



**Study to assess two (2) exemption requests in
Annexes III and IV to Directive 2011/65/EU:
renewal of exemption IV.42, and request for a
new exemption for lead and hexavalent chromium
compounds in electric and electronic initiators of
explosives for civil (professional) use
(Pack 16) –Final Report**

*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*

Prepared by Oeko-Institut e.V., Institute for Applied Ecology, and Fraunhofer-Institut for Reliability and Microintegration (IZM)

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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

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1. Executive summary – English

Under Framework Contract no. ENV.A.2/FRA/2015/0008 of 27/03/2015, 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 two exemption requests under the RoHS 2 regime. The work has been undertaken by the Oeko-Institut and has been peer reviewed by Fraunhofer Institute IZM.

1.1. Background and Objectives

The RoHS 2 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 electrical and electronic equipment (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 carried out evaluation of two exemptions in this study: one request for a renewal of an existing exemption and one request for a new exemption.

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. One request for the renewal of an existing exemption and one request for a new exemption were included in the scope of this project. The reader is referred to the corresponding sections of this report for more details on the evaluation results.

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

Ex. No.	Requested exemption wording	Applicant	Recommendation	Expiry date and scope
Existing exemptions				
Annex IV, 42	Mercury in electric rotating connectors used in intravascular ultra-sound imaging systems capable of high operating frequency (> 50 MHz) modes of operation	ACIST Medical	Mercury in electric rotating connectors used in intravascular ultra-sound imaging systems capable of high operating frequency (> 50 MHz) modes of operation.	Expires on 30 June 2026
Requests for new exemption				
2018-2	Lead and hexavalent chromium compounds in electric and electronic initiators of explosives for civil (professional) use	AUSTIN DETONATOR	Lead diazide, lead styphnate, lead dipicramate, orange lead (lead tetroxide), lead dioxide in electric and electronic initiators of explosives for civil (professional) use and barium chromate in long time pyrotechnic delay charges of electric initiators of explosives for civil (professional) use.	Five years

Note: As in the RoHS legal text, commas are used as a decimal separator for exemption formulations appearing in this table, in contrast to the decimal point used throughout the rest of the report as a separator.

2. Executive summary: French - Note de synthèse: Français

Conformément aux termes du contrat-cadre ENV.A.2/FRA/2015/0008 du 27/03/2015, un consortium mené par l'Oeko-Institut a été chargé par la direction générale (DG) de l'environnement de la Commission européenne afin d'apporter son concours technique et scientifique à l'évaluation des demandes d'exemption suivant le nouveau régime de la directive RoHS 2. Les travaux ont été réalisés par l'Oeko-Institut, et fait l'objet d'un examen par le Fraunhofer IZM (Institut Fraunhofer pour la fiabilité et la microintégration).

2.1. Contexte et objectifs

La directive RoHS 2011/65/UE est entrée en vigueur le 21 juillet 2011, ce qui a entraîné l'abrogation de la directive 2002/95/CE le 3 janvier 2013. Il est possible de considérer que la directive a prévu deux régimes qui ont permis de prendre en compte les exemptions, à savoir le régime RoHS 1 (l'ancienne directive 2002/95/CE) et le régime RoHS 2 (la directive actuelle 2011/65/UE).

- § Le champ d'application couvert par la directive est désormais plus large sachant qu'il englobe l'intégralité des équipements électriques et électroniques (EEE ; tel que mentionné dans les articles 2(1) et 3(1));
- § L'ancienne liste d'exemptions a été transformée en annexe III et est susceptible de s'appliquer à toutes les catégories de produits conformément aux limitations énumérées dans l'article 5(2) de la Directive. L'annexe IV a été ajoutée et énumère les exemptions spécifiques aux catégories 8 et 9;
- § La directive RoHS 2 inclut la disposition selon laquelle les demandes d'exemption doivent être déposées conformément aux termes de l'annexe V. Cependant, même si un certain nombre de points sont déjà énumérés dans cette annexe, l'article 5(8) prévoit qu'un format harmonisé et des lignes directrices détaillées prenant en compte la situation des PME, seront adoptés par la Commission européenne; et
- § La procédure et les critères relatifs à l'adaptation au progrès scientifique et technique ont fait l'objet de modifications et comportent désormais certains points et conditions supplémentaires qu'il est nécessaire de prendre en considération. Ces derniers sont détaillés ci-dessous.

La nouvelle directive détaille les différents critères relatifs à l'adaptation de ses annexes au progrès scientifique et technique. L'article 5(1) énumère les différents critères et questions qui doivent être considérés pour justifier l'ajout d'une exemption aux annexes III et IV:

- § Le premier critère est susceptible d'être perçu comme un critère de seuil et renvoie au règlement REACH (1907/2006/CE). Une exemption peut uniquement être accordée si elle ne fragilise pas la protection environnementale et sanitaire offerte par le règlement REACH;
- § De plus, une demande d'exemption doit être déclarée légitime selon l'une des trois conditions suivantes :

- Une substitution est irréalisable d'un point de vue scientifique ou technique. Autrement dit, un matériau de substitution ou un substitut pour l'application dans laquelle la substance faisant l'objet d'une restriction est utilisée, doit encore être découvert, développé et, dans certains cas, jugé apte à une utilisation dans l'application spécifique;
 - La fiabilité d'un substitut n'est pas garantie. En d'autres termes, la probabilité que les EEE recourant à un substitut assurent la fonction requise sans connaître de défaillance pendant une durée comparable à celle de l'application dans laquelle la substance d'origine est incluse, est inférieure à celle de l'application;
 - Les impacts négatifs de la substitution sur l'environnement, la santé, et la sécurité des consommateurs l'emportent sur ses avantages.
- § Dès lors que l'une de ces conditions est remplie, l'évaluation des exemptions, estimation de la durée nécessaire comprise, devra tenir compte de la disponibilité des substituts et de l'impact socio-économique de la substitution, ainsi que les effets néfastes sur l'innovation et une analyse du cycle de vie concernant les impacts globaux de l'exemption; et
- § Le fait que toutes les exemptions doivent désormais présenter une date d'expiration et qu'elles peuvent uniquement être renouvelées après soumission d'une nouvelle demande, constitue un aspect inédit.

Face à un tel contexte, et compte tenu du fait que les exemptions soumises au champ d'application élargi de la Directive RoHS 2 peuvent être demandées depuis l'entrée en vigueur de la directive (le 21 juillet 2011), les experts ont réalisé l'évaluation de deux exemptions dans le cadre de la présente mission (une renouvellement d'exemption et une nouvelle demande d'exemption).

2.2. Les principales conclusions – Synthèse des résultats de l'évaluation

Les demandes d'exemption couvertes dans le présent projet et les demandeurs concernés, de même que les recommandations finales et les dates d'expiration proposées, sont résumées dans le Tableau 2-1 ci-après. Une demande de renouvellement d'exemptions existantes, ainsi que une demande de nouvelles exemptions, ont été incluses dans le cadre du présent projet. Le lecteur est invité à se référer aux sections correspondantes du présent rapport pour plus de détails sur les résultats de l'évaluation.

Tableau 2-1: Récapitulatif des demandes d'exemption, des recommandations associées et des dates d'expiration

Traduction en français fournie par souci de commodité. En cas de contradictions entre la traduction française et la version originale anglaise, cette dernière fait foi.

Ex. n°	Termes de l'exemption demandée	Demandeur	Recommandation	Date d'expiration et champ d'application
Exemptions en vigueur				
Annexe IV, Ex. 42	Le mercure dans les collecteurs électriques rotatifs utilisés dans les systèmes d'imagerie intravasculaire ultrasonore supportant une fréquence de fonctionnement élevée (> 50 MHz).	ACIST Medical	Le mercure dans les collecteurs électriques rotatifs utilisés dans les systèmes d'imagerie intravasculaire ultrasonore supportant une fréquence de fonctionnement élevée (> 50 MHz).	Expire le 30 juin 2026.
Demandes de nouvelles exemptions				
2018-2	Composés de Plomb et de Chrome hexavalent dans les dispositifs de déclenchement électriques et électroniques d'explosifs à usage civil (professionnel)	AUSTIN DETONATOR	Diazone de plomb, styphnate de plomb, dipicramate de plomb, plomb orange (tétroxyde de plomb), dioxyde de plomb présent dans les dispositifs de déclenchement électriques et électroniques d'explosifs à usage civil (professionnel) et chromate de baryum dans les charges de retard pyrotechnique à combustion lente des dispositifs de déclenchement électriques d'explosifs à usage civil (professionnel)	5 ans

Note : Comme dans le texte juridique de la directive RoHS, les virgules sont utilisées comme séparateur décimal pour les formulations d'exemption figurant dans ce tableau, contrairement au point décimal utilisé comme séparateur dans le reste du rapport.

3. Introduction

3.1. Project scope and methodology

The scope of the project covers the evaluation of two exemptions: one for exemption renewal and one request for a new exemption. 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 31 October 2018 and held for duration of seven weeks, thus concluding on 19 December 2018.

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.

Following the stakeholder consultations, an in depth evaluation of the exemptions began. The requests were evaluated according to the relevant criteria laid down in Article 5 (1) of the RoHS 2 Directive, as shown in the section 1.1 on background and objectives.

The evaluations of the exemptions evaluated in the course of the project appear in chapters 5 and 6. The information provided by the applicants and by stakeholders is summarised in the first sections of the respective chapters. 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. In the Critical Review part, the submitted information is discussed, to clarify how the consultants evaluate the various information and what conclusions and recommendations have been made. The general requirements for the evaluation of exemption requests as set by the European Commission may be found in the technical specifications of the project.¹

3.2. Project set-up

Assignment of project tasks to Oeko-Institut, started in 14 September 2018. The overall project has been led by Carl-Otto Gensch. At Fraunhofer IZM, the contact person was Otmar Deubzer.

