Study to assess 2 RoHS new exemption requests: #1 for lead in bearings and bushes of professional-use non-road equipment engines; #2 for lead in solders used to construct and connect to Peltier thermal cyclers used for in-vitro diagnostic analysers that use polymerase chain reaction (Pack 11) – Final

Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation

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Disclaimer

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 Oeko-Institut and Fraunhofer IZM are not responsible for decisions or actions taken on the basis of the content of this report.

EUROPEAN COMMISSION

Directorate-General for Environment

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1. Executive summary - English

Under Framework Contract no. ENV.A.2/FRA/2015/0008, a consortium led by Oeko-Institut was requested by DG Environment of the European Commission to provide technical and scientific support for the evaluation of exemption requests under the new RoHS 2 regime. The work has been undertaken by the Oeko-Institut and Fraunhofer Institute IZM, and has been peer reviewed by the two institutes.

1.1. Background and objectives

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

- 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)(a) 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 Regulation (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, shall 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 since the entry into force of the Directive (21.7.2011), the consultants have undertaken evaluation of a range of exemptions in this work (new exemption requests).

1.2. Key findings – 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 summarised in Table 1-1. The reader is referred to the corresponding section of this report for more details on the evaluation results.

The – not legally binding – recommendations for the exemption requests for new exemptions (2016-1 and 2016-2) were submitted to the EU Commission by Oeko-Institut and have already been published at the EU CIRCA website on 20 December 2016. So far, the Commission has not adopted any revision of the Annex to Directive 2011/65/EU based on these recommendations.

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

Ex. Req. No.	Requested exemption wording	Applicant	Recommendation	Expiry date and scope
2016-1	"Lead in bearings and bushes of professional-use non-road equipment engines that meet the following criteria: I. 15 litre and larger total displacement professional use II. Less than 15 litre engines for professional	The European Association of Internal Combustion Engine Manufac-turers (EUROMOT)	Lead in bearings and bushes of diesel or gaseous fuel powered internal combustion engines applied in: I. Non-road professional use equipment and where engine total displacement is >15 litre; II. Non-road professional use equipment and where	For Cat. 11: 5 years; Add an exclusion of bearings and bushings falling under this

Ex. Req. No.	Requested exemption wording	Applicant	Recommendation	Expiry date and scope
	non-road equipment designed for use where the time between a signal to start and full load is required to be less than 10 seconds, for example in emergency, standby generators and peak shaving generators III. Less than 15 litre engines for professional non-road equipment designed for operation in harsh and dirty environments such as construction sites, quarries, mines, etc. for example, in drills, air compressors, rock crushers, irrigation pumps and tub grinders"		engines have a <15 litres displacement, designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds. III. Non-road professional use engines with <15 litres displacement, designed for operation in applications where regular maintenance is typically performed in an outdoor environment, such as mining, construction, and agriculture applications."	exemption to Ex. 6c of Annex III of the Directive.
2016-2	Lead in solders used to construct and connect to Peltier thermal cyclers used for in-vitro diagnostic analysers that use polymerase chain reaction	Roche Diagnostics Ltd.	Exemption denied	

2. Executive summary – French

Translation to be added in January 2017.

3. Introduction

3.1. Project scope and methodology

The scope of the project covers the evaluation of two requests for new exemptions. An overview of the exemption requests is given in Table 1-1 in the Executive Summary.

In the course of the project, a stakeholder consultation was conducted. The stakeholder consultation was launched on 14 April March and held for a duration of 8 weeks, thus concluding on 9 May 2016.

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 applicants' documents for each of the exemption requests, results of earlier evaluations where relevant, a specific questionnaire and a link to the EU CIRCA website. Contributions were not made to either of the exemptions.

The requests were evaluated according to the relevant criteria laid down in the RoHS 2 Directive, as shown in the Executive Summary in Section 1. The evaluations of each exemption request appear in the following chapters. The information provided by the applicants and by stakeholders is summarised in the first sections. This includes a general description of the application and requested exemption, a summary of the arguments made for justifying the exemption, information provided concerning possible alternatives and additional aspects raised by the applicants and other stakeholders. 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. [1]

3.2. Project set-up

Assignment of project tasks to Oeko-Institut, started 19 December 2016. The overall project has been led by Yifaat Baron. At Fraunhofer IZM the contact person is Otmar Deubzer.

[1] Cf. http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_11/Technical_Specifications.pdf

4. 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,[2] as well as for the evaluation of a range of requests assessed through previous projects in respect of RoHS 2.[3]

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[2] 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

[3] 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.

Furthermore, substances for which an authorisation or restriction process is already underway are also reviewed, so that future developments may be considered where relevant.

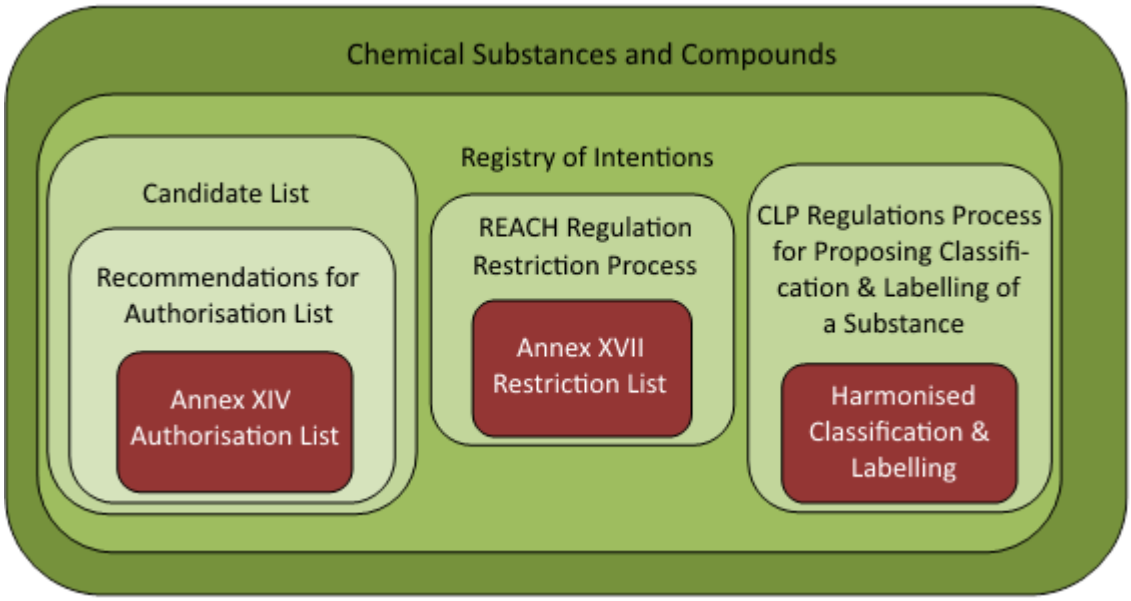
When evaluating the exemption requests, with regard to REACH compliance, we have checked whether the substance / or its substitutes are:

- 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 4-1 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.

Figure 4-1: Relation of REACH Categories and Lists to Other Chemical Substances



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

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 28 of September, 2015, the last amendment of the REACH Legal Text was dated from 28 May 2015 (Commission Regulation (EU) No 2015/830) and so the updated consolidated version of the REACH Legal Text, dated 01.06.2015, 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.

Relevant annexes and processes related to the REACH Regulation have been cross-checked to clarify:

- In what cases granting an exemption could "weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006" (Article 5(1)(a), pg.1)

- Where processes related to the REACH regulation should be followed to understand where such cases may become relevant in the future;

In this respect, restrictions and authorisations as well as processes that may lead to their initiation, have been reviewed, in respect of where RoHS Annex II substances are mentioned (i.e. lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE).[4]

Compiled information in this respect has been included, with short clarifications where relevant, in Tables 1-5, which appears in Appendix 1.

The information has further been cross-checked in relation to the various exemptions evaluated in the course of this project. This has been done to clarify that the Article 5(1)(a) pg.1 threshold-criteria quoted above is complied with in cases where an exemption is to be granted / its duration renewed/ its formulation amended/ or where it is to be revoked and subsequently to expire as an exemption. The considerations in this regard are addressed in each of the separate chapters in which the exemption evaluations are documented (Chapters 5 through 6) under the relevant section titled "REACH compliance – Relation to the REACH Regulation" (Sections 5.5.1 and 6.3.1 respectively).

[4] This review currently does not address the 4 phthalates, DEHP, BBP, DBP and DIBP, which according to Commission Delegated Directive (EU) 2015/863 of 31 March 2015, have been added to the Annex. Information regarding these substances shall be added in future reviews.

5. Exemption request 2016-1

"Lead in bearings and bushes of professional-use non-road equipment engines that meet the following criteria

- **15 litre and larger total displacement professional use;**
- **Less than 15 litre engines for professional non-road equipment designed for use where the time between a signal to start and full load is required to be less than 10 seconds, for example in emergency, standby generators and peak shaving generators;**
- **Less than 15 litre engines for professional non-road equipment designed for operation in harsh and dirty environments such as construction sites, quarries, mines, etc. for example, in drills, air compressors, rock crushers, irrigation pumps and tub grinders."**

Declaration

In the sections that precede the "Critical review" the phrasings and wordings of stakeholders' explanations and arguments have been adopted from the documents provided by the stakeholders as far as required and reasonable in the context of the evaluation at hand. Formulations were only altered in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and definitions

EUROMOT	The European Association of Internal Combustion Engine Manufacturers
EoL	End-of-life
Genset	Generation set
NRMM	Non-road mobile machinery
Pb	Lead
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment

5.1. Background

The European Association of Internal Combustion Engine Manufacturers (EUROMOT) has submitted a request for exemption for lead in bearings and bushes of professional use non-road equipment engines meeting certain criteria. EUROMOT (2015) explains that internal combustion engines are used as components of a variety of types of equipment that are in scope of the RoHS recast Directive (2011/65/EU, referred to as RoHS 2). Large size engines and those that are required to be used in harsh or demanding environments need to use bearings and bushes that contain lead in order to achieve satisfactory reliability.

It can be understood that alternative lead-free bushes and bearings exist. For example, these are explained to be successfully applied in engines that are specifically designed for road vehicles (excluded from the scope of RoHS). However it is explained that the different conditions that such vehicles experience allow for this application. EUROMOT (2015) states that research has shown that the lead-free bearing materials have a higher tendency of seizing, are less able to conform when misalignment occurs and are less able to cope with particulate debris in the lubricant. Engine manufacturers have carried out extensive bench tests to investigate these phenomena as well as field testing engines with lead based and lead-free bearings. The bench tests show that lead-based bearings give the best reliability and field testing clearly shows that in harsh and demanding conditions, engines with lead-free bearings fail on average much sooner than engines with leaded bearings. The following exemption was therefore requested on the basis of the inferior reliability of lead-free substitutes:

> *"Lead in bearings and bushes of professional-use non-road equipment engines that meet the following criteria:*
>
> *I. 15 litre and larger total displacement professional use*
>
> *II. Less than 15 litre engines for professional non-road equipment designed for use where the time between a signal to start and full load is required to be less than 10 seconds, for example in emergency, standby generators and peak shaving generators*
>
> *III. Less than 15 litre engines for professional non-road equipment designed for operation in harsh and dirty environments such as construction sites, quarries, mines, etc. for example, in drills, air compressors, rock crushers, irrigation pumps and tub grinders"*

EUROMOT request the exemption for category 11 equipment (EEE not covered by categories 1-10).

5.1.1. Amount of lead used under the exemption

EUROMOT (2015) estimates that the thin overlay coating of bearings and bushes contains up to 90% lead by weight and the inner lining material typically contains 20% lead by weight. Some bearings omit the outer overlay layer. Copper alloys containing up to 4% lead are used in some cases, but EUROMOT explains this application to currently be covered by RoHS exemption 6C of Annex III and do not discuss it further in the exemption request.

The amount of lead for products in scope of RoHS 2 varies, depending upon bearing; engine design and the engine displacement (larger engines typically utilize more lead due to larger component size). An audit of a representative electronic fuel injection diesel engine producing approximately 1800 kW of electricity revealed 176 grams of elemental lead to be present in the entirety of the 20 tonne assembly. Table 5-1 presents published worldwide market data representative of all power generation equipment, regardless of manufacturer, indicating the number of new engines placed on the market annually. (EUROMOT 2015)

Table 5-1: 2013 Diesel Genset market (annual turnover and units)[5]

2013 Diesel Genset Market, Parkinson's Data (annual turnover and units)						
	World		Europe		Europe % World	
Power Band (kVA)	Euro 000's	Units	Euro 000's	Units	Euro	Units
<7.5	910,928	608,705	54,295	33,266	6%	5%
7.5-250	3,357,914	507,664	408,023	50,241	12%	10%
251-750	1,989,620	71,025	242,811	8,453	12%	12%
751-2000	2,096,338	23,782	240,945	2,410	11%	10%
2000+	2,142,948	5,067	356,196	667	17%	13%
Total	10,497,747	1,216,243	1,302,270	95,037	12%	8%

EUROMOT (2015) estimates that 6.4 tonnes of lead are placed on the EU market annually in new engines, whereas, the global lead consumption is assumed to be 52 tonnes per annum in new engines. The quantity of lead used is based on the Parkinson Genset (generation set) data and calculated using the following assumptions:

- Non-Genset applications add 25% of numbers sold
- 5% of units of >275 kW are not "installed" (i.e. semi-mobile) and so are in scope of RoHS (>375kW installed are defined as large-scale fixed installations so excluded)
- Lead content of bearings is determined by chemical analysis of representative bearings.

It is noted that that professional engines may be rebuilt several times in their lifetime and the bearings replaced, i.e. old bearings are removed and recycled and new spare

[5] Submitted in EUROMOT (2015), referenced as based on Parkinson's data

part bearings installed. Lead from such spare parts is not included in the calculations. Results are as follows:

Table 5-2: Calculation of amount of lead in bearings used in engines in scope of this exemption request[6]

Power Band (kVA)	Average engine mass, kg	Average lead content from bearings (% by total engine mass)	Annual genset sales in EU market	Annual engine sales in EU market, add 25% for other applications	Percent in Scope of RoHS	Units in Scope	Engine mass in scope, kg	Annual Lead quantity into EU market, kg
7.5-250	447	0.0008%	50,241	62,801	100%	62,801	28,072,159	225
251-750	1020	0.0200%	8,453	10,566	47%	4,966	5,065,460	2,156
751-2000	4506	0.0200%	2,410	3,013	5%	151	678,716	2,715
2000+	7500	0.0200%	667	834	5%	42	312,656	1,251
							Total	6,346

In relation to the portion of bearings and bushes used for repair, EUROMOT (2016) explains that 2014 purchasing data from one of the representative engine manufacturers reflects that 22% of the bearings sold into the global market in a given year were sold for the purpose of rebuild and repair. It is common practice for half-shell bearings, for example those found in crankshaft main bearings and connecting rod bearings, to be replaced at an engine rebuild at overhaul. Other bearings and bushes, such as those found in connecting rod small end or gear bushes, will be evaluated at overhaul and either replaced or re-installed in the engine as is. The overhaul process is performed by disassembling the engine and replacing worn components, such as bearings and bushes, as needed, with the goal of reassembly to place the engine back into service. This process may be conducted not at all or up to 4 times for a large, heavy duty engine.

