy for disposal of the component which conforms to the WEEE Directive 2012/19/EU. ACIST's policy is to retrieve the entire sub-component from the customer and recycle and/or properly dispose of the system per applicable laws and regulations. The Mercury containing component will be recycled through the original manufacturer (Mercotac), who is committed to a long term recycling program.

[160] Op. cit. ACIST (2013b)

9.3 Stakeholders' Contributions

Two contributions were made during the stakeholder consultation.

The Swedish Ministry[161] of environment has expressed concern as to the proposed formulation of the requested exemption. They recommend the exemption be specified more clearly, to avoid its application by uses other than intended. It is suggested that the specification be available only to medical device applications for intravascular ultrasound imaging.

Moog Components Group[162], [163] (MOOG) provided a contribution opposing the requested exemption. The key issues addressed in the submitted information is detailed in Section 9.2.2 above and therefore not repeated in this section.

MOOG do not support the request for exemption and criticize the *"lack of rigor in evaluation of alternatives"* apparent in the exemption request. They further state that the negligible risk associated by the applicant regarding mercury emissions should be quantified and supported with *"a more rigorous analysis"*.

9.4 Critical Review

9.4.1 REACH Compliance - Relation to the REACH Regulation

Section 5.0 of this report lists entries 18 and 18a of Annex XVII of the REACH regulation, restricting the use of Hg compounds in anti-fouling or impregnation substances and in thermometers and other measuring devices intended for sale to the general public.

In the consultants' understanding, these entries do not apply to the use of Hg in IVUS devices, for which an exemption is requested. In other words, the use of Hg in question is not subject to any restrictions by REACH.

The consultants conclude that the use of Hg in IVUS devices for which an exemption has been requested does not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

9.4.2 Scientific and Technical Practicability of Hg Substitution

From the information submitted by the applicant and the various stakeholders, two issues appear to be paramount in the review of this request.

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[161] Swedish Ministry of Environment, Contribution to RoHS Stakeholder 2013 Consultation 1, submitted 11.11.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/SE_Comments_on_stakeholder_consultation_RoHS_Aug_Nov_2013.pdf

[162] Op. cit. Moog (2013a)

[163] Op. cit. Moog (2013b)

The first regards the possibility of replacing the mercury containing components in the IVUS device. In this respect, the main question concerns the practicability of substituting the mercury based electric rotating connectors with mercury free alternatives.

The second aspect is connected to the applicant's indication that this type of IVUS device is not yet marketed on the EU market. ACIST[164] states that approval of the requested exemption will allow it to immediately begin European regulatory submissions for full product commercialization. It is thus important to verify that other devices already available on the EU market do not provide the same function, or that the non-compliant device has a significant benefit over existing alternatives.

9.4.2.1 Substance Alternatives

The applicant's main explanation, concerning substance alternatives, identifies the qualities of Hg in comparison with other substances. The conductive properties of Hg and its liquid consistency at room temperature provide a plausible explanation why mercury cannot be substituted at present within this application.

9.4.2.2 Design Alternatives

A number of possible alternatives are raised by both the applicant and by MOOG, one of the contributing stakeholders. Most of these alternatives are explained to be impractical for the IVUS application for technical reasons:

- Elements used in current IVUS devices would not be compatible with the 60 MHz performance, resulting in a loss of analysis capabilities.
- Alternative slip ring technologies usually have higher maintenance requirements, cannot operate at the high rotational speeds required and produce significant electric-noise impairing imaging capabilities.

The only exception to this rule concerns fibre brush technology, which according to MOOG has a number of qualities that suggest it to be a possible design alternative. This includes a low wear rate (low maintenance requirements); high conductivity; suitability with low noise and high current hybrid applications; and acceptable high operating frequency in the operational range of 40 – 60 MHz

The applicant was thus asked to clarify if this specific kind of fibre brush technology could be a possible alternative. ACIST made a first screening of possible elements specified in a MOOG product catalogue to identify elements that would operate with three initial requirements: the current rating; the voltage rating and the speed rating.

A single component was identified and a first compatibility evaluation was performed by ACIST. The explanations provided as to the limitations of its applicability in the current device are detailed in Section 9.2.2 above and are viewed by the consultant as plausible. The main aspect is understood to be a technical non-compatibility, as the identified element lacks a 3 amp per channel capability and would require three

[164] Op. cit. ACIST (2014)

contacts for each leg of the signal path to handle the 3 amp signal. Though it could be argued that other described performance limitations would need to be observed in practice, it can be followed that a redesign of the electronics of the device would indeed be required, meaning that the element could not provide a practical substitute in the short term. It should however be noted that cooperation with a fibre brush technology supplier for the development of an element for use in the ACIST IVUS device, may allow for eliminating the use of the Hg based element in the future.