¹ Cf. http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_16/Technical_Specification_RoHS16.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 that:

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

Regulation (EC) No 1907/2006 on the **Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)** regulates the use of chemical substances on the Union market. 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 Chemicals 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 Annexes related to authorisation or restriction of substances and articles under the REACH Regulation, 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 it has first been adopted for the re-evaluation of some existing RoHS exemptions 7(c)-IV, 30, 31 and 40,² and in the following for the evaluation of a range of requests assessed through previous projects in respect of RoHS 2.³ Substances for which an authorisation or restriction

² See Zangl et al. 2012

³ Gensch, C., Baron, Y., Blepp, M., Deubzer, O., Manhart, A. and Moch, K. 2012

process is underway may be discussed in some cases in relation to a specific exemption, in order to check possible overlaps in the scope of such processes and of requested RoHS exemptions and to identify the need for possible alignments of these two legislations.⁴

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 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 Authorisation List); or
- § listed in REACH Annex XVII (the List of Restrictions).

As 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 register of the amendments to the REACH legal text.

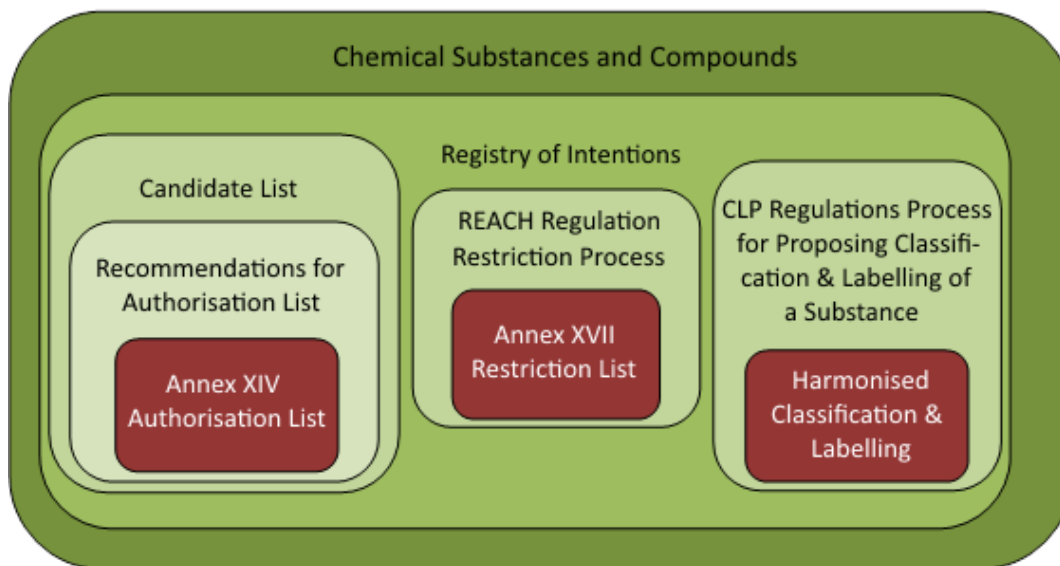
Figure 4-1 shows the relationship between the two processes under REACH as well as the process on harmonized classification and labelling under the CLP regulation (Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging). Substances included in the red areas may only be used when certain specifications and or conditions are fulfilled.

For further reports, see all archived reports of Oeko-Institut e.V. and Fraunhofer IZM at <http://rohs.exemptions.oeko.info/index.php?id=164>

⁴ In 2014, the European Commission has prepared a Common Understanding Paper regarding the REACH and RoHS relationship in 2014 with a view to achieving coherence in relation to risk management measures, adopted under REACH and under RoHS:

REACH AND DIRECTIVE 2011/65/EU (RoHS) A Common Understanding; Ref. Ares(2014)2334574 - 14/07/2014 at <http://ec.europa.eu/DocsRoom/documents/5804/attachments/1/translations>

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



Source: Own illustration

Before reaching the "Registry of Intentions" as shown in the figure above, there are additional activities and processes in order to identify substances of potential concern conducted by the ECHA together with the Member States and different ECHA Expert Groups.⁵ If a Member State evaluates certain substance to clarify whether its use poses a risk to human health or the environment, the substance is subject to a Substance Evaluation. The objective is to request further information from the registrants of the substance to verify the suspected concern. Those selected substances are listed by ECHA in the community rolling action plan (CoRAP).⁶ If the Substance Evaluation concludes that the risks are not sufficiently under control with the measures already in place and if a Risk Management Option (RMO) analyses does not conclude that there are appropriate instruments by other legislation / actions, the substance will be notified in the Registry of Intentions.

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

- § Member States Competent Authorities (MSCAs) / ECHA, on request by the Commission, may prepare Annex XV dossiers for identification of SVHCs, 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 inform interested parties of the substances for which the authorities intend to submit Annex XV dossiers and, therefore, to facilitate timely preparation of the

⁵ For an overview in these activities and processes see the ECHA webpage at: <https://echa.europa.eu/substances-of-potential-concern>

⁶ Updates and general information can be found under: <https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances>. The list can be found on the following page: <https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>

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:

<https://echa.europa.eu/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
<https://echa.europa.eu/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 previous ECHA recommendations for inclusion in the Authorisation List are available at the ECHA website at
<https://echa.europa.eu/previous-recommendations>;
- § 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;
- § 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; and
- § As of May 2019, the last amendment of the REACH Legal Text was dated from 18 April 2018 (Commission Regulation (EU) No 2018/589) and so the updated consolidated version of the REACH legal text, dated 09.05.2018, was used to to reference Annexes XIV and XVII: The consolidated version is available at the EUR-Lex website: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20180509>.

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) of the RoHS Directive)
- § 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) as well as bis(2-

ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP).⁷

Compiled information in this respect has been included, with short clarifications where relevant, in Tables 1 and 2, which appear in Appendix 1.

The information has further been cross-checked in relation to the exemptions evaluated in the course of this project. This has been done to clarify that the Article 5(1)(a) 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 (Chapter 5 and 6) under the relevant section titled "REACH compliance – Relation to the REACH Regulation" (Section 5.6.1 through Section 6.6.1).

⁷ The four phthalates, DEHP, BBP, DBP and DIBP have been added to the Annex according to Commission Delegated Directive (EU) 2015/863 of 31 March 2015.

5. Annex IV, Ex. 42

“Mercury in electric rotating connectors used in intravascular ultra-sound imaging systems capable of high operating frequency (> 50 MHz) modes of operation”

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 or completed 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

ACIST	ACIST Medical
EoL	End-of-life
Hg	Mercury
IVUS	Intravascular Ultrasound Imaging Systems
RF	Radio Frequency (signal)
rpm	revolutions per minute

5.1. Background

Exemption 42 in RoHS Annex IV expires 30 June 2019:

“Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation”

ACIST has requested the renewal of the exemption for an additional validity period of seven years.

The request for exemption had been reviewed in 2013 by (Gensch et al. 2013), page 95 and subsequent, resulting in the current exemption.

5.2. Amount of mercury used under the exemption

The applicant calculates the annual amount of mercury used under the exemption at hand to be 9 grams in total. This number is based on the assumption that 20 units will be sold annually in the EU, each unit containing 450 milligrams mercury. (ACIST Medical 2018a)(ACIST Medical 2018a).

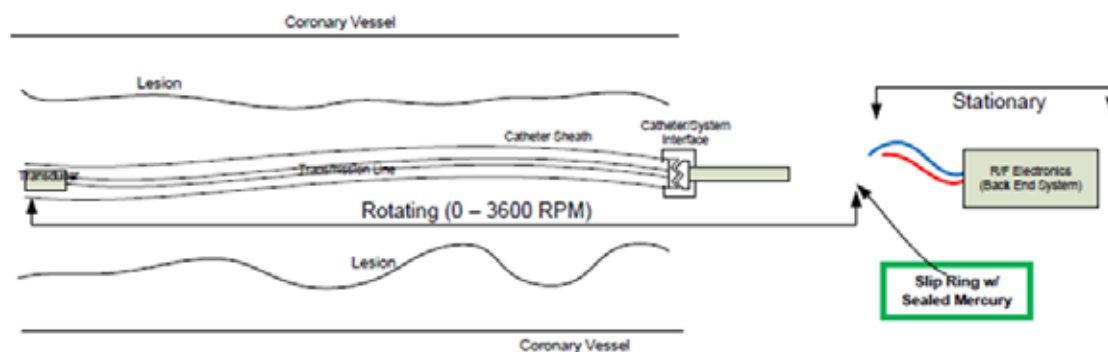
5.3. Technical description of the requested exemption

The requested exemption relates to an electro-mechanical component which is used in medical device applications for intravascular ultrasound imaging. In a user guide this technique is described as follows:

"Intravascular ultrasound (IVUS) imaging is a technique that emits sound energy from a transducer at the tip of a small catheter that is guided into the coronary arteries of the heart. Sound waves reflected from vascular tissues are received by the transducer and sent to the system console, where a high-resolution, cross-sectional image is displayed in real time. The IVUS technique provides in vivo visualization of the coronary artery lumen, coronary artery wall morphology, and devices (such as stents) at or near the surface of the coronary artery wall." (ACIST Medical Systems 2018)
Similar descriptions of this method are given by competitors like Philips⁸.