5.2. Description of requested exemption

EUROMOT (2015) explains that this exemption is requested for use of lead in professional use engine bearings and bushings. Only engines that use diesel and gaseous fuels for in-scope applications require this exemption. These engines have a wide variety of applications but are not intended solely for transport (vehicles) or for non-road mobile machinery as defined in RoHS 2. Lead-based bearings and bushes are needed to establish sufficient reliability in:

- all diesel and gaseous fuel powered internal combustion engines with a capacity of 15 litres and greater;
- engines with a capacity below 15 litres for professional off-road use, where the time between signal to start and full load is required to be less than 10 seconds. For example **emergency power** generators used for hospitals and uninterruptable power system (UPS) installations. It is essential that the time between power failing and being restored is as short a time as possible in these applications. Other applications are when the engine is connected directly to a flywheel or a drive belt.

[6] EUROMOT (2015)

- engines with a capacity below 15 litres for professional off-road use, designed for operation in **harsh and dirty environments**, such as for drills, compressors, rock crushers, irrigation pumps, tub grinders and other similar types of equipment. Harsh and dirty environments would include construction sites, farms, quarries, mines, some types of factories, desert regions, etc.

Such applications exclude commercial road vehicles and include industrial machinery where the engine provides power via a mechanical drive or by a hydraulic drive.

Figure 5-1: Examples of equipment using engines that would benefit from the requested exemption[7]

<table>
<tr><td colspan="2"> 

 </td></tr>
<tr><td colspan="2">Small, medium and large size generators that are used at fixed locations, sometimes on a temporary basis.</td></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td>Diesel engine powered compressor</td><td>Temporary power source with 6.7 litre diesel engine used in a construction site. Dirt and dust are an issue at these locations.</td></tr>
</table>

[7] EUROMOT (2015)

	
Leaf vacuum" is stationary in use, although it is moved between locations where it is used.	Almond tree shaker: operates while stationary and is not a form of transport.

Large capacity engines and engines for ensuring a supply of power

From the information provided, it can be understood that engines similar to those falling under the scope of the first two categories are used in various equipment which is excluded from the scope of RoHS. Some stationary engines would be installed in large scale fixed installations and in large scale stationary industrial tools, both excluded from scope, respectively through Article 2(4)(e) and 2(4)(d).

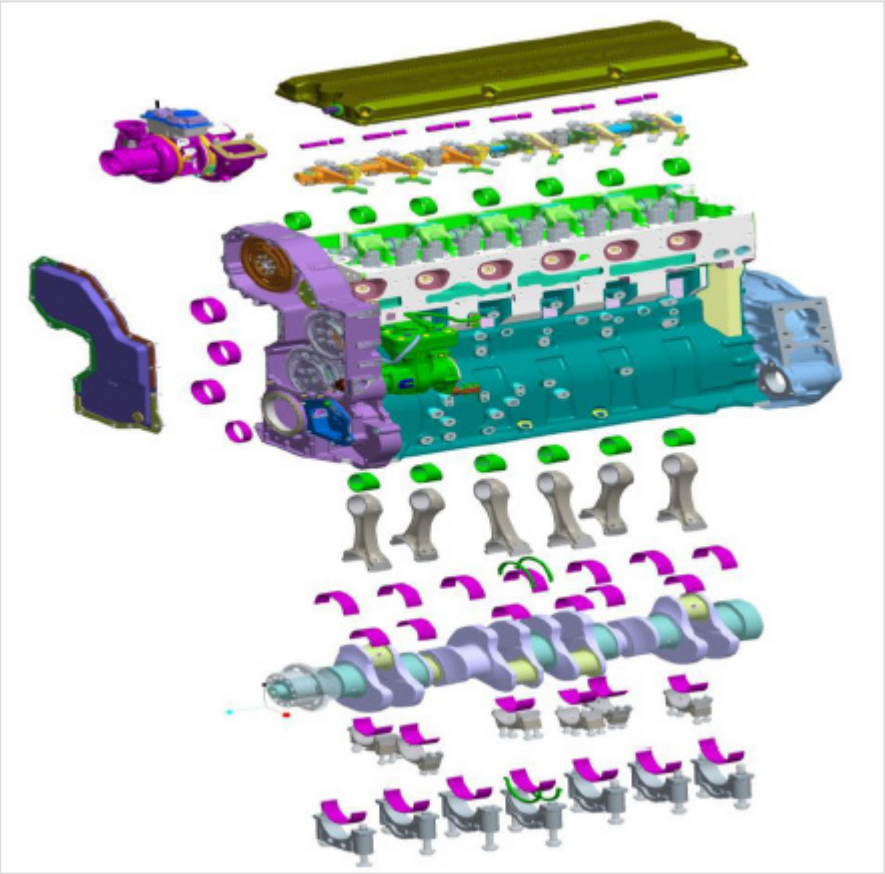
Similar engines designed for smaller fixed equipment do not benefit from these exclusions. A further exclusion for non-road mobile machinery also does not apply in cases, where machinery is moved in between operation locations, but not considered mobile during operation. (EUROMOT 2015)

Harsh and dirty environments

EUROMOT (2015) cannot define "harsh and dirty" environments quantitatively, as engine manufacturers do not use such values for engine design. Experience gained over many years by manufacturers, indicates the types of operating environment where lead bearings are needed to cope with the dust and dirt that is present. For example, the environment inside mines is especially harsh as the engine is operating in dirty air almost continuously. Quarries and construction sites are two other examples where the machinery itself may be the source of the dust in which it is required to operate. Engines of moving vehicles do not experience the same level of dust and dirt as equipment that operates at fixed locations. Vehicles usually move into and out of dusty areas so that for most of the time, they are not located in the harshest conditions, whereas a rock crusher, for example, creates dust and operates continuously in dusty air.

EUROMOT (2015) explains that each engine contains many different designs of bearings. An illustrative example engine is shown in Figure 5-2. The small end bearings shown in the example engine in Figure 5-2 are lead-free (green coloured), but in engines designed for harsh dirty conditions or for fast start-up applications, lead is necessary to achieve good reliability.

Figure 5-2: Parts of a typical internal combustion engine with bearings and bushes shown in pink in this example.[8]



Bearings are constructed in many different shapes, designs and sizes. Some are constructed in two parts, on each side of the crankshaft whereas others are press-fit in place, single piece round or more complex shapes. The types of bearings used that may contain lead in engines in scope of this exemption request include (EUROMOT, 2015):

- Turbo Bushings;
- Cam Follower Roller Pins;
- Gear Bushings;
- Connecting rod small end bushings;
- Connecting rod big end bearings;
- Crankshaft thrust bearings (bushings);
- Main bearings; and
- Gear bushings.

Larger size engines may also use lead in the following applications, although these are not used in automotive applications and in lighter duty applications:

- Rocker arm bushings;

[8] EUROMOT (2015)

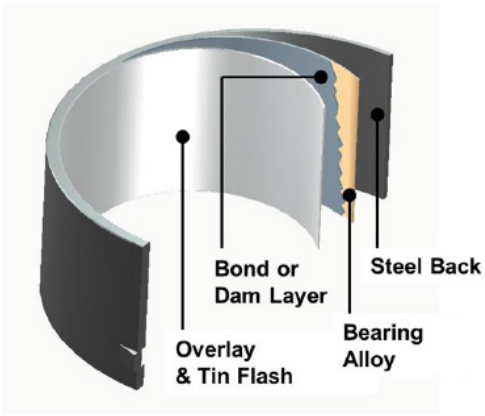
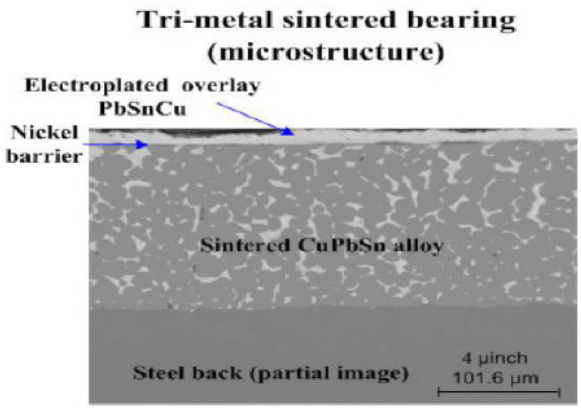
- Piston pin bushings; and
- Camshaft bushings.

The lead is present as an alloy element or thin layer in such bearings and bushings, where it provides conformability to help the bearing deal with slight misalignments that may occur following service or extreme high load operation. Lead coatings and alloys give bearings low friction and high load absorbing properties, which according to EUROMOT (2015) provide seizure resistance and conformability, as well as resistance to debris failures. Debris may be introduced during service procedures or from the environment in which the engine operates. As a thin coating, lead is explained to contribute a tribological interface to bearings and bushes, providing the required reliability and performance by absorbing damaging debris as well as providing conformability in critical bearings. These properties support reliability and facilitate service and rebuild of non-road engines to extend practical service life. (EUROMOT, 2015)

EUROMOT (2015) claims that there are currently no known materials suitable for a typical tri-metal bearing for professional heavy duty application, the very thin overlay may contain up to 90% lead and the bearing alloy may be up to 20% lead. Lead would typically comprise between 1 and 3% of a complete leaded bearing (based on total part weight). Lead from all these components would typically comprise less than 0.025% of a complete engine.

Bearings may be constructed in three layers as shown in Figure 5-3.

Figure 5-3: Illustrations of tri-metal bearings[9]

<table>
<tr>
<td> 
</td>
<td> 
</td>
</tr>
<tr>
<td>Construction of tri-metal bearing</td>
<td>Cross-section through tri-metal bearing with PbSnCu (up to. 90% lead) electroplated overlay, nickel barrier layer, CuPbSn alloy layer (typically with ca. 20% lead) and steel backing</td>
</tr>
</table>

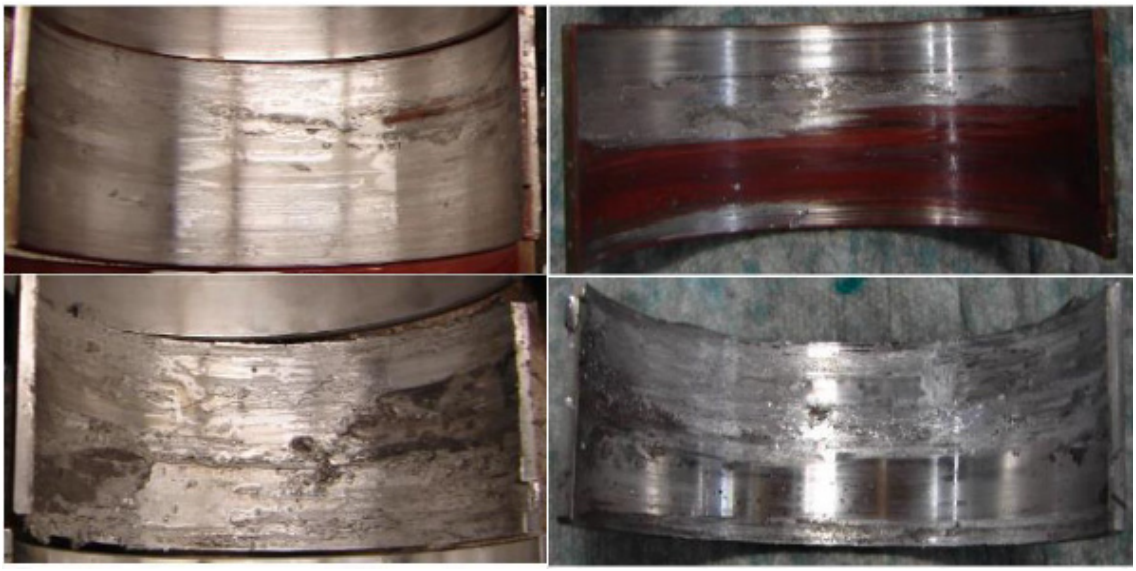
Bearings and bushes are required to have many important properties to provide the required performance and reliability for the intended conditions of use and lifetime. The specific requirements for each specific property depend on one or more of many variables

[9] EUROMOT (2015)

including engine capacity, conditions of use, conditions during rebuild and servicing, rotation velocity, loading, etc. The most important properties of bearings used in applications requiring this exemption are:

- **Seizure resistance and resistance to damage -** All bearings experience some metal-to-metal contact, especially when cold started and when lubrication oil has drained away. A good bearing material is one which will not weld easily to the shaft material. When the engine is running, especially at high speed, heat is generated at the bearing surface and this can cause the metal surfaces to melt and bond, causing the engine to seize. Seizure can cause catastrophic damage to an engine as parts such as connecting rods may fracture and can penetrate through the side of the engine.