9.4.2.3 Comparability with Alternative Devices

The applicant provides a comparison of the ACIST IVUS device with other IVUS devices currently on the market. This comparison allows a better understanding of the unique capabilities that the ACIST IVUS device provides, including higher resolution (both axial and lateral), higher frame rates and faster pull-back speeds. Although the soft tissue and blood penetration are somewhat reduced when the device operates in the 60 MHz frequency, the standard 40 MHz operation is comparable in this regard, still offering the detailed benefits which are also provided in the 60 MHz mode.

Higher resolution is understood to increase the diagnostic abilities. To further address this benefit, ACIST references a number of studies[165] comparing between the diagnostic abilities of the 60 MHz device and other devices. To summarize the studies ACIST[166] states: "*Human clinical data is limited to one study (23 patients). This study achieved its end point of no device related adverse events and image non-inferiority to conventional 40MHz IVUS. Additional pre-clinical in-vitro and cadaver studies have been conducted at Stanford Hospital. Several abstracts and posters have been presented at the American Heart Association (AHA) and Transcatheter Cardiovascular Therapeutics (TCT) medical conferences. These presentations reported on superiority of 60MHz IVUS over conventional 40MHz IVUS for microscopic atherosclerotic plaque evaluation and thrombus detection*".

Furthermore, higher pull-back speeds are understood to allow shortening of the procedure duration, resulting in a lower risk of developing catheter induced ischemia. Though it is difficult to quantify the degree of benefit that the ACIST device provides in relation to other devices currently on the market, ACIST provided a comparison with the dwell times of other devices. This comparison shows that though the ACIST device

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[165] Cited in ACIST (2014) as:

1) Tanaka S, Sakamoto K, Yamada R, et al. PLAQUE ASSESSMENT WITH A NOVEL HIGH–DEFINITION 60–MHZ IVUS IMAGING SYSTEM: COMPARISON WITH CONVENTIONAL 40 MHZ IVUS AND OPTICAL COHERENCE TOMOGRAPHY. *J Am Coll Cardiol.* 2013;61(10_S): doi:10.1016/S0735-1097(13)61878-1 (Link: http://content.onlinejacc.org/article.aspx?articleid=1666095)
2) Tanaka S, Sakamoto K, Kitahara H, et al. TCT-661 Assessments of Lipid Plaque and Thrombus With a Novel High-Definition 60-MHz IVUS Imaging System: Comparison with Conventional 40-MHz IVUS and Optical Coherence Tomography. *J Am Coll Cardiol.* 2013;62(18_S1):B201-B202. doi:10.1016/j.jacc.2013.08.1410. (Link: http://content.onlinejacc.org/article.aspx?articleid=1759976)

[166] Op. cit. ACIST (2014)

can perform with comparable dwell times (130 / 70 seconds), it can also perform with significantly shorter dwell times (34 / 22 / 16 seconds), depending on the pullback speed applied. ACIST further quote a number of studies[167] to show that ischemia can develop in as little as 30 to 60 seconds, supporting that any reductions would allow reducing the risk of developing ischemia to some degree.

In light of the mentioned advantages of the ACIST device, the consultant can follow that the new application would have benefits over the current devices on the market that would contribute to the health of patients.

9.4.3 Environmental Arguments

As in the consultants understanding, the main justification for the request regards the impracticability of substitution, these arguments were not reviewed. The consultants would like to point out, however, that this neither indicates agreement nor disagreement with the applicant's environmental arguments.

9.4.4 Review of Stakeholder Contributions

The Swedish Ministry[168] of environment has expressed concern as to the proposed formulation of the requested exemption. The applicant was asked prior to the consultation as to further applications in which mercury based electric rotating connecters are in use. Further uses which would need to be RoHS compliant were not identified in the applicant's response, which was included in the documents made available for the stakeholder consultation. As stakeholders did not provide further information in this regard, it is concluded that the exemption is only required for IVUS applications. Thus the Swedish Ministry's recommendations are to be taken into consideration, should an exemption be recommended.

MOOG has contributed information regarding various slip-ring applications that are considered as possible design alternatives. From the contributed information, explained in Section 9.4.2.2, it is understood that only fibre brush technology may be a practical alternative. In light of the applicant's evaluation of possible fibre brush elements, it can be followed that at present this alternative could not replace the Hg based ERC.