The ACIST IVUS system specifically consists of a mechanically rotating ultrasound element (transducer) and stationary electronic equipment. Mercury based slip rings provide the electrical conduction path between the rotating transducer and stationary electronic equipment. Through this connection pass both a high voltage RF signal at specific frequencies and a low voltage RF reflected ultrasound signal at specific frequencies. The connection is maintained as the transducer is rotated at varying rotational speeds (0 to 3600 rpm). See below for illustration.

Figure 5-1: Schematic structure of IVUS system, indicating critical function performed by mercury based electric rotating connector



Source: (ACIST Medical 2018a)

ACISTS already explained in their communication related to the first exemption evaluation in 2013 that there are several IVUS systems on the market, operating at different frequencies and providing different performance characteristics, see Table 5-1. The higher frequency operation enabled by the use of mercury is understood to allow obtaining higher resolution imaging beneficial for patients. Furthermore, system pullback speeds for the ACIST IVUS HDi, specified at 0.5, 1.0, 2.5, 5.0 or 10.0 mm/s are explained to allow a range of dwell times between 130 to 16 seconds whereas

⁸ E.g. <https://www.usa.philips.com/healthcare/education-resources/technologies/igt/intravascular-ultrasound-ivus>; last accessed 03/04/2019

other IVUS devices will have dwell times in the range of 130-70 seconds, depending on the applied pullback speed. ACIST reference two angioplasty studies indicating that ischemia⁹ generally occurs in patients undergoing balloon inflations in 30 to 60 seconds. This is to show that the possible reduced dwell times can assist in reducing the risk of catheter induced ischemia. (Gensch et al. 2014)

Table 5-1: Comparison of main characteristics of several IVUS systems

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

* Soft Tissue Penetration with contrast injection (blood clearing)

Source: ACIST cited in (Gensch et al. 2014)

⁹ Ischemia is a restriction in blood supply to tissues.

Against this background ACIST was asked in the course of the current evaluation to provide updated information, especially with regard to other systems operating with high frequency above 50 MHz. According to ACIST, there are (at least) two other systems available, namely the Boston Scientific OPTICROSS HD 60 MHz and the Terumo Visicube 60 MHz (ACIST Medical 2018b). Both enterprises were asked to provide more detailed information on their systems and the need to use mercury based electric rotating connectors, however, though urged to provide a statement, they did not reply.

5.4. Applicant's justification for the requested exemption

According to ACIST, there are several key requirements that the electric rotating connector must meet in order to maintain system functionality. These are the following (ACIST Medical 2018a):

- § Max. Freq.: <80 MHz
- § Contact Resistance: <1Ohm
- § Max. rpm: 3600
- § Temp Max. F (C)/Min. F (C): 140 (60)/45(7)
- § Life: 300 Million rotations

The applicant further states that the slip ring is the critical component in the mechanical imaging system that maintains electrical connection from the rotating transducer to the front-end ultrasound receive/transmit electronics contained within the imaging system. The slip ring is required to ensure transfer of ultrasound's RF signal in high-voltage, low current transmit mode, as well as low voltage, low current receive mode, while maintaining extremely low RF noise and not degrading the quality of the ultrasound signal itself for high rotational speed (ACIST Medical 2018a).

5.4.1. Substitution at component level

ACIST, as applicant of the request for exemption at hand, reviewed two different commercially available alternatives to mercury slip rings as possible replacements:

- § Gallium alloy liquid metal – used as a direct substitute of mercury (supplied by Asian Tool)
- § Fiber brush technology, consisting of precious metal brushes and rings (supplied by Moog Components Group)

The table below provides a comparison of the published specifications for the above mentioned components.

Table 5-2: Specifications of possible replacements

Specification	Mercotac 205-H	Asian Tool A2S NM	Moog EC3848-6
Technology	Mercury wetted	Gallium alloy	Fiber brush
Voltage	0-250 VAC	0-250 VAC	Low millivolt range to 100 VDC
Operating Speed	0-3600 rpm	0-1000 rpm	0 - 10,000 rpm
Number of Rings	2	2	6
Temperature	7°F - 60°F	8°C-80°C	50°C (120°F) over 1,000 rpm 80°C (175°F) up to 1,000 rpm
Current Rating	4.0 Amps	4.0 Amps	1.0 Amps maximum per ring
Max. Freq.	200 MHz	20 MHz	No spec stated
Contact Resistance	<1mOhm	No spec stated	No spec stated
Rotation Torque (gm-cm)	35	75	No spec stated
Insulation Resistance	>25MΩ	>25MΩ	No spec stated

Source: (ACIST Medical 2018a)

Based on these specifications ACIST concluded that both alternatives had to be ruled out as possible replacements for following reasons (ACIST Medical 2018a):

- § The speed rating of the Gallium alloy liquid metal solution is much less than the required 3600 rpm for the HDi system. Furthermore the frequency rating does not fit with the requirements.
- § The fiber brush technology does not meet the requirements to replace mercury based slip rings, as technology and components available from the supplier had not changed in the last five years since the submission of the first request for exemption.

ACIST details the analysis performed with regard to the fiber brush technology as follows:

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

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

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

- § *The published EC3848-6 spec sheets provide little data regarding RF performance. Only one parameter is listed that is of interest to an RF application. The 20 milliohms specification does not provide a complete picture due to being limited to the 5 rpm speed. This would have to be measured at operating speed, then the results would have to be shown in relation to frequency.*

- § *Other missing information that would be required to characterize an inline RF device includes: Return loss vs frequency; Loss vs frequency; and Noise vs frequency.*
- § *The EC3848-6 does not have a 3 amp per channel capability (rated at 1 amp per channel). It would require three contacts for each leg of our signal path to handle our 3 amp signal. This would impact noise susceptibility due to the transmission line differences between the Mercotac coax transmission line and the Moog solid wire flying lead and solder terminal design. To accommodate this difference, a complete redesign of the electronics would be required, and the make-and-break electrical contacts would still be subject to pitting and the reliability issues mentioned above.*
- § *Routing the signal path through 6 individual slip rings will not only upset the critical balance of the catheter connection, but also expose the signal path to interference from the motor driver circuitry as well as the digital circuit boards inside the PIM. The motor and digital circuit boards are located within millimetres of the slip ring.*

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

5.4.2. Substitution at system level

The applicant has been further asked to provide information on possible attempts for contactless signal transmission. In this context ACIST states that a contactless signal transmission does not seem feasible due to the sensitive nature of the imaging signal. Therefore, no resources were invested on research in this direction (ACIST Medical 2018b).

5.4.3. Environmental arguments

Similar to the initial request for exemption in 2013, ACIST does not expect environmental or health impacts to incur, as the product is fully recycled at the end of life and mercury is completely encapsulated with no access to operators or patients (ACIST Medical 2018a).

5.4.4. Socioeconomic impacts

With regard to possible socioeconomic impacts and especially regarding health, should the exemption not be granted, ACIST emphasized that the HDi System and Kodama catheter provides means to perform intravascular ultrasound (IVUS), a common technology for adjunctive imaging during percutaneous coronary interventions and monitoring progression/regression of coronary arterial disease. IVUS is a recognized method for determining if intervention of a stenosis lesion is necessary. Numerous clinical trials involving percutaneous coronary intervention and medical therapy have used IVUS imaging technology to evaluate primary and secondary clinical endpoints. Further, the scientific literature contains numerous reports that describe the safe and effective use of IVUS technologies for intracoronary imaging. The ACIST HDi System and Kodama catheter features, in addition to standard 40 MHz frequency, a 60 MHz frequency, which has the potential to provide better images in certain circumstances.

The system also provides, in addition to the standard pull-back speeds of 0.5 – 2.0 mm/sec, faster speeds (up to 10 mm/sec), which reduce the amount of time required to acquire an image and thereby reduces the risk for ischemia. (ACIST Medical 2018b)

5.5. Stakeholder contributions

No contributions were submitted regarding this exemption in the course of the stakeholder consultation.

5.6. Critical review

5.6.1. REACH compliance – Relation to the REACH Regulation

If granted, the exemption would allow the use of mercury in electric rotating connectors used in intravascular ultra-sound imaging systems capable of high operating frequency (> 50 MHz) modes of operation.

Annex XVII of the REACH Regulation contains several entries restricting the use of mercury compounds as well as mercury. In relation to the exemption request at hand, Entry 18a could be of relevance as it restricts the use of mercury (for details see Annex at page 50):

- § in fever thermometers;
- § in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers);
- § in a number of specified measuring devices intended for industrial and professional uses, in particular barometers, hygrometers, manometers, sphygmomanometers¹⁰, strain gauges to be used with plethysmographs¹¹, tensiometers, thermometers and other non-electrical thermometric applications, mercury pycnometers and mercury metering devices for determination of the softening point.

Seeing as the exemption for mercury in electric rotating connectors does not relate to these applications, it is concluded that a renewal of the exemption would not weaken the protection afforded by REACH through Entry 18a.

Other entries of Annex XVII of the REACH Regulation relate to mercury compounds (Entry 18 for anti-fouling, wood preservation etc.; Entry 62 phenylmercury compounds). As the request for exemption at hand uses mercury in its metallic form these entries are not applicable. No other relevant entries in regard to the use of mercury could be identified in Annex XIV and Annex XVII (status May 2019). 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.

¹⁰ Device used to measure blood pressure.

¹¹ Device for measuring changes in volume within an organ.