Figure 5-4: Results of an experimental lead-free bearing seizure[10]



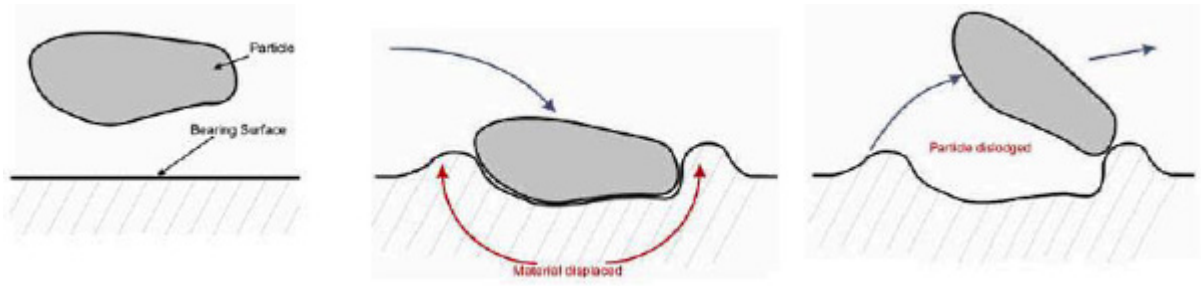
- **Conformability** – Conformability is the ability of a bearing to accommodate irregularities in mating surface. This is especially critical at start-up and the wear in period of an engine. At start-up, the metal surfaces likely have little or no lubrication. The soft properties of lead allow the bearing to conform to variation when there is metal to metal contact. Conformability is a soft property requirement of professional use engines, especially for larger size engines where very small variations in dimensions can result in misalignment of parts that require some conformability to enable the engine to function correctly. Because critical internal components of professional heavy duty diesel engines are generally many times larger than those found in passenger cars, components such as bearing journals, crankshafts, rods, and bearings must maintain their machining tolerances over greater distances and surface areas. Conformability is a term used to describe the ability of a bearing to "wear in" to the microscopic differences in internal mating surfaces. This may also be described as "misalignment" of the mating surfaces or components. Good conformability is a characteristic of soft material leading to permanent conformity, or materials with a low modulus of elasticity, result in elastic conformity. Poor conformability of the

[10] EUROMOT (2015)

bearing material can result in premature failure of the bearing and catastrophic failure of the engine.

- **Embedability** – This is defined as the ability of a bearing to accept debris or particles in the bearing clearance area. When these particles come in contact with the surface of the bearing, a localized impression is made in the bearing surface raising the bearing surface where the bearing material is displaced. When the peaks created by this displaced material interfere with the reciprocating parts, seizure can occur if the bearing material is too hard and will not conform to the reciprocating surfaces. Soot and debris are inherent in the operation of internal combustion engines. This debris in the form of metal shards or "chips" can be introduced during engine running-in, during servicing (dirt ingress as "clean-room" conditions are impossible in these environments), by deferring recommended service, and through general wear and tear as mating internal components conform to mating surfaces. The substandard embedability characteristics of lead free bearings is of particular concern as the ability to absorb dirt and other foreign particles is needed to avoid scoring and accelerated wear which significantly shortens engine lifetime. Usually, in metallic bearing material, good embedability is found in material with good conformability (i.e. soft materials). This is an ability to allow for dirt and contamination that can occur when engines are manufactured (but can be avoided) and during servicing, repairs and rebuilds (where dirt cannot be avoided). Many of the types of engine in scope of this exemption are used in industrial locations where there are significant amounts of fine dust that it is difficult to prevent from entry into the engine. This property is independent of engine capacity, speed or load and is especially important for all engines that are used and serviced in environments where dirt cannot be avoided.

Figure 5-5: Illustration of Embedability[11]



When particles come in contact with the surface of the bearing, a localized impression is made in the bearing surface raising the bearing surface where the bearing material is displaced.

- **Load Capacity** - A measure of the maximum hydrodynamic pressure which a material can be expected to endure. Important for some types of bearings and as mentioned above, high loads can cause misalignment, which lead based-bearings can more easily accommodate.

EUROMOT (2015) state that lead-based bearings give superior performance particularly to the first three properties: compatibility[12], conformability and embedability.

11 EUROMOT (2015)

EUROMOT (2015) explains, in relation to overlay materials, that an ideal material will be relatively soft to provide conformance and embedability, but will need a higher melting point to avoid seizure. In general, soft materials have low melting temperatures so a compromise is needed. Table 5-3 is provided to show the comparison of these two properties for various metals that can be used as bearing and bushing overlay materials.

Table 5-3: Melting point and hardness values of metals used in overlay materials[13]

Metal	Melting point °C	Brinell hardness (MPa)
Lead	327.5	38.3 MPa
Bismuth	271.4	94.2 MPa
Tin	231.9	51 MPa
Indium	156.6	8.8 MPa

Note: A higher Brinell value shows that a material is harder and a lower value that it is softer.

Further data is also presented in the request application to compare the Rockwell hardness of a lead alloy to that of lead-free alloys, further showing that the lead-based alloy is a softer material, important in relation to embedability for trapping debris.

In relation to lining materials, it is explained that most lead-free lining alloys are copper based with tin plus bismuth or zinc, but copper nickel silicon alloy is also used as a bearing alloy. Tin, nickel and bismuth all make copper significantly harder and less ductile so the lead-free lining alloys will all give inferior conformance performance. Alloys with these elements added are however stronger than pure copper, but nickel and bismuth and to a lesser extent zinc can reduce thermal conductivity, which is important for preventing overheating at the bearing surface to prevent seizure. According to EUROMOT (2015), lead gives good lubricity and combined with moderately good thermal conductivity makes it a good choice of bearing alloy. Good lubricity is very important for bearings, especially during a cold start when there may be no oil on the bearing surface. The only other metal that gives reasonable lubricity is bismuth in bismuth bronzes which can be polished to a very smooth and bright surface. However bismuth bronzes are less ductile than lead bronzes due to their higher strength and hardness.

12 This term is not mentioned elsewhere in the application. Based on the order of appearance of the detail for the various properties, the consultants assume that seizure resistance and resistance to damage is meant.

13 EUROMOT (2015) refers to the following source: Brinell hardness of metallic elements from http://periodictable.com/Properties/A/BrinellHardness.v.html

5.3. Applicant's justification for exemption

5.3.1. Possible alternatives for substituting RoHS substances

EUROMOT (2015) state that research carried out during the last 20 years has developed lead-free bearings that are used in internal combustion engines which are mainly used in road vehicles falling under the scope of Directive 2000/53/EC (End of Life Vehicles) and in larger commercial vehicles. This practice has been achieved only by utilising almost "clean-room" conditions for engine manufacture, service and rebuilds because lead-free bearings and bushes are much more susceptible to damage by dirt. Many examples of lead-free bearings obtained from bearing manufacturers have been tested in the types of engines that are covered by this exemption request, but the results show that they give inferior performance and reliability that is unacceptable for the intended uses.

Lead-free bearing materials have not matured to the required level to meet the reliability requirements of diesel engines used in professional applications. Additionally, because these formulations and constructions are proprietary to the bearing manufacturer, competition will be reduced. Availability will depend upon the given suppliers ability and willingness to produce. All these conditions will have direct effect on the consumer in terms of cost and availability of spare parts.(EUROMOT, 2015)

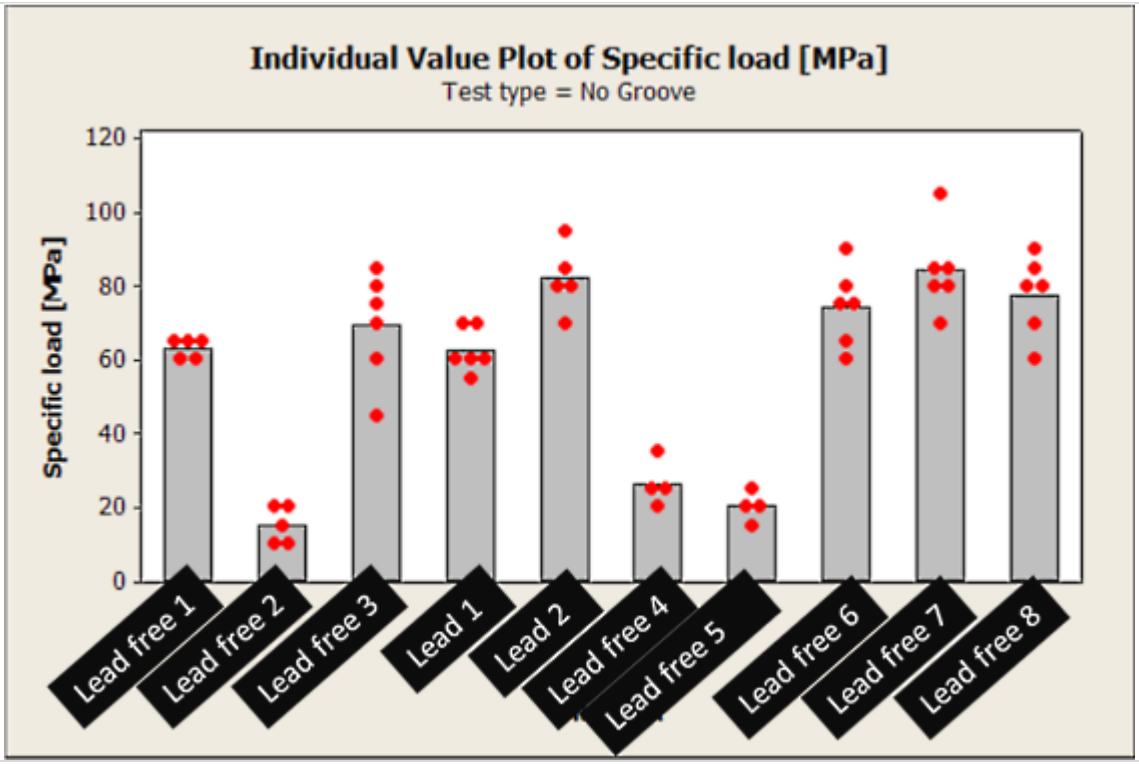
EUROMOT explain that tests of new materials or components for engines are carried out in two stages. The first stage is bench testing, used to simulate the conditions seen in service. Though accelerated test conditions, applied in bench testing, cannot truly reflect real engine conditions, they assist in eliminating bearing materials that will fail engine tests. In other words, bench tests are used to identify bearings that may be suitable and so are worthwhile for the second stage testing in engines to assess the new design under realistic conditions.

Bench testing results

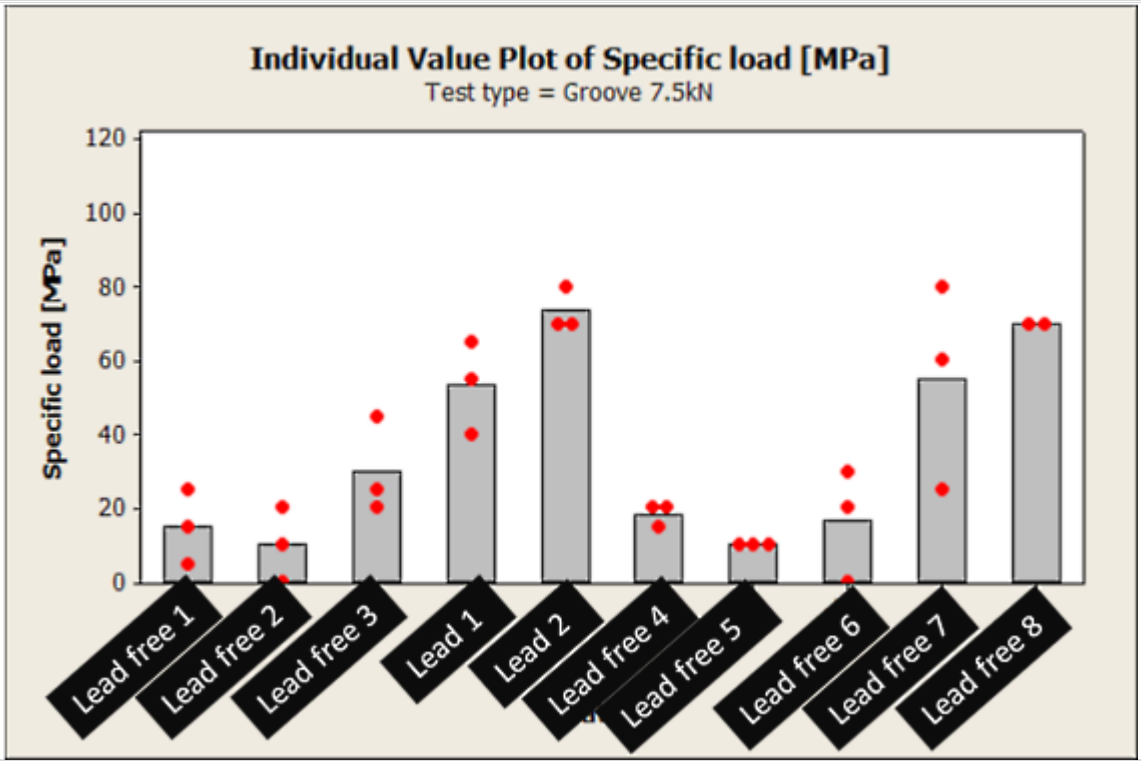
EUROMOT (2015) report a series of comparative tests of bearings carried out by an engine manufacturer in the laboratory using lead based bearings and lead-free versions specially made for these tests to evaluate lead-free bearing materials:

Seizure resistance testing - In such tests, the load on a test-bearing can be gradually increased until it fails (seizes). This method also allows comparing performance of bearings with damage from scoring (an introduced groove). In testing of bearings with a 7.5 kN groove introduced to the bearing surface the lead bearing material (Lead 2) with a groove maintained similar performance characteristics to new undamaged bearings and had more samples falling into the grouping range as compared to the next closest product (Lead-free 8). All other lead-free products failed extremely early in testing and/or load carrying capabilities were profoundly diminished. See figures below.