[167] Quoted in ACIST (2014) as:

1) Catheter Cardiovasc Interv. 2013 Feb; 81(3):446-53. doi: 10.1002/ccd.23343. Epub 2012 Jan 10
2) EUR Heart J. 1987, Apr; 8(4):347-53: The evolution of mycordial ischemia during percutaneous transluminal coronary angioplasty
3) J Am Coll Cariol 1986 Jun;7(6):1245-54 Regional myocardial dysfunction during coronary angioplasty: evaluation by two-dimensional echocardiography and 12 lead electrocardiography

[168] Op. cit. Swedish Ministry of Environment (2013)

9.4.5 Conclusions

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

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

From the information provided by the applicant, it is understood that at present, elimination or substitution of mercury in the ACIST IVUS device is impractical. As the device is currently not available on the EU market, in the consultants' view, it is further necessary to establish that it has advantages over similar devices that are already available on the EU market. Though this device is understood to be the only IVUS device that uses the mercury based ERC, it is also understood to have a number of advantages over other IVUS devices available on the market, from which treated patients could benefit. It is thus concluded that:

- The ACIST IVUS has unique capabilities that could have a positive impact on patients health; and
- The Hg based ERC component within it could not be replaced with a RoHS compliant component at present.

Assuming that the EU COM recognizes the health advantages of the ACIST IVUS as significant in comparison with other IVUS devices currently on the market, an exemption from the RoHS substance restrictions would be justified, as one of the main criteria is fulfilled.

As for the duration of a possible exemption, the applicant has not provided any quantitative information as to the time needed before a RoHS compliant IVUS device, performing at both 40 and 60 MHz, could become available on the market. This was explained in light of the lack of an alternative that could replace the Hg based ERC component. It can be understood that in any case, developing an alternative shall require time, as shall the reworking of a possible alternative into the design of the device. However, as it cannot yet be ruled out that fibre brush technology could provide a basis for developing a RoHS compliant replacement for the Hg based ERC, the consultants understand this technology to be a candidate for further research. The consultants would thus propose that the EU COM consider granting an exemption for a shorter duration, allowing the applicant time to perform further research concerning the candidate technology and the time needed before a RoHS compliant device could come on the market.

As for the exemption wording, the applicant[169] submitted a reformulation of the proposed wording:

> *"Mercury components used in high operating frequency (>50MHz) Intravascular Ultrasound Imaging Systems."*

The consultants agree with the Swedish Ministry of Environment, that the formulation should be more precise, to limit its application to the use for which it was intended. In this regard, the consultant proposes a few changes:

- Ø To limit the exemption to category 8, as stakeholders have supplied no indication that mercury based ERCs are in use in other devices regulated by the RoHS Directive;
- Ø To further limit the exemption scope by stating the component of relevance, as the proposed formulation would allow the use of Hg in all components used in IVUS devices;

The following wording is thus proposed should an exemption be granted:

> *"Mercury electric-rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (>50MHz) modes of operation."*

9.5 Recommendation

Assuming that the EU COM recognizes the health advantages of the ACIST IVUS as significant, in comparison with other IVUS devices currently on the market, an exemption from the RoHS substance restrictions would be justified, as one of the main criteria is fulfilled. Under these conditions the consultants recommend granting an exemption with the following wording:

> *"Mercury electric-rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (>50MHz) modes of operation." 22 July 2019*

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

9.6 References Exemption Request 2013-4

ACIST (2013a), Original Request for Exemption from the RoHS 2 Directive, submitted by the applicant 26.04.13, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/ACIST_Medical_Systems_Exemption_Application__Directive_2011-65-EU__4-26-13.pdf

ACIST (2013b), Answers to First Clarification Questions , submitted by the applicant 31.07.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20130731_ACIST_Medical_Systems_Response.pdf

[169] Op. cit. ACIST (2013b)

ACIST (2014), ACIST Response to 2nd Round of Clarification Questions, submitted per email on 01.02.2014.

Moog (2013a), Contribution to RoHS Stakeholder 2013 Consultation 1 – Answers to Questionnaire, submitted 02.10.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20131002_Moog_Contribution_RoHS_Ex_Re2013-4_mercury_slip_ring_response.pdf

MOOG (2013b), Application note submitted by MOOG during the 2013 Stakeholder Consultation 1: Fibre Brushes – The Low Maintenance, Long Life, High Power Contact Slip Ring Material ", available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20131003_Moog_App_note_207_long_life_contacts.pdf

Swedish Ministry of Environment (2013), Contribution to RoHS Stakeholder 2013 Consultation 1, submitted 11.11.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/SE_Comments_on_stakeholder_consultation_RoHS_Aug_Nov_2013.pdf