Study to assess three (3) exemption requests relating to Annex IV to Directive 2011/65/EU: request for amendment of existing exemption 31a; request for a new exemption for bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids; and request for a new exemption for DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils (Pack 17) – 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

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Disclaimer

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

EUROPEAN COMMISSION

Directorate-General for Environment

Directorate B - Circular Economy & Green Growth

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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 exemption requests under the RoHS 2 regime. The work has been undertaken by Oeko-Institut and Fraunhofer Institute IZM, and has been peer reviewed by the two institutes.

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 the table below (Table 1-1).**Fehler! Verweisquelle konnte nicht gefunden werden.** One request for a new exemption as an amendment of an existing exemption in Annex IV and two requests for new exemptions in Annex IV 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. Req. No.	Requested exemption wording	Applicant	Recommendation	Expiry date and scope
Existing exemptions				
Annex IV, 31a	Bis (ethylhexyl) phthalate, Dibutyl phthalate, Diisobutyl phthalate and Benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer	COCIR	"Bis (ethylhexyl) phthalate, dibutyl phthalate, diisobutyl phthalate and benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer" An alternative option is presented and discussed in the recommendations section.	21 July 2029
Requests for new exemption				
2019-1	Bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids	COCIR	Bis (ethylhexyl) phthalate (DEHP) in ion selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids	7 years
2019-2	Bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils	GE Health-care	Due to the similarity with another request, both will be merged. See more details in the recommendations section 7.6.	-

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 le Fraunhofer IZM (Institut Fraunhofer pour la fiabilité et la micro-intégration), et fait l'objet d'un examen par des pairs des deux instituts.

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 d'un éventail d'exemptions dans le cadre de la présente mission (nouvelles demandes d'exemption et demandes de renouvellement 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 nouvelle exemption à titre de modification d'une exemption existante à l'annexe IV et deux demandes de nouvelles exemptions à l'annexe IV ont été incluses dans la portée de ce projet. Le lecteur est invité à consulter les 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.

Dem. ex. n°	Termes de l'exemption demandée	Demandeur	Recommandation	Date d'expiration et champ d'application
Exemptions en vigueur				
Annexe IV, Ex. 31a	Phtalate de bis(éthylhexyle), phtalate de dibutyle, phtalate de diisobutyle et phtalate de benzyle butyle dans les pièces de rechange récupérées et utilisées pour la réparation ou la remise à neuf des dispositifs médicaux, y compris les dispositifs médicaux de diagnostic in vitro, et leurs accessoires, à condition que la réutilisation se fasse dans des systèmes auditables en circuit fermé et que chaque réutilisation des pièces soit notifiée au client	COCIR	"Phtalate de bis(éthylhexyle), phtalate de dibutyle, phtalate de diisobutyle et phtalate de benzyle butyle dans les pièces de rechange récupérées et utilisées pour la réparation ou la remise à neuf des dispositifs médicaux, y compris les dispositifs médicaux de diagnostic in vitro, et leurs accessoires, à condition que la réutilisation se fasse dans des systèmes auditables en circuit fermé et que chaque réutilisation des pièces soit notifiée au client" Une autre option est présentée et discutée dans la section Recommandation.	le 21 juillet 2029
Demandes de nouvelles exemptions				
2019-1	"Phtalate de bis(éthylhexyle) (DEHP) dans des électrodes sélectives d'ions appliquées à l'analyse au point de service de substances ioniques présentes dans les fluides corporels humains"	COCIR	"Phtalate de bis(éthylhexyle) (DEHP) dans des électrodes sélectives d'ions appliquées à l'analyse au point de service de substances ioniques présentes dans les fluides corporels humains et/ou dans les fluides dialysés. "	7 ans

Dem. ex. n°	Termes de l'exemption demandée	Demandeur	Recommandation	Date d'expiration et champ d'application
2019-2	"Phtalate de bis(éthylhexyle) (DEHP) dans les dispositifs de décharge de traction en plastique utilisés pour prévenir les dommages aux connexions de câbles des bobines d'imagerie IRM"	GE Healthcare	En raison de la similarité avec une autre demande, elles seront fusionnées, voir plus de détails dans les recommandations, section 7.6.	-

3. Introduction

3.1. Project scope and methodology

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

In the course of the project, a stakeholder consultation was conducted. The stakeholder consultation was launched on 18 March 2019 and was planned for duration of eight weeks and was then extended by another five days thus concluding 17 May 2019.

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 on background and objectives on page 8.

The evaluations of the exemptions evaluated in the course of the project appear in chapters 5 to 7. 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 12 December 2018. The overall project has been led by Carl-Otto Gensch. At Fraunhofer IZM the contact person is Otmar Deubzer.

[1] Cf. https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/Technical_Request_RoHS_Pack_17.pdf

4. Links from the Directive to the REACH Regulation

Article 5 of the RoHS 2 Directive 2011/65/EU on "Adaptation of the Annexes to scientific and technical progress" provides for 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 **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (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

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

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 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.

The figure below 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.