Figure 5-6: Seizure resistance testing results[14]



A) Seizure results with no damage – test to failure



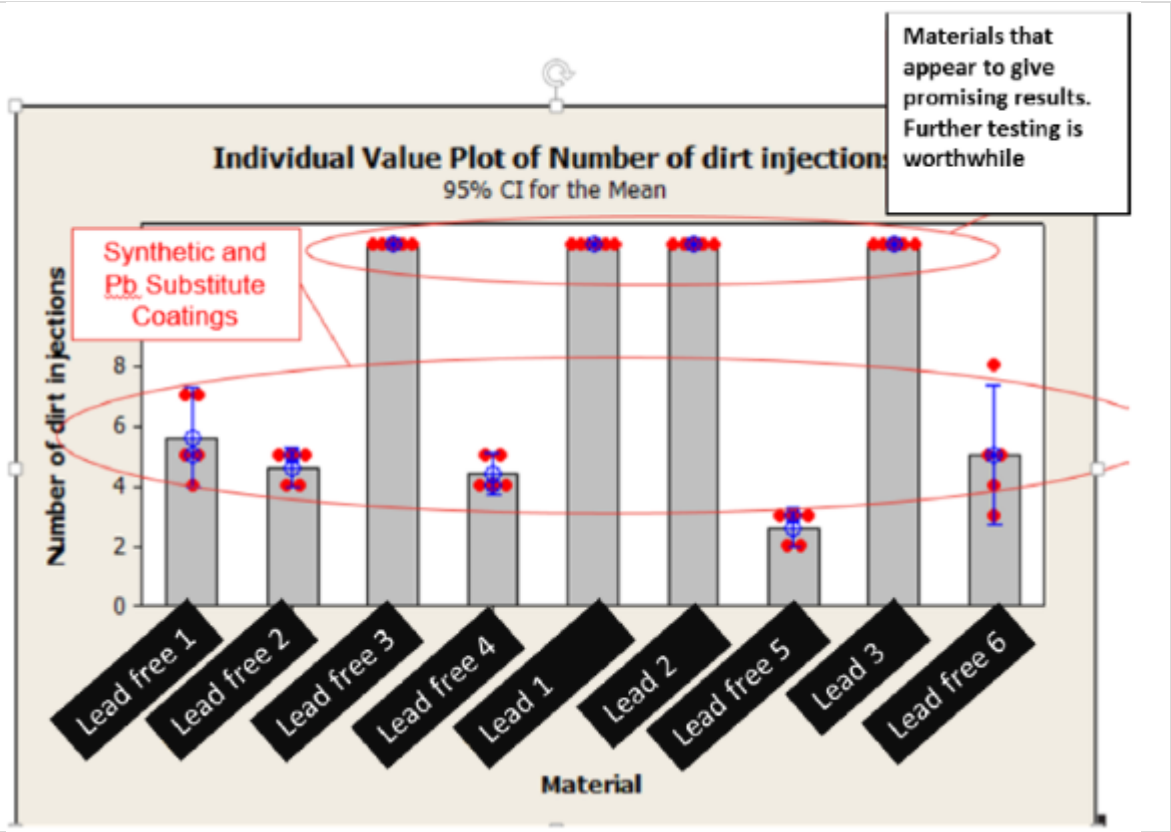
B) Seizure Resistance with 7.5kN groove in bearing surface

Note: Red dots represent actual values for individual bearings.
Grey bars are average values.

[14] EUROMOT (2015)

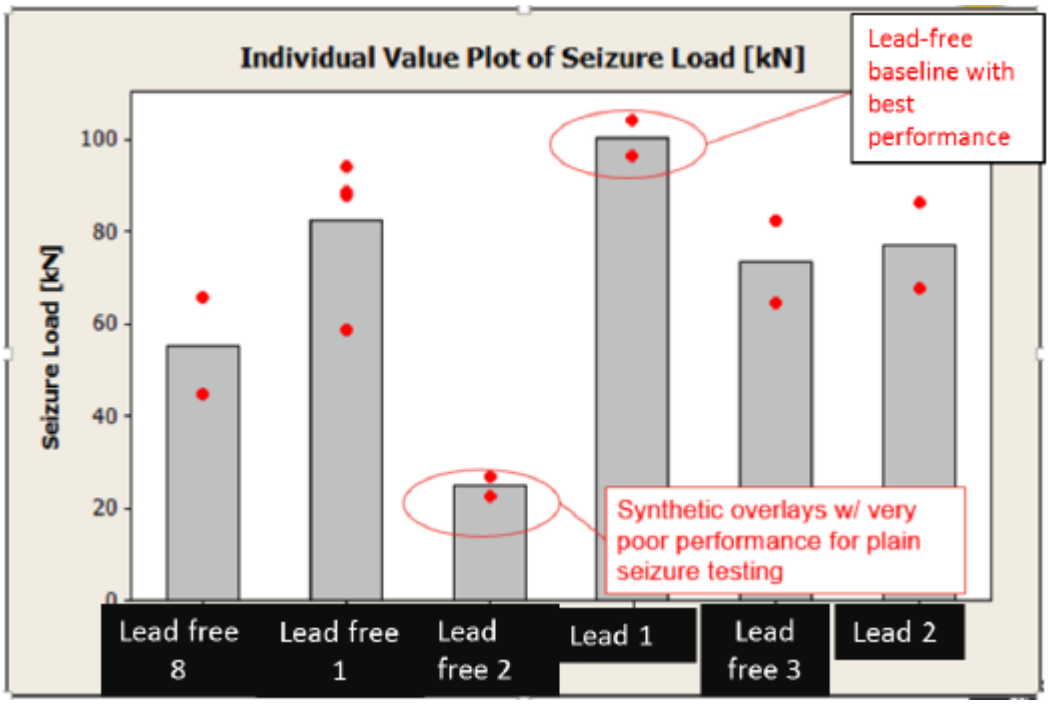
Embedability testing - Test rigs are designed to introduce "dirt shocks" into bearing clearance areas. The more dirt shocks a bearing is capable of accepting without seizing is indicative of good embedability and therefore a more reliable product for the user. Dirt shocks are administered into the bearing clearance area through the lubrication oil supply in the test rig. These shocks are administered until the embedding capacity of the bearing is exceeded and the bearing fails. This same test is repeated with a load simulating combustion loads placed upon the bearing.

Figure 5-7: Embedability testing results[15]



A) Test Results, Embedability – Shock count with no load on bearing

[15] EUROMOT (2015)



B) Test Results, Embedability – Shock count with a realistic load

Note: Red dots represent actual values for individual bearings. Grey bars are average values.

EUROMOT (2015) provide Table 5-4 that shows published comparative test results related to the number of "dirt shocks" that can be injected until failure occurs[16]. It is explained that results are comparable to those achieved by the engine manufacturer tests described above, though EUROMOT assumes the bearings were designed for an engine with a different capacity, although this is not specified in the publication (it refers to a high speed gaseous fuel engine). From these tests, it can be seen that the synthetic "sputter coated" and Pb free substitutes such as copper tin or aluminium alloys, offer 20-80% less debris holding capability as compared to bearings constructed with a lead overlay.

16 EUROMOT (2015) references: Modular Bearing Designs to Cope With the New Engine Designs Demanding High Performance, Lead-Free Solutions, and Robustness", Rainer Aufischer, Rick Walker, Martin Offenbecher and Gunther Hager, J. Eng. Gas Turbines Power 136(12), 122505 (Jul 15, 2014).

Table 5-4: Average number of dirt shocks before failure of one leaded and four lead-free bearings[17]

Bearing alloy / coating	Average number of dirt shocks survived before failure
Lead bronze trimetal bearing	13.0
AlSn25CuMn (lead-free)	11.5
Lead-free bronze with sputter coating	8.0
Lead-free sputter with synthetic coating	4.5
AlSn20Cu with sputter coating (lead-free)	3.2

The reduced debris holding capacity and dramatic difference in performance with lead free bearings, demonstrated in Table 5-4, is explained to be of particular concern for proposed use in power generation applications. All lead free options failed with approximately half of the dirt shocks of leaded options. This is further exacerbated by the reduced load capabilities illustrated in Figure 5-7-B. The consumer could expect equipment to fail early in the product life cycle and failures to occur at start up or shortly after as load is applied to the engine during the power generation process. This would have very serious implications, for example in a hospital where the generator is needed as an emergency back-up supply if there is a power cut.

Conformability testing - Very little comparative test data could be found to show the difference between leaded bearings and lead-free. EUROMOT detail one publication[18] from a bearing manufacturer which describes the "misalignment" tests of its bearings. Results are not straightforward, as three types of lead-free bearings, having synthetic polymer coatings, suffered significant wear (up to 21 µm), whereas the only leaded bearing tested seized in two out of the three tests, although this was superior to the equivalent lead-free version without a polymer coating that seized in all tests. The soft properties of lead will allow for slight variation in alignment without total failure. The results shown in this case illustrate a complete failure of the bearings resulting in material transfer between tribological surfaces. This failure mode can be minimized with the use of leaded bearings. As described above, the synthetic polymer coatings used for the conformability tests gave inferior reliability when debris was present in the lubricant, so this material is not always suitable as a substitute. In practice, only realistic long-term testing in engines is able to determine if a bearing will be reliable.

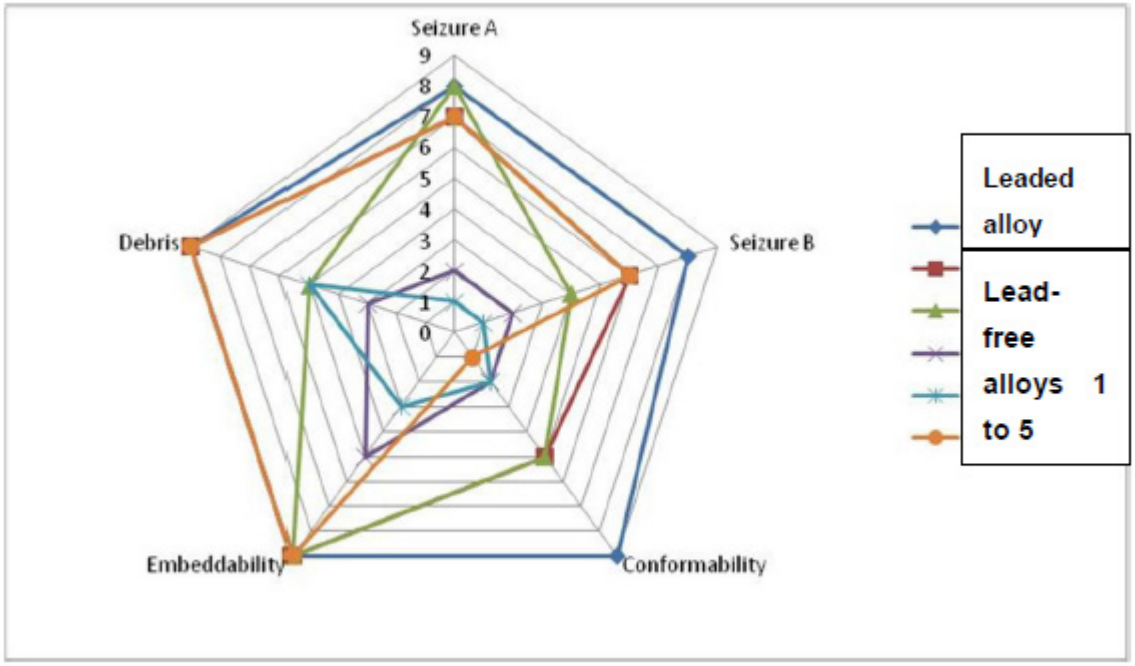
EUROMOT (2015) states that engine bearings are required to have a combination of performance parameters in order to provide the required reliability for the heavy duty engine applications in scope of the exemption. To demonstrate this Table 5-5 is provided, summarizing the results of the various bench tests described above, with the following clarifications:

- Seizure A is without groove (see Figure 5-6-A)
- Seizure B is with groove (see Figure 5-6-B)

[17] EUROMOT (2015)
[18] See footnote 16.

- Conformability of bearings is from the reference in footnote 16.
- Embedability (of debris) is from the engine manufacturers tests described in Figure Figure 5-7-A and Figure 5-7-B
- Debris tolerance is from ASME research results shown in Table 5-4 (reference in footnote 16).

Table 5-5: Summary of bench test results, Leaded vs. Lead Free Material testing[19]



EUROMOT explains these results, concluding that synthetic bearing overlays designed to mimic soft properties of lead underperformed all other designs. Other lead free designs utilizing a combination of alloys designed to replicate the tribological properties of lead were also found to be not equivalent and below the reliability benchmarks of current leaded material. EUROMOT thus conclude from the bench testing results that lead free products are not capable of matching the seizure resistance, conformability, embedability, or debris holding capacity without compromising other attributes critical to reliability.

On-engine testing in an engine manufacturer's laboratories

Testing must also be conducted on actual diesel engines to identify failure modes which can only be identified with loads and conditions that are consistent with the entire reciprocating engine assembly working as a complete engine system. These tests are routinely executed by engine manufacturers as a manner of procedure whenever one of the following conditions are true:

19 EUROMOT (2015)

- Change in material specification or source;
- Change in supplier's manufacturing location or process; or
- Change in OEM's manufacturing location or process;

It is explained that tests are carried out on an engine rig according to a predetermined test-cycle throughout 500-3,000 hours. Furthermore, final validation of changes to internal engine components must be validated through a field test of approximately 50 engines. According to EUROMOT (2015) field tests reflect the wide variation in operating conditions that are seen by engines and so are the most realistic tests that can be carried out.

Results of tests carried out by an engine manufacturer are presented by EUROMOT (2015) in the application in relation to a 15 litre diesel engine and the following conclusions are detailed:

- 16.1% of test engines utilizing lead free bearings failed during testing. Of the other engines with lead-free bearings, these required more frequent servicing and repairs and operated for fewer hours than the lead bearing counterparts. A rate of 83.7% of engines passing these test requirements is unacceptably poor. In comparison none of the engines with lead based bearings experienced main bearing failures during service.
- The main bearing failures of engines utilizing lead free bearings occurred in a range of 0.8 hours to 1,380 hours (~20% or less of expected useful life). Expected life of an engine used in an industrial application is typically upwards of 50,000 hours (e.g. genset operating intermittently for 20 years), but with lead-free bearings, first failures occur after less than 200 hours and some after much less time.
- Failures occurred in both light and heavily loaded engine applications
- Improper formation of main bearing relief (conformability) was found to be a contributing factor in post failure evaluation.
- Lead free bearings were found to be less tolerant to lube system excursions as compared to current leaded bearing offerings. In service, oil can become dirty and this restricts the flow to bearings (e.g. as oil filters become blocked) and this occurs in all engines irrespective of bearing composition. When this occurs, lead-free bearings are more likely to fail than lead-based bearings.

Field test results are also presented for a 9 litre engine, showing that a steel aluminium bimetal bearing shows more wear and fails earlier in comparison to a lead-based one, when the two are subjected to progressing loads.

It is further explained that tests with engines having a capacity <9 litres have not been carried out, as all of the bench tests with lead-free bearings showed that their performance is inferior to lead bearings with regard to the two main failure modes that are independent of engine size; debris tolerance and seizure resistance.

5.3.2. Environmental arguments

EUROMOT (2015) claims that within the commercial internal combustion engine sector, there is in effect a closed loop system for the recycling of mixed metal components generated during the rebuild process and at end-of-life (EoL). Bearings at EoL have a positive metal value whereas disposal to landfill entails a cost and so close to 100% of bearings are collected and recycled. Mixed metal components are harvested from the

engine or associated components as wear items and are placed in a mixed metal recycling bin where they are collected for processing by metal recyclers. The closed-loops are industry-wide as it is not possible for bearing or engine manufacturers to guarantee take back of their own bearings for recycling, however the metals are recovered by traditional metal recycling processes that occur within the EU and are reused, although not necessarily in bearings. Many metal recyclers will collect and recycle alloys containing lead and this includes used bearings[20]. Mixed metals, such as lead scrap contained in bearings, are commonly processed through pyrometallurgical processes in which assemblies containing more than one metal or alloy are separated with heat into their constituent substances based upon melting point and the separated metals are further refined before reuse. Further details are described in the original application document (EUROMOT; 2015) in relation to lead recovery from steel and copper recycling and are not reproduced here.