5.6.2. Relation to the Minamata Convention

It should be noted that mercury is also restricted in certain applications through the Mercury Regulation 2017/852 implementing the international Minamata Convention on Mercury of 2013. The Mercury Regulation refers to the RoHS Directive in Article 8(1) on *“New mercury-added products and new manufacturing processes”* and stipulates that *“Economic operators shall not manufacture or place on the market mercury-added products that were not being manufactured prior to 1 January 2018 (‘new mercury-added products’) unless authorised to do so by means of a decision taken pursuant to paragraph 6 of this Article or allowed to do so under Directive 2011/65/EU of the European Parliament and of the Council”*. As Ex. 42 was initially granted in 2015, the consultants understand the use of mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation and their placing on the market to have been authorised through the RoHS Directive in the past. In this sense, coherence with the Mercury Regulation is understood to be established.

5.6.3. Scientific and technical practicability of substitution

From the information submitted by the applicant and in absence of contributions by stakeholders, the main question concerns the practicability of substituting the mercury based electric rotating connectors with mercury free alternatives:

- § With regard to substance alternatives, besides existing data from a supplier, the applicant provided a thorough analysis of tests providing insights in durability of slip rings using gallium alloy instead of mercury. From this perspective the applicant provides a plausible explanation why mercury cannot be substituted at present in this application.
- § Furthermore the applicant describes in detail why design alternatives, especially fibre brush technology, do not comply with the particular requirements of signal transmission. The consultants consider the explanations of the limitations detailed and plausible.
- § Based on a later communication with ACIST representatives, it could be clarified that most competitor catheters utilize multiple transducers in their tip. This kind of transducer does not physically rotate, and therefore, there is no need for electric rotating connectors. However, 45 MHz is considered as the technical limit for arrayed transducer (non-rotational) image generation, whereas rotational image generation at the high frequency requires high speeds, particularly during high speed pullbacks. This characteristic necessarily requires electric rotating connectors like mercury slip rings.
- § Regarding other systems operating at 60 MHz, ACIST mentioned the Boston Scientific Opticross HD 60 MHz. Though this manufacturer did not reply to the consultant's inquiries, publicly available information suggests that this device may also use a rotating transducer: *“The imaging core is composed of a hi-torque, flexible, rotating drive cable with a radial looking 60 MHz ultrasonic transducer at*

the distal tip."¹² It could nonetheless not be concluded whether the device uses a mercury slip ring or another technology.

- § The comparison of systems operating below 45 MHz with non-rotational transducers versus rotational image generation allows a better understanding of the functionalities including resolution (both axial and lateral), higher frame rates and faster pull-back speeds. The higher resolution of IVUS devices operating with frequencies at 60 MHz is understood to increase the diagnostic abilities.

5.6.4. Environmental arguments and socioeconomic impacts

In the consultants understanding, the main justification for the request regards the impracticability of substitution. Therefore environmental and socioeconomic impacts were not further reviewed in the course of the evaluation at hand.

5.6.5. Conclusions

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

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

From the information provided by the applicant, it is concluded that elimination or substitution of mercury in IVUS devices using rotational transducers and operating at frequencies above 45 MHz is impractical. It is also understood that IVUS systems operating at 60 MHz have a number of significant advantages over other IVUS devices available on the market operating at lower frequencies, which do not require the use of the mercury-containing rings. An exemption from the RoHS substance restrictions would be justified, as substitution and elimination of mercury are scientifically and technically not practicable.

ACIST has requested the renewal of the exemption for an additional validity period of seven years. The request at hand complies with the maximum validity period of exemptions listed in Annex IV of the RoHS directive. Given the specific technical requirements especially with regard to the requirement to provide signal transfer via rotational connectors the consultants consider the requested duration to be justified.

5.7. Recommendation

It is recommended to renew the exemption until 30 June 2026 with its current wording:

¹² See product information under: https://www.bostonscientific.com/content/dam/Manuals/us/current-rev-en/50726168-01A_OptiCross_HD_6HD_eDFU_en-USA_s.pdf

“Mercury in electric rotating connectors used in intravascular ultra-sound imaging systems capable of high operating frequency (> 50 MHz) modes of operation.”

Expires on 30 June 2026.

6. Request 2018-2

“Lead and hexavalent chromium compounds in electric and electronic initiators of explosives for civil (professional) use”

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 or completed 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

AD	AUSTIN DETONATOR
EEL	Electric and electronic initiators
EoL	End-of-life
CrVI	Hexavalent chromium
LAD	Latest Application Date
MPO	Ministry of Industry and Trade of the Czech Republic (Ministerstvo Průmyslu a Obchodu)
Non EEL	Non-electric initiators for explosives
Pb	Lead
PNEC	Predicted No-Effect Concentration

6.1. Background

According to Austin Detonator (AD)¹³, electric and electronic initiators (EEL) are a part of electric and electronic detonators that are primarily used for the mining of minerals (e.g. building stones, ores and precious metals), the extraction of fossil fuels (e.g. natural gas, oil and coal) as well as for construction and demolition activities (e.g. tunnelling, demolition of chimneys and buildings). Moreover, EEL are also used for components of rescue integrated systems to remove the consequences of floods, snow-caps, ice-bumps and fallen trees as dangerous obstacles in waterways, etc.

As shown in Figure 6-1, for many fields of applications both electric and electronic detonators can be used. As pointed out by AD¹⁴, the choice of a suitable detonator is influenced by various aspects, but is primarily based on the practical experience. For

¹³ AUSTIN DETONATOR s.r.o. 2018b

¹⁴ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

example, electronic detonators are used to optimise fragmentation of extracted rock and to reduce vibrations generated during blasting operations. For some fields of application, however, the choice appears to be limited. For example, for the extraction of rock salt, only electric detonators could be used, whereas the mining of ores only requires electronic detonators (cf. following figure).

Figure 6-1: Fields of application for electric and electronic detonators

	Electric detonators	Electronic detonators
Mining of mineral resources		
Building stone	✓	✓
Ores	✗	✓
Rock-salt	✓	✗
Precious metals	✓	✓
Mining of fossil fuels		
Natural gas	✓	✗
Oil	✓	✗
Coal	✓	✓
Construction, demolition and other activities		
Tunneling	✓	✓
Demolition of chimneys	✓	✓
Demolition of buildings	✓	✓
Geological Research	✓	✓
Cleaning of deposits of hot plants (heating plants, power plants)	✓	✗

Source: Austin Detonator (2018b)

According to the applicant¹⁵, lead (Pb) compounds are contained in the following components of EEI:

- § Electric fuseheads (as primary explosive charge, relevant for both electric and electronic initiators);
- § Pyrotechnic delay charges (only relevant for electric initiators);
- § Primary explosives (relevant for both electric and electronic initiators).

¹⁵ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

Compounds of hexavalent chromium (CrVI) are only included in:

§ Pyrotechnic delay charge (only relevant for electric initiators).

Besides assembled EEI, also its components (electrical fuseheads, electrical igniters and electric elemented cups; cf. Section 6.3 for more details) are placed on the market and can be used separately by downstream users in other EEI manufacturing areas.¹⁶

AD¹⁷ points out that professional EEI are completely destroyed during their use. In their interpretation, AD considers EEI by their very nature to be beyond the scope of the WEEE-Directive and RoHS 2: “This means that there is no waste that can be reused, recycled or processed in the sense of Article 3 (d), (e) and (h) of Directive 2002/96/EC”¹⁸ (WEEE directive).

However, AD¹⁹ has submitted a request for exemption for the use of:

“Lead and hexavalent chromium compounds in electric and electronic initiators of explosives for civil (professional) use”

A duration for the requested exemption has not been specified by the applicant.

6.2. Amount of Pb and CrVI compounds used under the exemption

Average amounts of Pb and CrVI compounds used for EEI are not provided by the applicant. However, for a certain electric detonator that is used for the extraction of rock-salt, AD²⁰ reports 0.07 grams of Pb in Pb compounds and 0.18 grams of CrVI in CrVI compounds. Within this context the applicant mentions that these types of electric detonators contain the highest possible amount of Pb and CrVI compounds from all EEIs produced at AD. As another example, for electronic detonators used for the extraction of stones the amount of Pb in Pb compounds is quantified with 0.043 grams.

Regarding the amount of Pb from Pb compounds entering the EU market through the application for which the exemption is requested, AD²¹ calculates a total of 2.9 tonnes per year. For CrVI from CrVI compounds entering the EU market, a total of 0.6 tonnes per year is reported. These figures are calculated by the applicant from all Pb and CrVI compounds used to produce EEI based on 2016 figures and by the conversion of atomic and molar masses. It is understood that these figures refer only to EEI. AD's total annual use of Pb for its whole product range, also including non-electric initiators for explosives (referred to as “non EEI” by the applicant), is estimated at 10.6 tonnes per year. For CrVI, a total annual use of 0.74 tonnes per year is quoted by AD.

¹⁶ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

¹⁷ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

¹⁸ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

¹⁹ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

²⁰ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

²¹ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

These amounts, however, only cover the EEI produced by AD. Even though the applicant describes itself as “one of the largest producers of EEI in the EU”²², the consultants consider the total amount of Pb and CrVI compounds entering the EU market to be significantly higher. According to the applicant’s market share that is quantified by AD²³ with “up to 20% of the European market”, the consultants estimate the total amount of Pb from Pb compounds and CrVI from CrVI compounds placed on the EU market by all manufacturers and importers of EEI to be several (roughly five) times higher than the values mentioned above.