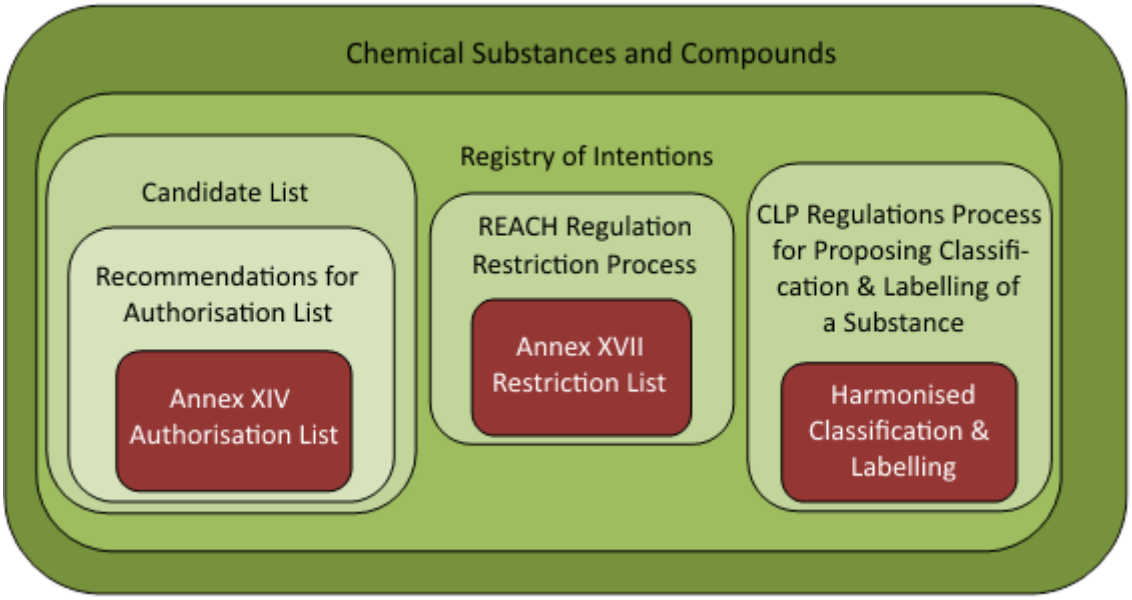
[3] Gensch, C., Baron, Y., Blepp, M., Deubzer, O., Manhart, A. & Moch, K. (2012) Assistance to the Commission on technological, socio-economic and cost-benefit assessment related to exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive), Final Report, Oeko-Institut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

For further reports, see archive of 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

[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

submit Annex XV dossiers and, therefore, to facilitate timely preparation of the interested parties for commenting later in the process. It is also important to avoid duplication of work and encourage co-operation between Member States when preparing dossiers. Note that the Registry of Intentions is divided into three separate sections: listing new intentions; intentions still subject to the decision-making process; and withdrawn intentions. The registry of intentions is available at the ECHA website at: 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 April 2020, the consolidated version of the REACH legal text, dated 27.02.2020, was used 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:02006R1907-20200227. 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, 6 and 7) under the relevant section titled "REACH compliance – Relation to the REACH Regulation" (Section 5.5.1, Section 6.5.1, Section 7.5.1).

[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. 31a Selected Phthalates in spare parts recovered from and used for the repair or refurbishment of medical devices

"Bis (ethylhexyl) phthalate, Dibutyl phthalate, Diisobutyl phthalate and Benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer"

Declaration

In the sections that precede the "Critical review" the phrasings and wordings of applicant's and 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

BBP	Benzyl butyl phthalate
Cat. 8	RoHS 2, Annex I, Category 8: Medical devices, as defined in RoHS Article 3(22): 'medical device' means a medical device within the meaning of point (a) of Article 1(2) of Directive 93/42/EEC and which is also EEE
Cat. 9	RoH2 Annex I, Category 9: Monitoring and control instruments including industrial monitoring and control instruments
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
DEHP	Bis (ethylhexyl) phthalate
DBP	Dibutyl phthalate
DiBP	Diisobutyl phthalate
EEE	Electrical and electronic equipment
EoL	End of life
LCA	Life Cycle Assessment
MD	Medical devices
OEM	Original equipment manufacturer
PCB	Printed circuit boards
PVC	Polyvinylchloride
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment
RRSM	Repair, refurbishment, servicing and maintenance

5.1. Background

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) submitted an application requesting an amendment of existing exemption in Annex IV for the maximum validity period (COCIR 2018a). The requested exemption is marked as relevant for both Cat 8 (medical devices and equipment) and Cat 9 (monitoring and control equipment). The applicant proposes the following formulation:

> "*Bis (ethylhexyl) phthalate, Dibutyl phthalate, Diisobutyl phthalate and Benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer*"

As the applicant specified within the application that this exemption formulation could be merged with the existing Ex. 31a, the consultant understands the above formulation as a proposal for a new item to be added to the existing exemption (Ex. 31a).

In the first round of clarification questions, the consultants thus asked the applicant to propose a formulation in which the new exemption is merged with the existing one. As part of its answer, the applicant expressed that merging this new exemption with the existing wording for Ex. 31a would represent advantages since both exemptions are necessary to ensure repair and refurbishment activities to the point that they can be considered as one. Additionally COCIR considers that renewing a single exemption will significantly reduce future efforts both from the industry and the European Commission (COCIR 2019a).