5.3.3. Road map to dubstitution

EUROMOT (2015) explains that engine manufacturers do not make or design bearings, but will evaluate any new types that become available. Bearing manufacturers have developed a range of lead-free bearings primarily for use in vehicles to comply with Directive 2000/53/EC (ELV) or in some cases for commercial vehicles. Several types of lining alloys and overlays have been evaluated and are suitable for many applications, but their long term reliability in applications covered by the requested exemption either cannot be assured or is known from R&D to be inferior. Therefore EUROMOT claim that more research is needed.

It is further explained that material testing and development activities necessarily take many years to complete to ensure long term reliability as the service life of relevant engines is usually above 20 years. EUROMOT (2015) explains that the following stages are required before alternatives become available:

- S1: Search for alternative lining and overlay alloys - Has been underway for many years, but none known that are suitable for applications in scope of this exemption. Therefore a completion date cannot be defined.
- S2: Evaluation in bearings - Can start only when a suitable material is identified.
- S3: Evaluation of lead-free bearings in engine assemblies - Can start if a suitable lead-free bearing is found to be satisfactory.
- S4: Engine redesign - Alternative alloys may not be suitable as drop-in replacements, so time needed for engine design may differ.
- S5: Evaluation of lead-free engines in the field - This phase can begin only when bench testing of engines with lead-free bearings shows that these are reliable and performance and emissions are not adversely affected.

The timescale for re-design and validation of engine bearings is a major undertaking which can easily require about 6 years duration and this cannot start until a suitable bearing alloy has been identified.

[20] EUROMOT (2015) provides examples http://www.omnisource.com/products/?p=nonferrous , http://www.cfbooth.com/Recycling/ and http://www.simsmm.co.uk/Contact-Us/Midlands/~/media/Documents/Items%20Accepted%20List/Acceptable%20Items%20-%20Metals%20UK.ashx

EUROMOT (2015) also explains that two or more bearing / bushing manufacturers need to exist having suitable lead free technology equivalent to or exceeding the tribological properties of lead to ensure long term availability of new bearings and replacement spare parts. Currently there are more than five global suppliers capable of supplying leaded bearings for professional applications to the many manufacturers of diesel and natural gaseous fuel engines. Multiple avenues of supply must be developed to avoid monopolistic situations and preserve healthy market competition which ensures high quality, and uninterrupted supply.

Further detail and estimation of time scales is provided in the application.

In a later communication, EUROMOT (2016) explained that manufacturers continue to work with the bearing industry to develop other potentially feasible lead-free candidates that perform as well as the leaded bearings and bushes to meet the regulatory and customer requirement.

One identified candidate is a copper/tin/bismuth alloy, and other derivations including those utilizing plastic or polymer coatings are undergoing continued testing. The exact formulation and construction methods of these bearings are considered a trade secret. In all cases, the alternative materials have not met reliability requirements in the applications requested for exemption. Further time and testing will be required to ensure reliability in these applications. (EUROMOT 2016)

5.4. Stakeholder contributions

Contributions were not submitted by stakeholders during the public consultation.

5.5. Critical review

5.5.1. REACH compliance – Relation to the REACH Regulation

If granted, the exemption would allow the use of lead in bearings and bushes of certain equipment. Annex XIV of the REACH Regulation contains several entries for lead compounds, use of which requires authorization:

- 10. Lead chromate
- 11. Lead sulfochromate
- 12. Lead chromate molybdate sulphate red

In the applications in the scope of the reviewed exemption, lead is used in bearings and bushes that become parts of articles. None of the above listed substances is relevant for this case, neither as directly added substance nor as substance that can reasonably be assumed to be generated in the course of the manufacturing process.

Annex XVII of the REACH Regulation bans the use of the following lead compounds:

- 16. Lead carbonates in paints
- 17. Lead sulphate in paints

Neither the above substances nor their applications are, however, relevant for the exemption request in the scope of this review.

Appendix 1 of this report lists entry 28 and 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 restrictions for substances under entry 28 and entry 30 of Annex XVII do not apply. The use of lead in bearings and bushes in the consultants' point of view is not a supply of lead and its compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, entry 30 of Annex XVII of the REACH Regulation would not apply.

Entry 63 of Annex XVII stipulates that lead and its compounds…

- "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."
  This restriction does, however, not apply to crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*), and to internal components of watch timepieces inaccessible to consumers
- "shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0.05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children."
  This restriction does, however, not apply to articles within the scope of Directive 2011/65/EU (RoHS 2). Nor are bearings and bushes to be used in professional use non-road equipment engines articles expected to be accessible to children under normal or reasonably foreseeable conditions of use.

The restrictions of lead and its compounds listed under entry 63 thus do not apply to the applications in the scope of this requested exemption.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status September 2016). 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.

5.5.2. Scientific and technical practicability of substitution

EUROMOT requests an exemption for the use of lead in bearings and bushes of professional use non-road equipment engines. It explains the unique properties of lead-based bearings and bushes, necessary to achieve the reliability required in applications for which the exemption is requested, referring to seizure resistance and resistance to damage, to conformability, to embedability and to load capacity (the last of which is understood to be relevant only in some cases). Lead based bearings are said to have a particularly high level of performance in relation to the first three properties, and thus

provide a sufficient level of reliability necessary for their application in professional use non-road equipment engines.

EUROMOT explains that certain substitutes have been developed, such as those used for example in vehicles, however these are explained not to provide a sufficient level of reliability for the relevant applications. This is due among others to longer service lives of engines used in professional use non-road equipment engines as well as to the environmental conditions in which they are operated and often serviced, in which the engine can be exposed to harsher conditions in terms of dirt and dust.

EUROMOT (2016) further details that for each specific type of engine and its intended applications, both lead-free and lead-based bearings have been tested to identify the materials and designs that meet the combinations of performance requirements for each bearing and bush in the engine. With some designs and applications, lead-free bearings are found to be suitable, meeting all performance requirements and so are used, whereas with others only lead-based provide all of the performance requirements. This is not always the case, but when a lead free bearing or bushing material meets the requirements and is a feasible option it will be selected. (EUROMOT 2016)

EUROMOT provides results of research into possible alternatives, in which lead based bearings and bushings have been compared with lead free ones to determine their performance in relation to seizure, conformability, embedability and debris tolerance (see summary in Table 5-5). The results support their claims, that alternatives tested still do not provide a sufficient level of performance in relation to the various properties of relevance, and that they would thus not provide sufficient reliability for all applications in professional use non-road equipment engines.

In other words, though it can be understood that various lead-free bushings and bearings are available, their reliability is understood to be inferior in comparison with lead based ones currently in use for professional use non-road equipment engine applications, in which a higher reliability level is required in comparison with other application areas (e.g., vehicles). These statements can be followed in light of the supporting information and data that EUROMOT provide from research into possible alternatives.

Though the time needed for suitable substitutes to become available is not clear, EUROMOT further provides information as to a few possible candidates that are being investigated, as well as in respect of the general timescales required to implement substitutes once a suitable candidate is found. This information suggests that at least 6 years shall be needed once a candidate is found and can be followed.

5.5.3. Environmental arguments

EUROMOT put forward some information as to the practice of recycling of mixed metals from components generated during the rebuild process and at end-of-life (EoL) of engines of professional use non-road equipment, claiming that this practice "is in effect a closed loop system for the recycling of mixed metals…" (EUROMOT 2015). This practice is explained also to be relevant for bearings and bushes used in such equipment, whereas turbo bushings, cam follower roller pins, gear bushings and main and rod bearings are explicitly mentioned in this respect. Though these statements may support a lower environmental impact of bearings and bushes collected and recycled at these stages, there is no information to clarify that the situation would be different in the case of lead-

free bearings and bushes. From the consultants' experience, recycling practices for mixed metals are suitable for reclaiming a wide range of metals and it cannot be concluded based on the information made available that lead based bearings and bushings would necessarily have an environmental advantage over lead-free ones in this respect.

5.5.4. Scope of the exemption

Following the initial review of the exemption request application, and in light of the information made available, an effort was made to detail the range of equipment falling under the scope of the requested exemption, since the scope criteria focus on a few parameters that are not necessarily associated with specific products. In its original application, EROMOT specifies the exemption request to three sub-categories of professional use non-road equipment, referring to:

I. *15 litre and larger total displacement professional use*

II. *Less than 15 litre engines for professional non-road equipment designed for use where the time between a signal to start and full load is required to be less than 10 seconds, for example in emergency, standby generators and peak shaving generators*

III. *Less than 15 litre engines for professional non-road equipment designed for operation in harsh and dirty environments such as construction sites, quarries, mines, etc. for example, in drills, air compressors, rock crushers, irrigation pumps and tub grinders*"

EUROMOT argue that the exemption is only relevant for equipment understood to be newly in the scope of the recast RoHS Directive (RoHS 2), and that such equipment is understood to fall under category 11. They were asked to detail the scope of the exemption and provided Table 5-6 with examples, explaining that it is a non-exhaustive list. EUROMOT (2016) explains that "*All equipment for which we request an exemption is diesel, and/or gas-powered, and did not fall under the scope of RoHS 1 based on all available guidance reviewed at the time of promulgation as electricity was not the primary power source for such equipment. Accordingly, all the sub-groups listed above are being considered newly in scope of RoHS 2*."

Table 5-6: Possible equipment sub-groups that would benefit from the requested exemption[21]

Non-stationary heavy equipment designed for professional use in applications including but not limited to mining, petroleum, construction and power generation, and which does not require either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working	Comment	Equipment designed for professional use in harsh and/or dirty environments	Comment
Mobile Power Generation Units	Because of the mobile or portable nature of the equipment, it does not qualify for the LSFI exclusion, nor does it fit the RoHS II definitioni of Non-Road Mobile Machinery because it does not require either mobility or continuous or semi-continuous movement between a succession of fixed locations while working.	Power Generation Equipment Powered by Diesel or Gaseous Fuel Internal Combustion Engine	All of the equipment in this category is designed for professional use. However, due to its size, power output or other limiting factor, it may not qualify for an exclusion as a large scale fixed installation. These applications by design, operate in dusty, dirty, or otherwise harsh conditions which require the use of lead containing bearings and bushes so that reliability may be assured.
Mobile HVAC Units		HVAC Units Powered by Diesel or Gaseous Fuel Internal Combustion Engine	
Mobile Dehumidifying Machines		Dehumidifying Units Powered by Diesel or Gaseous Fuel Internal Combustion Engine	
Mobile Air Compressors		Air Compressors Powered by Diesel or Gaseous Fuel Internal Combustion Engine	
Mobile Welding Equipment		Welding Equipment Powered by Diesel or Gaseous Fuel Internal Combustion Engine	
Mobile Mixing, Grinding, Cutting and Crushing Equipment		Drilling or Trenching Equipment Powered by Diesel or Gaseous Fuel Internal Combustion Engine	
Mobile Fluid Pumping Equipment		Fluid Pumping Equipment Powered by Diesel or Gaseous Fuel Internal Combustion Engine	
Mobile Vacuum Equipment		Vaccum Equipment Powered by Diesel or Gaseous Fuel Internal Combustion Engine	
Mobile Cranes, Hoists, or Man Lifts		Crane, hoists, or Man Lifts Powered by Diesel or Gaseous Fuel Internal Combustion Engine	

As EUROMOT could not provide an exhaustive list of equipment for which the exemption is requested to demonstrate this understanding, it was asked what the basis for assuming that all equipment is under Cat. 11 is. EUROMOT (2016) explained to have initially determined that the equipment for which the exemption is requested would not fall under Category 6 of RoHS 1 (electrical and electronic tools) based on guidance provided to the original WEEE 1 and RoHS 1 directives published May 2005 by the European Commission[22]. It is there stated that "electricity is the (e.g. not petrol or gas) primary energy" in order for equipment to fall in scope of RoHS 1, and proceeds to give examples of products outside the scope of RoHS, including combustion engines with ignition and petrol-driven lawnmowers (see FAQ 1.2). Based on that guidance, EUROMOT originally determined that their members' diesel and gas-powered equipment would be out of the scope of RoHS 1. EUROMOT continue that it is unclear whether the equipment for which the exemption is requested falls under Cat. 6 or Cat. 11, because Category 6 is still described as "electrical and electronic tools", which based on the original guidance would not include petrol, diesel, and gas-powered equipment. EUROMOT's members thus decided to include all such equipment under the catch-all EEE provision of Cat. 11. If Cat. 6 is also to be determined as appropriate, this should be reflected in the scope of an exemption, should one be recommended.

With the aim of simplifying the formulation, EUROMOT was asked to make some reformulations in the exemption wording and agreed to the following formulation:

> "Lead in bearings and bushes of diesel or gaseous fuel powered internal combustion engines applied in:
>
> i. Non-road professional use equipment and where engine total displacement is >15 litre;

[21] EUROMOT (2016)

[22] EUROMOT (2016) refer to the following source: http://ec.europa.eu/environment/waste/pdf/faq_weee.pdf

ii. Non-road professional use equipment and where engines have a <15 litres displacement, designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds.

iii. Non-road professional use engines with <15 litres displacement, designed for operation in applications where regular maintenance is typically performed in an outdoor environment, such as mining, construction, and agriculture applications."

Though EUROMOT was asked whether the third item could be limited further by specifying a threshold for the air emissions level[23] (for example in parts per million), it explained that it is not practical to base the exemption for the equipment on operating in certain air emission conditions as dirt may enter an engine during servicing in the field (EUROMOT 2016) (i.e., not only during operation). It can be understood from this information that such a specification could exclude equipment where the potential for contamination occurs only or mainly during service. It can further be understood in this respect that contamination may also be introduced through handling during maintenance and service, i.e., that it cannot always be attributed to the quality of air in which equipment is operated or serviced. In this sense the proposal is acceptable. Though the consultants would usually avoid giving examples of typical equipment in the exemption wording, in this case, this is understood to communicate a level of environmental conditions of relevance for applicability of item III. The argumentation presented by the applicant further demonstrates the advantages of lead when performing in such environments, particularly in relation to embedability and debris tolerance.

Though an attempt was made to specify performance levels of relevance to these various properties (seizure resistance, conformability, embedability and debris resistance), the consultants can follow the lack of quantifiable performance indicators, as demonstrated in the various research testing results provided.