6.3. Technical description of the requested exemption

6.3.1. Electric detonators

As described by AD²⁴, an assembled electric detonator consists of an electric igniter (i.e. an electric fusehead including the lead wires), an electric elemented cup (a cylindrical capsule containing a pyrotechnic delay charge and an explosive primary charge) and an explosive secondary charge (also called industrial explosive). When an electric detonator is used, the electrical energy is fed into the electric fusehead via lead wires that are connected to the electric fuse. Due to electrical current the electric fusehead releases thermal energy, which ignites the explosive fusehead and produces an intense flame (see Figure 6-2, letter A). From the fusehead header, the flame will flare on the pyrotechnic delay charge and ignites it. The delay charge burns with a defined time and then initiates the primary charge (see Figure 6-2, letter B). The detonation wave initiates the secondary charge of the detonator (see Figure 6-2, letter C). The secondary charge of the detonator generates a strong shock wave, which subsequently initiates an industrial explosion (see Figure 6-2, letter D).

This principle of operation is schematically shown in the following figure.

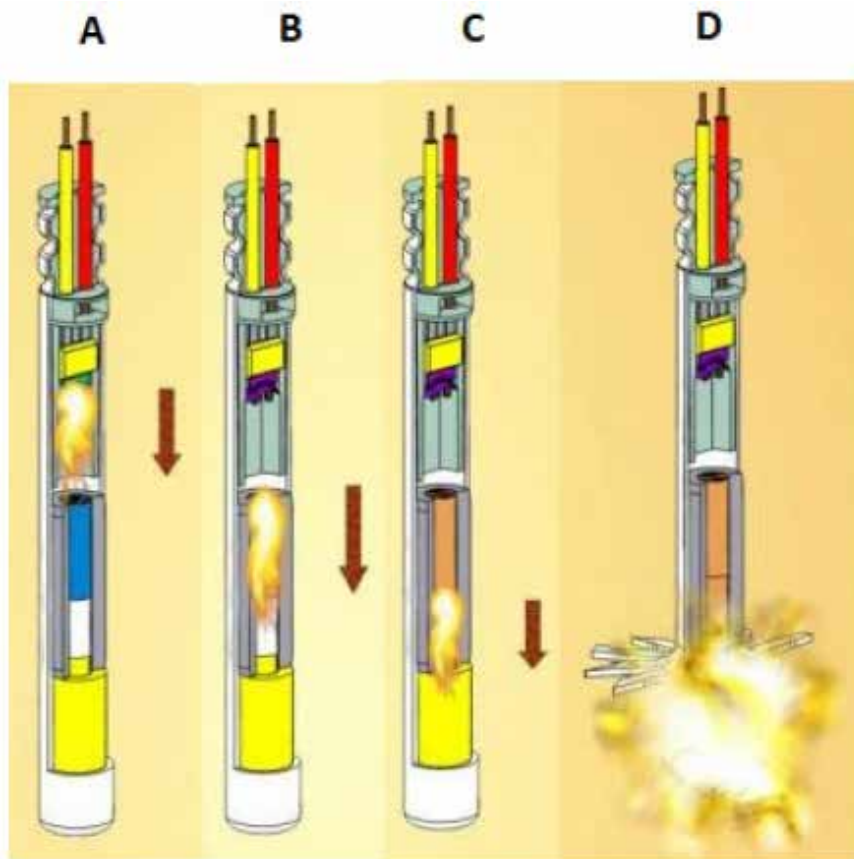
²² Op. cit. AUSTIN DETONATOR s.r.o. 2018b, p. 41

²³ Op. cit. AUSTIN DETONATOR s.r.o. 2018b, p. 45

²⁴ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

Figure 6-2: Principle of operation for electric detonators

A) fusehead ignition, B) ignition of pyrotechnic charge and primary charge initiation, C) initiation of secondary charge, D) detonator explosion and initiation of industrial explosion;



B)

Source: Austin Detonator (2018b)

6.3.2. Electronic detonators

Basically, the principle of operation of an electronic initiator is similar to an electric initiator. As depicted by AD²⁵, electronic initiators consist of an electrical initiation module (containing a small printed circuit with a microchip and a capacitor), an electric igniter (i.e. an electric fusehead with lead wires connected to it), an explosive primary charge and an explosive secondary charge. During the operation of an electronic initiator, the electrical initiation module controls the function of the entire detonator, i.e. the delay time, control and firing. By means of a specific device (a so-called "logger"), the electrical initiation module is programmed to release at the certain time that is determined by the energy stored in its capacitor. The electric current is then passed through the electric fusehead where it generates an intense flame, which ignites the primary charge. Ignition and explosion of the primary charge will cause the explosion of the secondary charge of detonator, which then initiates an industrial explosion.

In all these components Pb and CrVI compounds have the function of explosives and oxidisers. In order to ensure the reliability of detonators, these substances have to be

²⁵ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

chemically and thermally stable for extended periods on the one hand, on the other hand, they have to provide optimal sensitivity to external stimuli (cf. Section 6.4.1). The chemical identity of the used substances and mixtures cannot be disclosed in this report since AD²⁶ requested to keep them confidential.

6.4. Applicant's justification for the requested exemption

6.4.1. Substitution or elimination of Pb and CrVI compounds

According to AD²⁷, the company has been involved in the development and research of alternative substances for Pb and CrVI compounds used in EEI since 1995. These R&D activities have been performed in cooperation with leading Czech and foreign universities specialised in explosive technologies as well as with Austin Group research centres worldwide.

Further, AD²⁸ points out that “non EEI” (see Section 6.2) are by no means possible replacements for EEI (in the sense of a technological substitute), because they also contain Pb and CrVI compounds and cannot:

- § be used instead of electric detonators in places where an explosive dust-air mixture is present, in applications requiring separation of debris initiators, or in applications that require precise timing or resistance to high pressure and temperature;
- § achieve the exact timing required in applications where electronic detonators are used.

Within this context, AD²⁹ distinguishes the analysis and testing of possible substitutes into two groups:

- § Pb compounds used in primary explosives and primary explosive charges;
- § Pb a CrVI compounds used in pyrotechnic charges.

Substitutes for Pb compounds used in primary explosives and primary explosive charges

According to AD³⁰ candidates for primary explosives substitutes have to meet a number of essential criteria, such as:

- § High initiating strength;
- § Thermal stability within the required temperature range (up to 245 °C);
- § Optimal sensitivity to external stimuli;
- § Safe and continuous production.

²⁶ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

²⁷ AUSTIN DETONATOR s.r.o. 2018a

²⁸ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

²⁹ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

³⁰ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

Based on literature research and initial tests of physico-chemical parameters, the following compounds were tested by AD³¹ as possible substitutes:

- § High nitrogen derivatives and their salts;
- § Heterocyclic derivatives and their salts;
- § Complex azide compounds;
- § Amino compounds.

As pointed out by AD³², tests with these materials revealed that none of the groups of possible substitutes tested so far could meet all of the essential criteria mentioned above.

Substitutes for Pb and CrVI compounds used in pyrotechnic charges

Due to the fact that pyrotechnic charges are mixtures of substances with different properties (oxidisers, combustibles, binders, stabilizers, phlegmatists, etc.), AD³³ points out that alternative materials have to meet a broader set of criteria, such as:

- § Physico-chemical properties (e.g. humidity, purity, particle size, specific surface, crystalline modification, reactivity);
- § Stability in mixtures;
- § Technology of pre-treatment of feedstocks;
- § Technology of fabrication of pyrotechnic charges.

Against the background of these criteria and based on literature research as well as practical experience it is understood that AD³⁴ has tested the following compounds as possible substitutes:

- § Oxides and peroxides;
- § Heavy metal compounds;
- § Inorganic nitrogen compounds;
- § Heavy metal salts.

After having performed the tests, AD³⁵ came to the conclusion that only heavy metal salts could meet the criteria for physico-chemical properties and were suitable to be used as oxidisers. However, due to the non-fulfilment of other criteria (especially their stability in mixtures), AD considers heavy metal salts not as *“a full substitution for Pb and CrVI compounds”*³⁶.

Concerning the reliability of substitutes, AD³⁷ generally highlights that potential candidates *“must (...) be fully compatible with the individual initiator components in order to limit unwanted explosions and human health hazards”*. Within this context,

³¹ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

³² Op. cit. AUSTIN DETONATOR s.r.o. 2018b

³³ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

³⁴ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

³⁵ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

³⁶ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

³⁷ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

AD³⁸ is highly concerned of work accidents due to testing of alternatives and is rather reluctant to “change existing process and production technologies due to direct threat to human life”³⁹.

Besides risks arising from accidents, AD has observed several cases of adverse effects of the tested alternatives with regard to occupational health. For example, tests with diazodinitrophenol, a substance AD⁴⁰ considers as “REACH friendly”, revealed non-specific negative health outcomes during development activities, e.g. headaches, abdominal pain or nausea.

With more than 20 years of experience concerning substitution-related R&D, AD⁴¹ concludes that substitution is scientifically and technically impracticable and the required reliability cannot be fully guaranteed by the substitutes that have been investigated so far.

6.4.2. Environmental arguments

Impacts of Pb and CrVI compounds on occupational health

AD⁴² performs regular Pb and CrVI measurements in the work environment by using personal exposure meters. From the measured data, both the time-weighted average concentration and the short-term maximum concentration of the chemical are calculated. Based on this monitoring, AD⁴³ has implemented various risk management measures and points out that so far no occupational disease or death due to long-term exposure to Pb and CrVI compounds have been reported.

Impacts of the production of EEI on the environment

AD⁴⁴ states that the company also performs regular monitoring of soil, surface and groundwater pollution in the premises and the surrounding areas, whereas no contamination with Pb and CrVI could be observed. Environmental risk assessments of Pb have shown that the expected exposure concentrations of the Pb components do not exceed the limit values as quantified by the Predicted No-Effect Concentrations (PNEC). Based on these results, AD⁴⁵ comes to the conclusion that environmental risks from Pb exposure are negligible and sufficiently controlled.