5.5.5. 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 available information it is observed that substitutes have become available on the market. However, in the consultants' view, the provided results and information as to research into alternatives sufficiently show that such alternatives do not provide a sufficient level of reliability in application areas of professional use non-road equipment

[23] This question was aimed at providing a threshold for the quality of air, under which relevant equipment is operated in. It is understood that in many cases the air quality is at least in part a result of the operation of the equipment, for example in mining, thus the term emissions has been used, though the air quality can also be a function of the ambient pollution levels.

engines, where seizure resistance, conformability, embedability and debris resistance play an important role in the operation of equipment and or in its service and maintenance. Though some information related to environmental impacts of lead based bearings and bushes was provided, the consultants cannot follow from the available information that lead-based components would have advantages over lead-free ones in relation to the recycling of mixed metals.

In this sense, the consultants conclude that even though substitution of lead is in principle scientifically and technically viable in bearings and bushes, the reliability of these substitutes is not ensured for the specific use in the equipment in the scope of this requested exemption. An exemption can therefore be justified based on the Article 5(1)(a) criteria.

5.6. Recommendation

There is currently a lack of lead-free bushings and bearings with a suitable level of reliability for professional use non-road equipment engines. Seizure resistance, conformability, embedability and debris resistance play an important role in the operation of this equipment and in its service and maintenance. The consultants can follow that an exemption would be justified. Therefore the consultants recommend granting the exemption request with the following wording:

> "*Lead in bearings and bushes of diesel or gaseous fuel powered internal combustion engines applied in non-road professional use equipment:*
>
> *I. with engine total displacement ≥ 15 litres;*
>
> *II. with engine total displacement < 15 litres and the engine is designed to operate in applications where* the time between signal to start and full load is required to be less than 10 seconds; or regular maintenance is typically performed in a harsh and dirty outdoor environment, such as mining, construction, and agriculture applications."

EUROMOT have requested an exemption for the maximum validity period of five years. The various stages of substitute development are detailed, clarifying that 6 years shall be needed once a candidate is found to implement substitution. As a suitable candidate is yet to be identified (September 2016), it can further be assumed that at least an additional year would be needed to allow a suitable candidate to be found before the six year process could begin. Though 7 years and more may be needed for the implementation of substitutes, exemptions for Cat. 11 equipment cannot be granted for duration above 5 years. It is thus recommended to grant an exemption valid for 5 years.

A further point relevant for the requested exemption is related to possible overlaps with exemption 6c of Annex III of the Directive, for lead in copper alloys. The applicants mention that bearings and bushings produced from copper alloys with up to 4% lead are also used in professional use non-road equipment engines, however that these are understood to be covered by exemption 6c. This aspect was also recently discussed in an evaluation of an application for the renewal of that exemption. During that process it was not possible to verify if indeed copper alloys with up to 4% lead are needed for bearings and bushes used in other than Cat. 11 equipment, however it was not possible to clarify

the opposite either. The current recommendation of Ex. 6c recommends a renewal for a shorter term, to allow a possible limitation of its scope to specific application areas. In this sense, though at present a renewal of the exemption would still benefit such alloys used in bearings and bushes applied in professional use non-road equipment engines, it is not clear if this is to be the case in the future, particularly should Cat. 11 first come into scope in 2019 with the exemptions validity starting thereafter.

The current recommended exemption would not exclude the use of up to 4% lead in copper alloys for bushings and bearings when used in professional use non-road equipment engines. The consultants would thus further recommend excluding such applications from exemption 6c, so as not to produce a situation in which a certain application is covered by two exemptions. This could be done by adding the following formulation to exemption 6c: "excluding applications covered by exemption XX" (the number of the proposed exemption should it be granted).

5.7. References Exemption request 2016-1

EUROMOT (2015): The European Association of Internal Combustion Engine Manufacturers, Original Application for Exemption, submitted 27.7.2015, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_11/Request_2016-1/RoHS_Lead_Bearings_Exemption_Request_Form_EUROMOT_2015-07-27.pdf

EUROMOT (2016): The European Association of Internal Combustion Engine Manufacturers, Answers to 1st Questionnaire on Exemption Request No. 2016-1, submitted 25.2.2016, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_11/Request_2016-1/20160225_Ex_2016-1_1st_round_of_Clarification-Questions_for_EUROMOT_Final_version_24.02.16.pdf

6. Exemption request 2016-2

"Lead in solders used to construct and connect to Peltier thermal cyclers used for in-vitro diagnostic analysers that use polymerase chain reaction"

Declaration

In the sections that precede the "Critical review" the phrasings and wordings of stakeholders' explanations and arguments have been adopted from the documents provided by the stakeholders as far as required and reasonable in the context of the evaluation at hand. Formulations were only altered in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and definitions

Ag	silver
Cat. 8	Category 8 of Annex II of the RoHS Directive – Medical devices
CTM	COBAS TaqMan
CTM48	COBAS TaqMan 48
Cu	copper
IVD	in-vitro diagnostics
Pb	lead
PCR	polymerase chain reactions
Sn	tin
TCE	thermal coefficient of expansion; also used for thermal mismatch between materials

6.1. Description of the exemption

Roche Diagnostics Ltd.(2015) has applied for an exemption for

> *"Lead in solders used to construct and connect to Peltier thermal cyclers used for in-vitro diagnostic analysers that use polymerase chain reaction"*

The applicant requests the exemption to remain valid until 31 December 2020.

6.1.1. Summary of the exemption request

Roche Diagnostics Ltd. (2015) requests an exemption for the use of lead in solder to attach Peltier elements in in-vitro diagnostics (IVD) analysis instruments that analyse samples from human blood and tissue samples for a variety of diseases. The analysis procedure requires multiple, very precise thermal cycles which are provided by the Peltier heating elements.

Roche Diagnostics Ltd. (2015) describe that the Peltier thermal cyclers are connected electrically with solder. The applicant researched lead-free soldered Peltier elements, but none of the tested lead-free bonded samples could provide the necessary reliability and precision of temperature control for the thermal cycles.

According to Roche Diagnostics Ltd. (2015), several different IVD analysers are on the market produced by several manufacturers. Roche does not know which solders its competitors use. Roche also designed three IVD analysers that use lead-free soldered Peltier thermal cyclers. However, Roche Diagnostics Ltd. (2015) say that none of these other instruments can perform the same range of tests, which often is the most important factor for a laboratory, or they are designed for much larger, laboratories with high-throughput of samples.

Roche Diagnostics Ltd. (2015) argue that due to budget restrictions, national health service laboratories in EU Member States, as well as smaller private laboratories, require low throughput instruments if they are sufficient for their needs. Additionally, stringent regulations associated with the accreditation or licensing of these laboratories by regulatory bodies require extensive planning and validation to implement use of new instruments. The costs and effort associated with these requirements can be extensive.

Roche Diagnostics Ltd. (2015) state that if the requested exemption is not granted, these laboratories may be forced to continue using old instruments for longer than planned. These instruments could become increasingly unreliable, which could also have a negative effect on patients' health.

6.1.2. Technical background

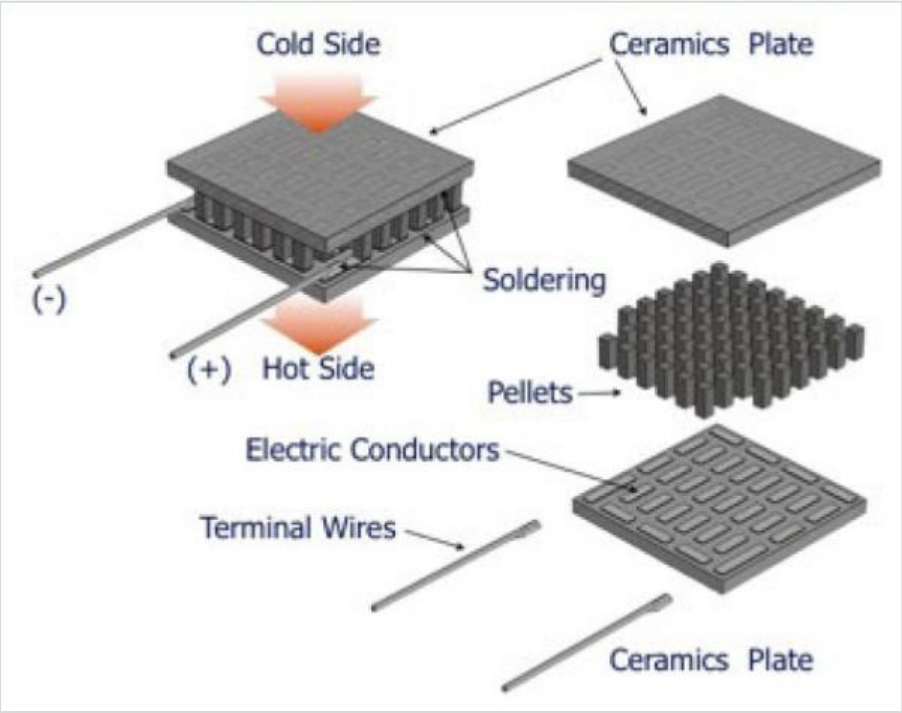
The Roche Diagnostics Ltd. COBAS TaqMan (CTM) and COBAS TaqMan 48 (CTM 48) in-vitro diagnostics (IVD) analysers (Cat. 8) analyse samples from human blood and tissue for a variety of diseases.

Figure 6-1: Roche COBAS TaqMan (left) and COBAS TaqMan48 analyzers[24]

[24] Roche Diagnostics Ltd. (2015)

Roche Diagnostics Ltd. (2015) uses Peltier elements in these two IVD analysers. Peltier elements are used for either heating or cooling. They are constructed from a series of p-n junctions made from bismuth telluride. When a voltage is applied across the p-n junction, heat is transferred from one end to the other giving a hot end and a cold end so that these devices can be used for either heating or cooling. (Roche Diagnostics Ltd. 2015)

Figure 6-2: Peltier elements[25]



The CTM and the CTM 48 IVD analysers use Peltier elements for heating. Peltier elements are an ideal choice for this application as reversal of the applied voltage draws heat away from the heated end so that accurately controlled temperature cycling is possible by controlling the applied voltage. The temperature control the Peltier elements provide is fundamental for successful polymerase chain reactions (PCR). Accurate temperature control is critical for primer and probe hybridization as well as for DNA polymerase activity, which includes extension rate, processivity, and fidelity. (Roche Diagnostics Ltd. 2015)

Lead solder joins together the various internal components of the Peltier element, which include copper cables, ceramic, and copper elements affixed to the ceramic. The joining of these components within the Peltier element is critical for the efficient transfer of electrical and thermal energy. Lead solders such as 63%Sn37%Pb (tin-lead solder alloy) are known to have very different thermal fatigue properties than lead-free solders such as Sn0.7%Ag0.3%Cu (tin-silver-copper alloy). Lead-free solders that can be cycled over the ambient to 100 °C temperature range are all harder and less ductile than SnPb solders. The frequent temperature changes required during the IVD analyses impose thermal stresses on the Peltier heater and in particular on the solder bonds that are used to make electrical connections to each element. (Roche Diagnostics Ltd. 2015)

[25] Roche Diagnostics Ltd. (2016)

An additional challenge with soldering to Peltier elements is that the bismuth telluride is a brittle semiconductor material that can fracture and fail under strain. When stress is imposed due to dimensional changes caused by thermal expansion mismatch, the more ductile SnPb can distort more easily and so reduce stress levels imposed on the bismuth telluride compared to lead-free solders. The use of lead solders is therefore required in Roche's CTM and CTM 48 IVD analysers. (Roche Diagnostics Ltd. 2015)

6.1.3. Amount of lead used under the exemption

Roche Diagnostics Ltd. (2015) indicates the below amounts of lead being used in the IVD analysers:

- CTM: 4 elements x 0.56 g per element = 2.25 g per device
- CTM48: 2 elements x 0.56 g per element = 1.125 g per device

Roche Diagnostics Ltd. (2016) state that the amount of lead used worldwide annually in the requested exemption does not exceed 1.5 kg. The applicant did not provide figures for the amount of lead entering the EU market.

6.2. Justification for the exemption

Roche Diagnostics Ltd. (2015) states that the frequent temperature changes during IVD analyses impose thermal stresses on the Peltier heater and in particular on the solder bonds that are used to make electrical connections to each element. In a lead-free application, the thermal mismatch would be higher between the solder, the bismuth telluride and the metal used for making electrical connections, which would induce higher stresses.

Roche Diagnostics Ltd. (2015) references the publication of Ferrotec[26], a Peltier element manufacturer, describing reliability issues around lead free solders. The "Mean Time Between Failures" (MTBF) of 200,000 hours is possible, but the MTBF is "significantly worse" in applications involving thermal cycling. Ferrotec explains that four thermal cycling parameters affect the reliability of the Peltier element:

1. the total number of cycles;
2. the temperature range;
3. the upper temperature; and
4. the rate of temperature change.

Roche Diagnostics Ltd. (2015) explains that parameters 2, 3 and 4 are fixed for PCR analysis and cannot be changed, and that the number of cycles needs to be as many as is possible to maximize equipment lifetime. The first failure in the Ferrotec lead-free tests occurred after approximately 30,000 cycles, while the MTBF in the test series was 68,000 cycles. The results of the reliability analysis performed by Roche indicate that in some cases the lead-free elements will achieve less than half, and in one case less than one-third of the specified number of cycles, which supports the Ferrotec results. The lead-free

[26] For details see Ferrotec: https://thermal.ferrotec.com/technology/thermoelectric/thermalRef10

alternatives also demonstrated markedly variable performance, with a wide range of cycle counts at element failure.

Roche has conducted several tests with lead-free solders, but could not find a reliable and viable solution for the substitution of the lead solder in the CTM and CTM48 IVD PCR analysers. As the exemption request is scientifically and technically not justified (see section 6.3), these experiments are not described in detail here, but they nevertheless prove that the applicant has undertaken some efforts to find a lead-free solution. The tests are described in detail in the applicant's exemption request.[27]

Roche Diagnostics Ltd. (2015) describes technical and diagnostic advantages of its CTM systems when used in Roche's CAP/CTM platform. When looking individually at key features such as throughput, the level of automation between sample preparation and amplification/detection, and the ability to run multiple tests in parallel, the CAP/CTM platform in many cases provides an outright technical advantage over alternative solutions. There is no single alternative PCR analysis platform that offers the flexibility and technical advantages afforded by the CAP/CTM platform. The portfolio of CAP/CTM and Cobas s 201 assays also differentiates the Roche platform from the alternatives. None of the alternative platforms provide as extensive a menu of assays, combined with the ability to perform both IVD and donor screening assays.