Impacts of Pb and CrVI compounds on the users of EEI

According to AD⁴⁶, the exposure of professional workers and end-users is prevented due to the fact that EEI are hermetically sealed.

Impacts of the use of EEI on the environment

³⁸ Op. cit. AUSTIN DETONATOR s.r.o. 2018a

³⁹ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁴⁰ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁴¹ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁴² Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁴³ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁴⁴ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁴⁵ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁴⁶ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

Concerning the impacts on EEI on the environment during their use, AD⁴⁷ claims that *“only trace amounts of Pb and CrVI compounds, which are not detectable by sensitive analytical methods and do not cause contamination of the extracted raw materials, are infiltrating the extracted raw material itself.”*

This claim is substantiated by AD⁴⁸ with results of rock-salt analyses showing that the concentration of lead and chromium in the tested samples of the end product is below detection limit of the used equipment (<0.02 mg/kg). Furthermore, calculations based on the average number of used EEI per tonne of extracted material result in figures that are below the mentioned detection limit (Pb: 0.004 mg/kg; CrVI: 0.01 mg/kg).

Based on these findings, AD concludes *“that the use of electric detonators for professional use does not pose any risk either from the point of view of the threat to the environment or to human health”*⁴⁹.

6.4.3. Socioeconomic impacts

Impacts on producers of EEI

AD⁵⁰ points out that for the company, the Union market is of great importance, since the largest share (55%) of worldwide sales is generated by sales on this market. Furthermore, total EEI sales represent almost half of total EU sales. In case the requested exemption would not be granted, AD expects to lose almost half of its revenues in the EU. Besides the losses in revenues, AD expects further monetary consequences of this potential development. This would refer especially to the fixed costs of EEI marketed in the EU that AD estimates to reach almost 2.4 Mio. EUR per year. In a worst case scenario, AD expects total monetary losses up to 39 Mio. EUR per year including lost gross profit from EEI production and the value of fixed costs of EEI production marketed in the EU. AD expects that these economic impacts would eventually result in necessary dismissal of employees.

Impacts on users of EEI

In case of not granting an exemption for EEI applications, AD⁵¹ expects also negative impacts on professional EEE users: Due to the dependency of the mining of mineral resources and fossil fuels on EEI, a ban would cause an overall weakening of the EU's fossil fuel and mineral market. As a result, the demand for imports of these raw materials from non-EU countries would increase, which could cause rising costs for the industries that are dependent on minerals and fossil fuels (e.g. agriculture, aviation and automotive industry, computers and information technology), and finally price increases of products that are used in everyday life.

⁴⁷ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁴⁸ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁴⁹ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁵⁰ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁵¹ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

6.5. Stakeholder contributions

Ministry of Industry and Trade of the Czech Republic

The contribution submitted by Ministry of Industry and Trade of the Czech Republic (MPO)⁵² expresses support for the proposal to grant an exemption as requested by AD. For the decision-making concerning the request for exemption, MPO recommends to take into consideration that in their practical application EEI eventuate in their total consumption with no remaining waste that could be collected and properly used for recycling or disposal. Therefore, it is considered to be impossible to meet several objectives of the preamble of RoHS 2. In detail, eight articles out of 30 from the preamble could not be met, including articles 2, 4, 7, 8, 13, 17, 20 and 30.

Consequently, in case of EEI the restriction of their use would not contribute to the mitigation of potential problems at end-of life waste treatment.

Furthermore, MPO⁵³ points out that in the EU, both EEI and non-EEI are subject to the rules regulated by the Directive 2014/28/EU⁵⁴. This Directive, which specifically applies to explosives for civil uses, sets essential product safety requirements, according to which each EEI:

- § “must be designed, manufactured and supplied in such a way as to present a minimal risk to the safety of human life and health, and to prevent damage to property and the environment”⁵⁵ and
- § “must attain the performance characteristics specified by the manufacturer in order to ensure maximum safety and reliability”⁵⁶.

Within this context, MPO⁵⁷ is of the opinion that the principle of *lex specialis* providing that a special legal regulation (like Directive 2014/28/EU) takes precedence over a general regulation (like RoHS 2). Therefore, MPO considers it necessary to understand the following two provisions of Directive 2014/28/EU, which set out that:

- § “Member States shall not prohibit, restrict or hinder the making available on the market of explosives which satisfy the requirements of this Directive” (Article 3 of Directive 2014/28/EU)⁵⁸; and
- § “Member States shall take the necessary measures to ensure that explosives may be made available on the market only if they comply with the requirements of this Directive” (Article 3 of Directive 2014/28/EU)⁵⁹.
- § In addition to this, in the case of EEI, MPO⁶⁰ considers also the aspect of market surveillance over the meeting of RoHS requirements to be crucial: Due to their

⁵² Ministry of Industry and Trade of the Czech Republic 2018

⁵³ Op. cit. Ministry of Industry and Trade of the Czech Republic 2018

⁵⁴ European Parliament (EP), Directive 2014/28/EU

⁵⁵ Op. cit. European Parliament (EP), Directive 2014/28/EU

⁵⁶ Op. cit. European Parliament (EP), Directive 2014/28/EU

⁵⁷ Op. cit. Ministry of Industry and Trade of the Czech Republic 2018

⁵⁸ Op. cit. European Parliament (EP), Directive 2014/28/EU

⁵⁹ Op. cit. European Parliament (EP), Directive 2014/28/EU

⁶⁰ Op. cit. Ministry of Industry and Trade of the Czech Republic 2018

special nature, sampling procedures of EEI are regarded to be “either virtually impossible to perform, or only partially feasible at a great expense”⁶¹.

- § Taking into account the above mentioned aspects (and a few other issues that are documented in its stakeholder contribution), MPO⁶² comes to the conclusion that EEI should be granted the maximum possible exemption for a period of five years and, with a future perspective, they should be permanently excluded from the scope of RoHS 2.

Davey Bickford

In the contribution of Davey Bickford⁶³, another important manufacturer of EEI, submitted on 19.12.2018, it was also mentioned that EEI by their very nature are completely destroyed upon their usage and therefore EEI are not considered to fall within the definition and meaning of “equipment” under RoHS 2.

Nonetheless, Davey Bickford considers that *“any exemption for the use of certain hazardous compounds in detonators or initiators should be submitted, to the extent required, in accordance with Regulation (EC) No 1907/2006 (REACH)”*⁶⁴.

6.6. Critical Review

6.6.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV *“provided that such inclusion does not weaken the environmental and health protection afforded by”* the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the consultants as a threshold criteria: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

The application initially did not specify the substance identity of the Pb and CrVI compounds. However, the REACH compliance check revealed that an exemption formulation referring to lead and CrVI compounds in general can lead to possible conflicts with regards to the following provisions of the REACH regulation related to authorisation:

Annex XIV of the REACH Regulation contains several entries for Pb and CrVI compounds, the use of which requires authorisation:

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

⁶¹ Op. cit. Ministry of Industry and Trade of the Czech Republic 2018

⁶² Op. cit. Ministry of Industry and Trade of the Czech Republic 2018

⁶³ Davey Bickford 2018

⁶⁴ Op. cit. Davey Bickford 2018

- § 16. Chromium trioxide
- § 17. Acids generated from chromium trioxide and their oligomers
 - Oligomers of chromic acid and dichromic acid
 - Chromic acid
 - Dichromic acid
- § 18. Sodium dichromate
- § 19. Potassium dichromate
- § 20. Ammonium dichromate
- § 21. Potassium chromate
- § 22. Sodium chromate
- § 28. Dichromium tris(chromate)
- § 29. Strontium chromate
- § 30. Potassium hydroxyoctaoxodizincatedichromate
- § 31. Pentazinc chromate octahydroxide

From the above listed substances, e.g. lead chromate is relevant for this case:⁶⁵
According to the ECHA background document⁶⁶ for lead chromate of 17 December 2010, lead chromate is used in the manufacture of pyrotechnics, which “*may include pyrotechnic delay compositions for ammunition, ignition compositions for ammunition, and delay detonators for the mining and demolition sectors*”. For lead chromate, there was one application of authorisation submitted that covered the industrial use of lead chromate in manufacture of pyrotechnic delay devices contained into ammunition for naval self-protection⁶⁷, which was granted by the European Commission on 4 August 2017 with a duration of seven years.⁶⁸

Granting an exemption under RoHS for Pb and CrVI compounds in electrical and electronic initiators of explosives for civil (professional) use would also *de facto* include uses of lead chromate which is, however, not allowed for manufacture and use in the EU unless an authorisation is granted. Thus, this would create a loophole for uses of CrVI compounds that are listed in REACH Annex XIV and could weaken the environmental and health protection afforded by the REACH Regulation. Thus, an exemption formulation under RoHS referring to Pb and CrVI compounds in general would have to exclude Pb and CrVI compounds of REACH Annex XIV where the sunset date was reached and where no authorisation for this specific application is granted.

⁶⁵ The information on substances used in the manufacture of explosives is available in the ECHA database “Substance information”.

⁶⁶ European Chemicals Agency (ECHA) 2010

⁶⁷ See ECHA webpage “Adopted opinions and previous consultations on applications for authorisation” at https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/5601/del/200/col/synonymDynamicField_302/type/asc/pre/1/view

⁶⁸ Summary of European Commission Decisions on authorisations for the placing on the market for the use and/or for use of substances listed in Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (2017/C 264/03) at [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC0811\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC0811(01)&from=EN)

To avoid this possible conflict, the applicant was asked to identify the substance compounds so that they can be included in the exemption formulation. The applicant⁶⁹ agreed and confirmed the use of the following substances:

- § lead diazide
- § lead styphnate
- § lead dipicramate
- § orange lead (lead tetroxide)
- § lead dioxide
- § barium chromate.

With regards to a **future inclusion in Annex XIV**: The applicant points out that *“most of the Pb compounds used are identified as SVHC substances (substances of very high concern) based on their dangerous properties under Article 57 (a) to (f). [...] These substances have been included in the [...] Candidate List as of 2011 pursuant to Article 59 (10) of the REACH Regulation. Substances listed in the Candidate List are progressively assigned a priority for inclusion in Annex XIV of the REACH Regulation”*⁷⁰.

Thus, if these Pb compounds are included in REACH Annex XIV, placing on the market and the use of the substance will be prohibited after the so called sunset date. The time frame for the sunset date has to be specified according to REACH Article 58(1) by ECHA for each substance recommended for inclusion in Annex XIV. This time frame comprises a date by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s). That date is referred to as Latest Application Date (LAD). The sunset date is usually 18 months after the LAD.

The applicant notes that for one Pb substance, ECHA recommended to set the LAD at the date of inclusion in Annex XIV plus 27 month. The sunset date - 18 months after LAD – would then be reached 3.75 years after the date of inclusion in Annex XIV. This is a shorter period than the longest possible exemption duration of a RoHS exemption. Thus, future inclusions of i.e. orange lead (lead tetroxide) in Annex XIV could potentially create conflicts between a RoHS exemption and provisions under REACH. However, as the inclusion process of Candidate List substances is ongoing and in terms of timescale not foreseeable, this potential conflict is not taken into account for the exemption formulation. However, a future review of this exemption should to consider this. If the Commission should see the need to anticipate this potential conflict, a note could be added to the exemption which excludes the substances listed in Annex XIV of the REACH Regulation which sunset date is reached, except where an authorisation of the use in electrical and electronic initiators of explosives for civil (professional) use is granted.

With regards to **restriction**, Appendix 1 of this report lists entry 28 and entry 30 in Annex XVII of the REACH Regulation, stipulating that lead and CrVI and their

⁶⁹ AUSTIN DETONATOR s.r.o. 2019c: Personal communication by Jaroslav Konarik on 07.08.2019.

⁷⁰ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

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.

In the consultants' understanding, the restrictions for substances under entry 28 and entry 30 of Annex XVII do not apply. The use of Pb and CrVI in electric and electronic initiators of explosives for civil (professional) use in the consultants' point of view is not a supply of Pb and CrVI and their compounds as a substance, mixture or constituent of other mixtures to the general public. Pb and CrVI in the form used as described by the applicant, entry 30 of Annex XVII of the REACH Regulation would not apply.

There are two further entries on Pb and CrVI compounds which however do not cover the applications of this exemption request:

- § Entry 47 of Annex XVII restricts Chromium VI compounds in cement and cement-containing mixtures and in leather articles coming into contact with the skin; thus entry 47 covers (consumer) articles which are not in the scope of RoHS.
- § Entry 63 of Annex XVII restricts lead and its compounds in jewelry and other articles supplied to the general public. However, entry 63 explicitly derogates articles within the scope of the RoHS Directive.

To summarize, the requested exemption might weaken the environmental and health protection afforded by the REACH Regulation, if an exemption was granted for the group of Pb and CrVI and its compounds as a whole. Therefore, it is recommended to list the specific compounds in the exemption formulation.

6.6.2. Scientific and technical practicability of substitution

Based on the application for exemption request provided by AD⁷¹ and the stakeholder contribution by Davey Bickford⁷², it is understood that EEI manufacturers like AD and Davey Bickford have been working on alternative substances for more than 20 years. The information provided by AD⁷³ on potential substances / substance groups for the substitution of Pb and CrVI compounds is backed by open literature submitted by the European Chemical Agency (ECHA)⁷⁴.

In these ECHA dossiers, also further potential substitutes for primary explosives based on complex metal anions and environmentally benign cations are described⁷⁵. However, it is concluded that the alternatives identified as promising "would only achieve partial rather than complete replacement"⁷⁶. Furthermore, the dossiers mention significant concern among EEI manufacturing companies regarding the qualification and formal certification of substitutes in their target mixtures. Finally, in terms of a roadmap of R&D that is required for the development and qualification of

⁷¹ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁷² Op. cit. Davey Bickford 2018

⁷³ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁷⁴ European Chemicals Agency (ECHA) 2011a and European Chemicals Agency (ECHA) 2011b.

⁷⁵ Op. cit. European Chemicals Agency (ECHA) 2011a

⁷⁶ Op. cit. European Chemicals Agency (ECHA) 2011a

alternative compositions based on substitute materials, the dossiers⁷⁷ assume time horizons of more than 20 or 25 years, *“without a clear indication that efforts might be fruitful for all applications”*⁷⁸. In order to prove the safety and reliability level of alternatives at a scale comparable to that of the currently used substances, the Federation of European Explosives Manufacturers believes that *“function of millions of detonators needs to be tested”*⁷⁹.

When relating these findings to the essential product safety requirements for EEI as set out by Directive 2014/28/EU (cf. Section 6.5), according to which each EEI

- § *“must be designed, manufactured and supplied in such a way as to present a minimal risk to the safety of human life and health, and to prevent damage to property and the environment”*⁸⁰ and
- § *“must attain the performance characteristics specified by the manufacturer in order to ensure maximum safety and reliability”*,

the consultants can follow the view of AD and the contributions provided by stakeholders (cf. Section 6.5) that substitution of Pb compounds via design changes or materials and components is currently technically impracticable.

Concerning CrVI compounds, however, the consultants have received information that EEI manufacturers like Davey Bickford appear to be able to produce pyrotechnic delay charges only with Pb compounds, but without CrVI compounds. Concerning the question as to whether their EEI and especially pyrotechnic delay charges contain Cr VI compounds, Davey Bickford⁸¹ has stated: *“We can confirm that we have no chrome in our product”*⁸².

Upon request on this issue, AD⁸³ explains that the pyrotechnic delay charge is (only) part of an electric fusehead, i.e. the electric initiator (cf. Section 6.1). According to AD, Pb compounds are used for short-time delay charges and CrVI compounds are used for longer time delay charges, whereat the timing has to be stable and repeatable. AD considers this parameter to be crucial for accurate blasting and safety during use: *“Variability and accuracy of timing is necessary for fragmentation of stone mining and also safety.”*⁸⁴ AD⁸⁵ specifies *“long time delay charges”* with a timing step (period) longer than 100 ms for their production. However, AD claims that there is no global standard for the timing step (period) for industry use (professional). AD explains that in general timing steps mostly depend on the application of the detonator, e.g. *“mining calculation for required fragmentation”*.

⁷⁷ Op. cit. European Chemicals Agency (ECHA) 2011a and op. cit. European Chemicals Agency (ECHA) 2011b

⁷⁸ Op. cit. European Chemicals Agency (ECHA) 2011a

⁷⁹ Op. cit. European Chemicals Agency (ECHA) 2011a

⁸⁰ Op. cit. Ministry of Industry and Trade of the Czech Republic 2018

⁸¹ Davey Bickford 2019

⁸² Op. cit. Davey Bickford 2019, written information from Davey Bickford, received 24 March 2019

⁸³ AUSTIN DETONATOR s.r.o. 2019a

⁸⁴ Op. cit. AUSTIN DETONATOR s.r.o. 2019a

⁸⁵ AUSTIN DETONATOR s.r.o. 2019b

To conclude, the consultant agrees with AD that there is no generally recognized timing step that could be used to define a long-time delay charge. It is therefore recommended to describe the application for CrVI as for pyrotechnic delay charges of electric initiators.

On the repeated clarification question whether Davey Bickford also manufactures long-time delay charges (e.g. enabling delay periods of more than one second) and as to whether also these products are without hexavalent chromium compounds, no clear answer was given. Thus, the consultant cannot take the conclusion that the portfolio of Davey Bickford also covers long-time delay charges as specified by AD. To summarize, the consultants assume that there is not sufficient evidence that pyrotechnic delay charge can be produced and reliably used without CrVI compounds. In particular, long-time pyrotechnic delay charges still seem to require CrVI compounds.

6.6.3. Environmental arguments and socioeconomic impacts

As already explored in Section 6.4.2, from information provided by AD, the consultants understand that the environmental impacts of the production of EEI is prevented, because the used Pb and CrVI compounds are hermetically sealed in EEI before their use.

The use of EEI gives a slightly different picture. As stated in Section 6.4.2, AD claims that *“the use of electric detonators for professional use does not pose any risk either from the point of view of the threat to the environment or to human health”*⁸⁶. AD aims to substantiate this claim with measurements regarding the contamination of raw materials extracted with the help of EEI. Even though the measurements presented by AD do not show any contaminations above the detection limits of the used analytical instruments, the consultants recognise an uncontrolled release of Pb and CrVI compounds into the environment during their use. In this context, it needs also to be considered that Pb and CrVI compounds are used in total on a tonne scale for the mentioned applications fields of EEI. Hence, products / materials such as building stones, rock salt and waste from the demolition of buildings (cf. Figure 6-1) are affected by this release. On the other side, however, it needs to be taken into account that hazardous substances e.g. CrVI compounds contained in the EEI react chemically during the explosion process: CrVI compounds are expected to be reduced to less toxic CrIII compounds.