Finally, Roche Diagnostics Ltd. (2015) claim that the CAP/CTM reagent technology highlights the following differences versus the alternatives:

- CAP/CTM and Cobas s 201 assay reagents can be stored in the refrigerator and do not require additional preparation such as reconstitution or centrifugation. Several of the alternative platforms require the reagents to be reconstituted, frozen, or both.
- CAP/CTM and Cobas s 201 assay reagents include UNG to prevent cross contamination, which is critical to the integrity of PCR; assays on some alternative platforms require manual addition of UNG, the use of bleach, or do not provide methods to prevent cross contamination.
- CAP/CTM and Cobas s 201 assays do not require the user to perform any calibration; while not a unique feature, the alternative platforms that also do not require assay calibration are only intended for IVD testing and not donor screening.

Roche Diagnostics Ltd. (2015) highlights that Roche has developed next-generation PCR analysis platforms, the Cobas 6800/8800 Systems, which are CE marked under the IVD Directive 98/79/CE and were launched for sale in the EU market in September 2014. The platform consists of two separate instruments, the Cobas 6800 System and the Cobas 8800, both of which offer fully-integrated sample preparation, PCR amplification, and target detection in a single instrument. Both the Cobas 6800 and 8800 Systems are fully RoHS-compliant.

Roche Diagnostics Ltd. (2015) also offers for sale in the EU another IVD CE-marked PCR analysis platform, the Cobas 4800 System, which provides sample preparation and PCR amplification/target detection in two separate instruments. The Cobas 4800 System is also RoHS-compliant. However, Roche Diagnostics Ltd. (2015) claims that Table 6-1 shows that neither of these platforms are suitable alternatives to the CAP/CTM platform.

[27] Roche Diagnostics Ltd. (2015), page 5 et sqq.

Table 6-1: Roche's and other manufacturers' IVD PCR analysers[28]

Feature / Parameter	Roche CAP/CTM (cobas s 201)	Abbott m2000[1]	Hologic Panther[2]	Siemens kPCR[3]	Beckman Veris[4]	Cepheid[5]	Qiagen[6]	Roche cobas 4800	Roche cobas 6800/8800
Sample Throughput (8 hours)	144 (CAP/CTM) 72 (cobas s 201)	96	275	96	150 for DNA 100 for RNA	Will depend on the size of the module	*	Varies by assay	384 / 960
Interleaving (Processing of multiple assays simultaneously)	Yes (up to 3)	Yes (HIV & HCV only)	Mixed batching of up to 4 assays	No	Each sample is processed individually. Up to 20 assays can be run at one given time.	Each sample is processed individually. Number of assays depends on the size of the module.	Yes (up to 2)	Mixed batching of up to 3 assays within the microbiology portfolio only (MRSA, C. diff & HSV 1/2)	Mixed batching of up to 3 assays
Automated transfer between sample preparation and amplification / detection processes	Yes (via Docking Station; CTM 96 only)	No	Yes – Sample preparation and amplification / detection processes integrated in single instrument	No	Yes – Sample preparation and amplification / detection processes integrated in single instrument	Yes – Sample preparation and amplification / detection processes integrated in single instrument	No	No	Yes – Sample preparation and amplification / detection processes integrated in single instrument
Hands-on Time (minutes)	10 (96 tests)	65 (96 tests)	37	35 (48 tests)	15 (48 tests)	2 (per test)	*	30 (96 tests)	30 (384 tests)
Daily Maintenance (minutes)	30	10	14	*	30	0	*	< 10 minutes	0
Ready-to-Use Reagents	Yes	No	No	No	Yes	Yes	Yes	Yes, but they need to be manually transferred to reservoirs	Yes
Contamination control	Yes (UNG)	Yes (UNG; manual addition)	Yes (Bleach)	Yes (UNG)	Yes (UNG)	No	No	Yes (UNG)	Yes (UNG)
Assay calibration required by user	No	Yes	Yes	Yes	Yes	No	No	No	No
Reagent Storage	Refrigerator	Freezer	Freezer	Refrigerator	Refrigerator	Refrigerator	Freezer	Refrigerator	Refrigerator
Required Floor Plan	1 single room	2 separated areas are recommended	1 single room (integrated system)	1 single room	1 single room (integrated system)	1 single room (integrated system)	1 single room	1 single room	1 single room
IVD Assays (Quantitative)	• HIV • HBV • HCV • CMV	• HIV • HBV • HCV • CMV • EBV • BKV	• HIV	• HIV • HBV • HCV	• HBV • CMV • HIV • HCV	• HIV • HCV	• HIV • HBV • HCV	N / A	• HIV • HBV • HCV • CMV

[28] Source: Roche Diagnostics Ltd. (2015)

Feature / Parameter	Roche CAP/CTM (cobas s 201)	Abbott m2000[1]	Hologic Panther[2]	Siemens kPCR[3]	Beckman Veris[4]	Cepheid[5]	Qiagen[6]	Roche cobas 4800	Roche cobas 6800/8800
IVD Assays (Qualitative)	• HIV • HCV • HLA*B5701 • Mtb†	• HIV • HCV Genotyping • CT/NG • HPV • C. diff • HSV • Mtb/MAI • Influenza A/B • RSV	• HPV • CT/NG • Progensa PCA3	• HCV Genotyping • kPCR PLX (CMV, EBV, HSV, VZV, HHV-6, BKV, JCV, Adenovirus, Parvovirus B19) • CT/NG	N / A	• HIV • Mtb • Flu/RSV • HPV • CT/NG • Group B Strep • Trichomonas • MRSA/SA • C.diff • VRE • Norovirus • Enterovirus • Carba-R	• CMV • BKV • EBV • VZV • HSV • CT/NG • C.diff • MRSA • VanR • Group B Strep • EGFR (plasma)	• CT/NG • HPV • C. diff • MRSA • HSV 1/2	N / A
Donor Screening Assays	• MPX (Qualitative HIV/HBV/HCV) • DPX (Quantitative Parvo B19, Qualitative HAV) • WNV (Qualitative)	N / A	• Ultrio Elite (Qualitative HIV/HBV/HCV) • WNV • Parvo B19 • HAV • HEV	N / A	N / A	N / A	N / A	N / A	• MPX (Qualitative HIV/HBV/HCV) • DPX (Quantitative Parvo B19, Qualitative HAV) • WNV (Qualitative) • HEV

[1] Abbott Global website; MaxCycle Brochure; m2000 rt Brochure; Abbott RealTime HIV-1, HCV & HBV Package Inserts; CAP-Today; Argent Blood Screening Analysis 2008
[2] Novartis Global Website; Procleix® Panther® System Brochure; Argent Blood Screening Analysis 2008; CAP-Today
[3] Siemens Website
[4] Beckman European Customer Presentation; GenomeWeb
[5] Cepheid Website; Argent Microbiology Analysis 2013; GeneXpert Brochure
[6] Qiagen website
* Information not available
* Information not available
† COBAS TaqMan 48 only – Manual sample preparation

According to Roche Diagnostics Ltd. (2015), the Cobas 6800/8800 Systems offer a similar assay portfolio as CAP/CTM, but are much larger instruments that are intended for use in significantly higher-throughput laboratories. Laboratories that currently use the CAP/CTM would not use this system. As for the Cobas 4800 System, while similar in functionality and throughput to the CAP/CTM platform, the assay portfolio is completely different; there are no quantitative IVD assays, in particular for HIV/HBV/HCV, currently offered for use on the Cobas 4800 System, nor are there any donor screening assays.

Roche Diagnostics Ltd. (2015) sum up that the lead-free Peltier elements evaluated by Roche do not meet design specifications for temperature control or reliability, or both. Incorrect temperatures applied during PCR could have significant detrimental effects. For qualitative tests, this could lead to invalid, false negative or false positive results; for quantitative tests, this could additionally cause underquantification or overquantification. Such errors in patient results can lead to significant disability, permanent harm, or even death in some cases, due to incorrect or delayed diagnoses and/or improper clinical management. Unexpected instrument downtimes as a result of poor reliability of the Peltier element increase the risk that a time-sensitive result cannot be obtained in time for a physician to take potentially life-saving action. The unique combination of features offered by the CAP/CTM and Cobas s 201 PCR analysis platforms provide optimum diagnostic performance in lower-throughput IVD diagnostic and viral load monitoring as well as for donor screening applications. There are no alternatives on the market that provide the same combination of functions, analyses and performance.

Roche Diagnostics Ltd. (2015) conclude that the CTM Analyzers with their existing lead-soldered Peltier elements must remain available because a suitable replacement Peltier for the CTM is not available, and because alternative PCR analyzers do not provide equivalent medical value. Any restriction on the availability of these instruments will thus introduce unacceptable levels of medical risk.

6.3. Critical review

6.3.1. REACH compliance - Relation to the REACH Regulation

The exemption allows the use of lead. Annex XIV contains several entries for lead compounds, use of which requires authorization:

- 10. Lead chromate
- 11. Lead sulfochromate
- 12. Lead chromate molybdate sulphate red

In the applications in the scope of the reviewed exemption, lead is used in electronic components that become parts of articles. None of the above listed substances is relevant for this case, neither as directly added substance nor as substance that can reasonably be assumed to be generated in the course of the manufacturing process.

Annex XVII bans the use of the following lead compounds:

- 16. Lead carbonates in paints
- 17. Lead sulphate in paints

Neither the above substances nor their application are, however, relevant for the exemption in the scope of this review.

Appendix 1 of this report lists entry 28 and 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 restrictions for substances under entry 28 and entry 30 of Annex XVII do not apply. The use of lead in this requested exemption in the consultants' point of view is not a supply of lead and its compounds as a substance, mixture or constituent of other mixtures to the general public. Lead is part of an article and as such, entry 30 of Annex XVII of the REACH Regulation would not apply.

Entry 63 of Annex XVII stipulates that lead and its compounds…

- *"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."*
  This restriction does, however, not apply to crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC, and to internal components of watch timepieces inaccessible to consumers
- *"shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0.05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children."*
  This restriction does, however, not apply to articles within the scope of Directive 2011/65/EU (RoHS 2)

The restrictions of lead and its compounds listed under entry 63 thus do not apply to the applications in the scope of this RoHS exemption.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annex XIV and Annex XVII (status August 2016). Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

6.3.2. Substitution and elimination of lead in solders of Peltier elements

IVD PCR analysers with Peltier elements that do not require the use of lead solder as in the applicant's requested exemption are available on the market. Roche Diagnostics Ltd. (2016) themselves offer the Cobas 4800 and the Cobas 6800/8800 systems that use Peltier elements, but do not require the use of lead solders. According to Roche Diagnostics Ltd. (2016), these systems were developed much more recently than the COBAS TaqMan (CTM) and TaqMan48 (CTM48) instruments, and were initially designed with RoHS-compliant Peltier elements. The elements used in the Cobas 4800/6800/8800 Systems have significant differences in design and performance requirements versus the elements used in the CTM and CTM48, and could not be deployed in these instruments without significant modifications to the hardware and temperature control firmware.

Roche's competitors offer IVD PCR analysers on the market as illustrated in Table 6-1 on page 48. Roche Diagnostics Ltd. (2016), based on market intelligence, conclude that all but one of its competitors' instruments appear to use Peltier technology for heating and cooling during PCR. One instrument, the Hologic Panther, uses incubators instead of Peltier elements. However, Roche Diagnostics Ltd. (2016) state that their IVD PCR assays are not designed to be used with incubators and therefore this technology is unsuitable for deployment in the COBAS TaqMan instruments.

The fact that none of Roche's competitors supports the exemption request underlines the applicant's conclusion that these competitors achieve RoHS compliance without the use of lead solders in Peltier elements. The applicant raises the additional justification for the exemption request that the CTM and CTM48 systems provide a unique combination of properties, which neither any other Roche IVD PCR analyser system nor any competitors' systems can provide. There is, however, no evidence that this unique combination of properties is the reason why lead-solders cannot be substituted or eliminated in the CTM and CTM48 systems different from all other systems on the market. Vice versa, there is no evidence either that these properties could not be achieved with lead-free soldered Peltier elements. The applicant states that their other IVD PCR analysers are RoHS compliant because they were from the very beginning designed for use with lead-free soldered Peltier elements while the COBAS CTM and CTM48 are older instruments. The lead-free solder experiments which the applicant describes in its exemption request were conducted on the Peltier elements as they are used in the current design of CTM and CTM48 systems without any other design changes. The applicant does not provide any evidence that a thorough redesign of the CTM and CTM48 systems would not allow the lead-solder to be substituted or eliminated.

Additionally, Roche Diagnostics Ltd. (2016) state that the requested exemption is proposed only until 31 December 2020 because by this time Roche intends to end support for the instruments in the European Union and to convert existing CTM and CTM48 customers to the newer Cobas 4800 System or Cobas 6800/8800 Systems. If the CTM and CTM48 systems' performance and features were actually unique to the degree that the non-availability of these systems after July 2016 poses a serious medical risk for patients and a financial burden on laboratories as the applicant puts

forward, it would be expected that the marketing of the CTM and CTM 48 systems would be continued after 2020. It is not plausible that converting the laboratories using these systems to the other Roche systems after 2020 would not imply the same diagnostic and medical risks than transferring these customers to alternative, RoHS-compliant IVD PCR analysers in 2016.

6.3.3. Conclusion

Overall, the situation clearly shows that scientifically and technically, the substitution of lead in the requested exemption is practicable, but requires a thorough redesign of the devices, here of the CTM and CTM48 IVD PCR analyser systems. The RoHS Directive requires manufacturers to adapt their designs if this allows eliminating the use of a restricted substance.

Further on, the exemption, if granted as requested, would be available for all Peltier elements in IVD PCR analysers, even though it would only be required in Roche's CTM and CTM 48 devices. Restricting the scope of the exemption to these two devices only cannot be justified unless the properties of the devices are unique, technically superior to other available devices or beneficial to health or environment in comparison, and could not be achieved without using lead-solders. The information available rather suggests that the CTM and CTM48 devices could be produced RoHS-compliant after a thorough redesign. The reviewers conclude that granting the requested exemption would therefore not be in line with the stipulations of RoHS Art. 5(1)(a).