Furthermore, the concentration of Pb in mined rock salt calculated by AD show values three orders of magnitude below the existing limit value for Pb according to the existing standard for food grade salt.⁸⁷

⁸⁶ Op. cit. AUSTIN DETONATOR s.r.o. 2018b

⁸⁷ According to AUSTIN DETONATOR s.r.o. (2018b) the Pb concentration in 1 tonne of disintegrated rock salt is calculated with 0,0041 g/t = 0,0041 mg/kg. The current limit value of Pb in food grade salt is 2 mg / kg, see CODEX STANDARD FOR FOOD GRADE SALT, CX STAN 150-1985, Rev. 1-1997, Amend. 1-1999, Amend. 2-2001, available under http://www.ceecis.org/iodine/07_legislation/00_mainpage/codex_food_grade_salt.pdf

Taken all these aspects into account, the consultants come to the conclusion that although the environmental impacts during use cannot be considered negligible, they appear to be rather limited.

Socio-economic impacts are expected to be significant. As described in Section 6.4.3, a ban on EEI would cause negative economic effects to the producers of EEI, but would also weaken e.g. the EU's mineral market. In this context, the consultants can especially follow the limitations concerning market surveillance over the meeting of RoHS requirements, as pointed out by MPO: Without effective market surveillance, EEI producers in the EU are potentially at risk of being disadvantaged against non-EU producers (cf. Section 6.5).

6.6.4. Applicability of the RoHS Directive

As described in section 6.1, AD considers professional EEI to be beyond the scope of the WEEE Directive and RoHS 2, because they are completely destroyed during their use with no waste remaining that can be reused, recycled or processed.

In this context, it needs to be taken into account that the RoHS Directive applies to EEE, as defined in Articles 3(1) and (2) of the Directive, having inter alia the objective to address and minimise risks from substances in EEE that could lead to uncontrolled release of the substance into the environment. In this context, the EEI are considered within the scope of the RoHS Directive.

6.6.5. 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 formation, it can be observed that substitutes for both Pb and CrVI compounds that would fulfil all essential requirements for EEI in order to ensure their safe operation currently do not exist.

To conclude against the Article 5(1)(a) criteria:

- Research conducted by AD (and other EEI manufacturers) did not result in substitutes that are scientifically or technically practicable since essential requirements concerning their functionality are not fully met;
- Potential substitutes currently cannot assure the reliability of the product, especially as required by Directive 2014/28/EU;
- Negative occupational health and consumer safety impacts caused by a substitution, especially in terms of potential accidents due to not sufficiently

reliable substitutes are likely to outweigh the total environmental, health and consumer safety benefits of these substitutes.

6.7. Recommendation

It is recommended to grant the requested exemption. The wording of the exemption should be adapted as follows:

“Lead diazide, lead styphnate, lead dipicramate, orange lead (lead tetroxide), lead dioxide in electric and electronic initiators of explosives for civil (professional) use and barium chromate in long time pyrotechnic delay charges of electric initiators of explosives for civil (professional) use.”

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Appendix

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 A-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 A-1: Relevant entries from Annex XIV: List of substances subject to authorisation

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)	
4. Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	21 August 2013 (*)	21 February 2015 (**)	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/ 2004, Directive 2001/82/EC, and/or Directive 2001/83/EC
5. Benzyl butyl phthalate (BBP) EC No: 201-622-7 CAS No: 85-68-7	21 August 2013 (*)	21 February 2015 (**)	
6. Dibutyl phthalate (DBP) EC No: 201-557-4 CAS No: 84-74-2	21 August 2013 (*)	21 February 2015 (**)	
7. Diisobutyl phthalate (DIBP) EC No: 201-553-2 CAS No: 84-69-5	21 August 2013 (*)	21 February 2015 (**)	
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 (**)	-

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)	
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 EC No: 236-881-5 CAS No: 13530-68-2 Oligomers of chromic acid and dichromic acid EC No: not yet assigned CAS No: not yet assigned	21 Mar 2016 (*)	21 Sep 2017 (**)	-
18. Sodium dichromate EC No: 234-190-3 CAS No: 7789-12-0 10588-01-9	21 Mar 2016 (*)	21 Sep 2017 (**)	-
19. Potassium dichromate EC No: 231-906-6 CAS No: 7778-50-9	21 Mar 2016 (*)	21 Sep 2017 (**)	-
20. Ammonium dichromate EC No: 232-143-1 CAS No: 7789-09-5	21 Mar 2016 (*)	21 Sep 2017 (**)	-
21. Potassium chromate EC No: 232-140-5 CAS No: 7789-00-6	21 Mar 2016 (*)	21 Sep 2017 (**)	
22. Sodium chromate EC No: 231-889-5 CAS No: 7775-11-3	21 Mar 2016 (*)	21 Sep 2017 (**)	
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 (**)	

() 1 September 2019 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without that spare part, and for the use of the substance (on its own or in a mixture) for the repair of such articles where that substance on its own or in a mixture was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.*

*(**) 1 March 2021 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without those spare parts, and for the use of the substance (on its own or in a mixture) for the repair of such articles, where that substance was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.*

For the substances currently restricted according to RoHS Annex II: cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls and polybrominated diphenyl ethers and their compounds, as well as bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), we have found that some relevant entries are listed in Annex XVII of the REACH Regulation. The conditions of restriction are presented in Table A-2 below.

Table A-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 CAS No 7440-43-9 EC No 231-152-8 and its compounds	For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87 (1). 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 use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be

Designation of the substance, group of substances, or mixture	Conditions of restriction
	restricted. 2. Shall not be used or placed on the market in paints with codes [3208] [3209] in a concentration (expressed as Cd metal) equal to or greater than 0,01 % by weight. For paints with codes [3208] [3209] 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. Substances which are classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2, respectively: Cadmium carbonate Cadmium chloride Cadmium dihydroxide Cadmium dinitrate Cadmium fluoride Cadmium hydroxide Cadmium (pyrophoric) Cadmium nitrate Cadmium oxide Cadmium Sulphate	Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30: 1. Shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'.

Designation of the substance, group of substances, or mixture	Conditions of restriction
Cadmium sulphide Chromium (VI) trioxide Zinc chromates including zinc potassium chromate Nickel Chromate Nickel dichromate Potassium dichromate Ammonium dichromate Sodium dichromate Chromyl dichloride; chromic oxychloride Potassium chromate Calcium chromate Strontium chromate Chromium III chromate; chromic chromate Sodium chromate Lead Chromate Lead hydrogen arsenate Lead Nickel Salt Lead sulfochromate yellow; C.I. Pigment Yellow 34; Lead chromate molybdate sulfate red; C.I. Pigment Red 104;	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. Substances which are classified as germ cell mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 3 or Appendix 4, respectively: Cadmium carbonate Cadmium chloride Cadmium dihydroxide	

Designation of the substance, group of substances, or mixture	Conditions of restriction
Cadmium dinitrate Cadmium fluoride Cadmium hydroxide Cadmium nitrate Cadmium Sulphate Chromium (VI) trioxide Potassium dichromate Ammonium dichromate Sodium dichromate Chromyl dichloride; chromic oxychloride Potassium chromate Sodium chromate	
30. Substances which are classified as reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or Appendix 6, respectively.'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	

Designation of the substance, group of substances, or mixture	Conditions of restriction
Lead Arsenate Lead acetate Lead alkyls Lead azide Lead Chromate Lead di(acetate) Lead hydrogen arsenate Lead 2,4,6-trinitroresorcinoxide, lead styphnate Lead(II) methane- sulphonate Trilead bis- (orthophosphate) Lead hexa-fluorosilicate Mercury Silicic acid, lead nickel salt	
47. Chromium VI compounds	1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002 %) soluble chromium VI of the total dry weight of the cement. 2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1. 3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin. 4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1. 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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
51. The following phthalates (or other CAS and EC numbers covering the substance): (a) Bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 EC No 204-211-0 (b) Dibutyl phthalate (DBP) CAS No 84-74-2 EC No 201-557-4 (c) Benzyl butyl phthalate (BBP) CAS No 85-68-7 EC No 201-622-7	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. 1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles. 2. Toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market. 4. For the purpose of this entry 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.
62. (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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
63. Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight. 2. For the purposes of paragraph 1: (i) 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; (ii) 'any individual part' shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*); (b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C. 5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles 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/cm² 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.

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

Designation of the substance, group of substances, or mixture	Conditions of restriction
67. Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) CAS No 1163-19-5 EC No 214-604-9	- Shall not be manufactured or placed on the market as a substance on its own after 2 March 2019. - Shall not be used in the production of, or placed on the market in: - another substance, as a constituent; - a mixture; - an article, or any part thereof, in a concentration equal to or greater than 0,1 % by weight, after 2 March 2019. - Paragraphs 1 and 2 shall not apply to a substance, constituent of another substance or mixture that is to be used, or is used: - in the production of an aircraft before 2 March 2027. - in the production of spare parts for either of the following: - an aircraft produced before 2 March 2027; - motor vehicles within the scope of Directive 2007/46/EC, agricultural and forestry vehicles within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council (*) or machinery within the scope of Directive 2006/42/EC of the European Parliament and of the Council (**), produced before 2 March 2019 - Subparagraph 2(c) shall not apply to any of the following: - articles placed on the market before 2 March 2019; - aircraft produced in accordance with subparagraph 3(a); - spare parts of aircraft, vehicles or machines produced in accordance with subparagraph 3(b); - electrical and electronic equipment within the scope of Directive 2011/65/EU. - For the purposes of this entry 'aircraft' means one of the following: - a civil aircraft produced in accordance with a type certificate issued under Regulation (EU) No 216/2008 of the European Parliament and of the Council (***) or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation; (b) a military aircraft. (*) Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OL L 60, 2.3.2013, p. 1). (**) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24). (***) Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79 19.3.2008, p. 1).

As of May 2019, the REACH Regulation Candidate list includes various substances of relevance for RoHS. 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 revocations).