Roche Diagnostics Ltd. (2016) mentions that the motivation for the exemption request was that they want to continue the support for the CTM and CTM48 systems after July 2016 until end of 2020. In the reviewers' understanding, the applicant can continue supplying spare parts for repair and upgrade of those devices that were placed on the market before 22 July 2016 even without the requested exemption. It will just no longer be possible to continue putting new CTM and CTM48 systems on the EU market after 21 July 2016.

The applicant puts forward that certification and licensing processes for the establishment of new equipment in laboratories require time and effort. Roche does, however, not explain why they have not started the conversion to those systems early enough to be ready in July 2016 rather than targeting the end of 2020.

6.4. Recommendation

It is recommended not to grant the exemption. The substitution or elimination of lead solders used to construct and connect to Peltier thermal cyclers in IVD PCR analysers is scientifically and technically practicable. The applicant as well as competitors already put RoHS-compliant IVD PCR analysers on the market. Granting an exemption can thus not be justified based on the criteria for exemptions of RoHS article 5(1)(a).

6.5. References Exemption request 2016-2

Roche Diagnostics Ltd. (2015): Exemption request for lead in Peltier thermal cyclers in in-vitro diagnostic analysers; document "Roche_CTM_Exemption_Request_-_01_July_2015__Public_.pdf". Exemption request document. http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_11/Request_2016-2/Roche_CTM_Exemption_Request_-_01_July_2015__Public_.pdf.

Roche Diagnostics Ltd. (2016): Answers to questionnaire 1 (clarification questionnaire), document "Exe-Req-Roche_Questionnaire-1_2016-02-29_Roche_Response_10_Mar_2016__Public_.pdf". Questionnaire 1 (clarification questionnaire), http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_11/Request_2016-2/Exe-Req-Roche_Questionnaire-1_2016-02-29_Roche_Response_10_Mar_2016__Public_.pdf.

7. Appendix

7.1. Aspects relevant to the REACH Regulation

Relevant annexes and processes related to the REACH Regulation have been cross-checked to clarify:

- In what cases granting an exemption could "weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006" (Article 5(1)(a), pg.1)
- Where processes related to the REACH regulation should be followed to understand where such cases may become relevant in the future;

Compiled information in this respect has been included, with short clarifications where relevant, in the following tables:

Table 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 1: Relevant entries from Annex XIV: 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	-
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	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)	
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			
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	
28. Dichromium tris(-chromate) EC No: 246-356-2 CAS No: 24613-89-6	22. Jul 2017	22 Jan 2019	
29. Strontium chromate EC No: 232-142-6 CAS CAS No: 7789-06-2	22 Jul 2017	22 Jan 2019	
30. Potassium hydroxyoctaoxodizincatedichromate EC No: 234-329-8 CAS No: 11103-86-9	22 Jul 2017	22 Jan 2019	
31. Pentazinc chromate octahydroxide EC No: 256-418-0 CAS No: 49663-84-5	22 Jul 2017	22 Jan 2019	

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 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 3.

Table 2: Conditions of Restriction in REACH Annex XVII for RoHS Substances and Compounds

Designation of the substance, group of substances, or 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 2Pb CO 3 -Pb(OH) 2 CAS No 1319-46-6 EC No 215-290-6	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
17. Lead sulphates: (a) PbSO 4 CAS No 7446-14-2 EC No 231-198-9 (b) Pb x SO 4 CAS No 15739-80-7 EC No 239-831-0	Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use. Where a Member State makes use of this derogation, it shall inform the Commission thereof.
18. Mercury compounds	Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use: (a) to prevent the fouling by micro-organisms, plants or animals of: the hulls of boats, cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, any totally or partly submerged appliances or equipment; (b) in the preservation of wood; (c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture; (d) in the treatment of industrial waters, irrespective of their use.

Designation of the substance, group of substances, or mixture	Conditions of restriction
18a. Mercury CAS No 7439-97-6 EC No 231-106-7	1. Shall not be placed on the market: (a) in fever thermometers; (b) in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers). 2. The restriction in paragraph 1 shall not apply to measuring devices that were in use in the Community before 3 April 2009. However Member States may restrict or prohibit the placing on the market of such measuring devices. 3. The restriction in paragraph 1(b) shall not apply to: (a) measuring devices more than 50 years old on 3 October 2007; (b) barometers (except barometers within point (a)) until 3 October 2009. 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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
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 Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the

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

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

Designation of the substance, group of substances, or mixture	Conditions of restriction
	8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C. 9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons. 10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in: (i) metal beads and other metal components for jewellery making; (ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including: — bracelets, necklaces and rings, — piercing jewellery, — wrist-watches and wrist-wear, — brooches and cufflinks. 11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011.
28. Carcinogen category 1A or 1B or carcinogen category 1 or 2 According to Appendices 1 and 2: Cadmium oxide Cadmium chloride Cadmium fluoride Cadmium Sulphate Cadmium sulphide Cadmium (pyrophoric) Chromium (VI) trioxide Zinc chromates including zinc potassium chromate Nickel Chromate Nickel dichromate	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:

Designation of the substance, group of substances, or mixture	Conditions of restriction
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;	'Restricted to professional users'. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.
29. Mutagens: category 1B or category 2 According to Appendices 3 and 4: Cadmium chloride Cadmium fluoride Cadmium Sulphate Chromium (VI) trioxide Potassium dichromate Ammonium dichromate Sodium dichromate Chromyl dichloride; chromic oxychloride Potassium chromate Sodium chromate	

Designation of the substance, group of substances, or mixture	Conditions of restriction
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 compounds with the exception of those specified elsewhere in this Annex Lead Arsenate Lead acetate Lead alkyls Lead azide Lead Chromate Lead di(acetate) Lead hydrogen arsenate Lead 2,4,6-trinitroresorcinoxide, lead styphnate Lead(II) methane- sulphonate Trilead bis- (orthophosphate) Lead hexa-fluorosilicate Mercury Silicic acid, lead nickel salt	

Designation of the substance, group of substances, or mixture	Conditions of restriction
47. Chromium VI compounds	1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002 %) soluble chromium VI of the total dry weight of the cement. 2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1. 3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin. 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. 5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather. 6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part. 7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.
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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	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 articles produced before 10 December 1961. 6. By 9 October 2017, the Commission shall re-evaluate paragraphs 1 to 5 of 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. 7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm 2 per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size. 8. By way of derogation, paragraph 7 shall not apply to: (a) jewellery articles covered by paragraph 1; (b) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Directive 69/493/ EEC; (c) non-synthetic or reconstructed precious and semi-precious 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 mineral melted at a temperature of at least 500 ° C; (e) keys and locks, including padlocks; (f) musical instruments; (g) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal)

Designation of the substance, group of substances, or mixture	Conditions of restriction
	in the brass alloy does not exceed 0,5 % by weight; (h) the tips of writing instruments; (i) religious articles; (j) portable zinc-carbon batteries and button cell batteries; (k) articles within the scope of: (i) Directive 94/62/EC; (ii) Regulation (EC) No 1935/2004; (iii) Directive 2009/48/EC of the European Parliament and of the Council (**); (iv) Directive 2011/65/EU of the European Parliament and of the Council (***) 9. By 1 July 2019, the Commission shall re-evaluate paragraphs 7 and 8(e), (f), (i) and (j) of 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 7, including the requirement on coating integrity, and, if appropriate, modify this entry accordingly. 10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 1 June 2016. --- (*) OJ L 326, 29.12.1969, p. 36. (**) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1). (***) 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 (OJ L 174, 1.7.2011, p. 88).

Table 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 substances, 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 28 September 2015, the REACH Regulation Candidate list includes those substances relevant for RoHS listed in Table 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))[29]:

Table 4: Summary of Relevant Substances Currently on the REACH Candidate List

Substance Name	EC No.	CAS No.	Date of inclusion	Reason for inclusion
Cadmium fluoride	232-222-0	7790-79-6	17 Dec 2014	Carcinogenic (Art. 57 a); Mutagenic (Art. 57 b); Toxic for reproduction (Art. 57 c); Equivalent level of concern having probable serious effects to human health (Art. 57 f)

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

Substance Name	EC No.	CAS No.	Date of inclusion	Reason for inclusion
Cadmium sulphate	233-331-6	10124-36-4 31119-53-6	17 Dec 2014	Carcinogenic (Art. 57 a); Mutagenic (Art. 57 b); Toxic for reproduction (Art. 57 c); Equivalent level of concern having probable serious effects to human health (Art. 57 f)
Cadmium chloride	233-296-7	10108-64-2	16 Jun 2014	Carcinogenic (Art. 57a);
Cadmium sulphide	215-147-8	1306-23-6	16 Dec 2013	Carcinogenic (Art. 57a); Equivalent level of concern having probable serious effects to human health (Art. 57 f)
Lead di(acetate)	206-104-4	301-04-2	16 Dec 2013	Toxic for reproduction (Art. 57 c);
Cadmium	231-152-8	7440-43-9	20 Jun 2013	Carcinogenic (Art. 57a); Equivalent level of concern having probable serious effects to human health (Art. 57 f)
Cadmium oxide	215-146-2	1306-19-0	20 Jun 2013	Carcinogenic (Art. 57a); Equivalent level of concern having probable serious effects to human health (Art. 57 f)
Pyrochlore, antimony lead yellow	232-382-1	8012-00-8	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Lead bis(tetra-fluoroborate)	237-486-0	13814-96-5	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Lead dinitrate	233-245-9	10099-74-8	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Silicic acid, lead salt	234-363-3	11120-22-2	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Lead titanium zirconium oxide	235-727-4	12626-81-2	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Lead monoxide (lead oxide)	215-267-0	1317-36-8	19 Dec 2012	Toxic for reproduction (Art. 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*	272-271-5	68784-75-8	19 Dec 2012	Toxic for reproduction (Art. 57 c)

Substance Name	EC No.	CAS No.	Date of inclusion	Reason for inclusion
1272/2008]				
Trilead bis(carbo-nate)dihydroxide	215-290-6	1319-46-6	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Lead oxide sulfate	234-853-7	12036-76-9	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Lead titanium trioxide	235-038-9	12060-00-3	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Acetic acid, lead salt, basic	257-175-3	51404-69-4	19 Dec 2012	Toxic for reproduction (Art. 57 c)
[Phthalato(2-)]di-oxotrilead	273-688-5	69011-06-9	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Tetralead trioxide sulphate	235-380-9	12202-17-4	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Dioxobis(stearato)tri lead	235-702-8	12578-12-0	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Tetraethyllead	201-075-4	78-00-2	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Pentalead tetraoxide sulphate	235-067-7	12065-90-6	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Trilead dioxide phosphonate	235-252-2	12141-20-7	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Orange lead (lead tetroxide)	215-235-6	1314-41-6	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Lead cyanamidate	244-073-9	20837-86-9	19 Dec 2012	Toxic for reproduction (Art. 57 c)
Lead(II) bis(me-thanesulfonate)	401-750-5	17570-76-2	18 Jun 2012	Toxic for reproduction (Art. 57 c)
Lead diazide, Lead azide	236-542-1	13424-46-9	19 Dec 2011	Toxic for reproduction (Art. 57 c),
Lead dipicrate	229-335-2	6477-64-1	19 Dec 2011	Toxic for reproduction (Art. 57 c)
Dichromium tris(chromate)	246-356-2	24613-89-6	19 Dec 2011	Carcinogenic (Art. 57 a)
Pentazinc chromate octahydroxide	256-418-0	49663-84-5	19 Dec 2011	Carcinogenic (Art. 57 a)
Potassium hydroxyoctaoxodizin catedichromate	234-329-8	11103-86-9	19 Dec 2011	Carcinogenic (Art. 57 a)
Lead styphnate	239-290-0	15245-44-0	19 Dec 2011	Toxic for reproduction (Art. 57 c)
Trilead diarsenate	222-979-5	3687-31-8	19 Dec 2011	Carcinogenic and toxic for reproduction (Art. 57 a and 57 c)
Strontium chromate	232-142-6	7789-06-2	20 Jun 2011	Carcinogenic (Art. 57a)
Acids generated from chromium trioxide and their	231-801-5, 236-881-5	7738-94-5, 13530-68-2	15 Dec 2010	Carcinogenic (Art. 57a)

Substance Name	EC No.	CAS No.	Date of inclusion	Reason for inclusion
oligomers. Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid.				
Chromium trioxide	215-607-8	1333-82-0	15 Dec 2010	Carcinogenic and mutagenic (Art. 57 a and 57 b)
Potassium dichromate	231-906-6	7778-50-9	18 Jun 2010	Carcinogenic, mutagenic and toxic for reproduction (Art. 57 a, 57 b and 57 c)
Ammonium dichromate	232-143-1	7789-09-5	18 Jun 2010	Carcinogenic, mutagenic and toxic for reproducetion (Art. 57 a, 57 b and 57 c)
Sodium chromate	231-889-5	7775-11-3	18 Jun 2010	Carcinogenic, mutagenic and toxic for reproduction (Art. 57 a, 57 b and 57 c)
Potassium chromate	232-140-5	7789-00-6	18 Jun 2010	Carcinogenic and mutagenic (Art. 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 (Art. 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 (Art. 57 a and 57 c)
Lead chromate	231-846-0	7758-97-6	13 Jan 2010	Carcinogenic and toxic for reproduction (Art. 57 a and 57 c)
Lead hydrogen arsenate	232-064-2	7784-40-9	28 Oct 2008	Carcinogenic and toxic for reproduction (Art. 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 (Art. 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 (Fall 2015), 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.[30]

As for registries of intentions to identify substances as SVHC, as of 28 September 2015, Sweden has submitted intentions regarding the classification of cadmium fluoride and cadmium sulphate as CMR, intending to submit dossiers in August 2014.None of the current registries of intentions to propose restrictions apply to RoHs regulated substances.[31]

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

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

Restriction / SVHC classifica-tion	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

30 European Chemicals Agency (ECHA), Registry of intentions to propose restrictions: http://echa.europa.eu/registry-of-current-restriction-proposal-intentions/-/substance/1402/search/+/term (28.09.2015)

31 ECHA website, accessed 28.09.2015: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions

Restriction / SVHC classifica-tion	Substance name	Submission date	Submitted by	Comments
	Mercury in measuring devices	15 Jun 2010	ECHA	Mercury compounds
	Lead and its compounds in jewellery	15 Apr 2010	France	Substances containing lead
SVHC Classificatio n	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;
	Cadmium oxide	04 Feb 2013	Sweden	Substances containing Cd 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;	01 Aug 2011	ECHA	CMR; Substances containing lead

Restriction / SVHC classifica-tion	Substance name	Submission date	Submitted by	Comments
	Lead diazide; Lead azide; Lead dipicrate			
	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
	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.