The proposed suitable wording for the future exemption 31a as merged from the current Exemption 31a as suggested by the applicant for adoption to Annex IV reads:

> *"Bis (ethylhexyl) phthalate, Dibutyl phthalate, Diisobutyl phthalate, Benzyl butyl phthalate, Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer"*

5.1.1. History of the exemption

The following information serves as relevant background information for this request.

In 2014 Gensch und Baron conducted the evaluation for exemption request 2013-6 which was related to one exemption on lead and hexavalent chromium in reused spare parts, recovered from industrial monitoring and control instruments. This exemption was originally requested for Cat. 9 applications, but was also deemed to be relevant for medical devices of Cat. 8.

The recommendations resulting from Gensch und Baron (2014) evaluation served as input for the Commission Delegated Directive (EU) 2016/585 of 12 February 2016. This amended the Annex IV to Directive 2011/65/EU as regards an exemption for lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes.

The point 31a added through this amendment to Annex IV of the RoHS Directive reads:

"Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer".

The exemption expires on:

(a) 21 July 2021 for the use in medical devices other than in vitro diagnostic medical devices;

(b) 21 July 2023 for the use in in vitro diagnostic medical devices;

(c) 21 July 2024 for the use in electron microscopes and their accessories.

5.1.2. Amount of Bis-(ethylhexyl)-phthalate, Dibutyl-phthalate, Diisobutyl-phthalate and Benzyl-butyl-phthalate used under the exemption

COCIR claims that this exemption will results in no net change in the amount of substances entering the EU market annually. In the original application, COCIR explains that even though parts that are produced for medical devices after 21 July 2021 will not contain the four restricted phthalates, recovered parts may contain these substances.

On this the applicant adds that "*the phthalates that are in parts that are recovered from medical devices placed on the EU market before 21 July 2021 will not enter the EU market after 21 July 2021 as they will already be on the market." (COCIR 2018a)*

COCIR justifies its claim about the no net change in the amount of phthalates in the EU market on the assumption that similar quantities will be entering and leaving the EU market. In COCIR's words:

"The exemption will extend the life of parts already on the market only. Some non-EU parts that contain phthalates will enter the EU market after this date, but also, a similar quantity of parts recovered from medical devices placed on the EU market before 21 July 2021 will also leave the EU. Overall, therefore, there will be no net change in the amounts of these phthalates present in the EU as the amounts entering will be similar to the amounts leaving" (COCIR 2018a).

According to COCIR "*about 2200 tonnes of parts and 1000 tonnes of equipment (total 3200 tonnes) are refurbished and then reused in the EU annually*" (COCIR 2018a). The applicant provides an estimation of less than 2 tonnes per year for RoHS substances (DEHP, DBP, DiBP and BBP) present in EEE waste accumulated per annum in articles which are refurbished. This amount is based on an average of 0.1% of the total of recovered and reused parts and a content range of 1- 50% weight of substance in homogeneous material as declared in section 4.3 of the original application.

As part of the first round of clarification questions, the consultants requested more details about the data behind those estimations. COCIR answered that "*it is impossible to know the content of phthalates or their concentration when the equipment was produced as there were no restrictions for in place. The total weight of the recovered parts mentioned in the dossier, refers to parts made of steel, aluminium, electronics and plastics" (COCIR 2019a).*

The applicant clarifies that the 1% to 50% concentration range refers to the concentration in plastics containing phthalates. Additionally, a distinction is made between plastics and the ones which could contain phthalates since, as they put it: "*COCIR estimated, based on expert opinion, that phthalates in "plastic likely to contain phthalates" can amount to a 0,1% of the weight of parts of medical imaging devices that are, for the most part, made by heavy metals and alloys."*

Based on the above, the consultants understand that the term "*plastic likely to contain phthalates*" does not refer to all plastic but only to a small percentage of the total weight of the recovered parts. This shall be taken into account in understanding the information discussed in the evaluation of this exemption.

5.2. Technical description of the requested exemption

The previous request for exemption on repair, refurbishment, servicing and maintenance (RRSM) was reviewed by Gensch und Baron (2014). A detailed technical description of the exemption is available on page 28 of the 2014 review report. Recommendations from this evaluation led to the amendment of the Annex IV to Directive 2011/65/EU resulting in the current exemption 31a.

According to the applicant, bis (ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), diisobutyl phthalate (DiBP) and benzyl butyl phthalate (BBP) are added to polymers (including rubber), adhesives, sealants, paints and lacquers for a variety of possible uses a listed below (COCIR 2018a):

- Plasticiser in PVC wire and cable insulation;
- Additive in rubber seals and O-rings used in connectors;
- Additive in rubber grommets that support cables;
- Plasticiser in PVC labels including those used on components such as capacitors;
- Added to give flexibility to adhesives used to seal capacitors and other electronic components;
- Added to give flexibility to die attach material in integrated circuit packages;
- As a processing aid in polymer mouldings.

In the exemption request, COCIR also lists a few examples of applications of relevance for medical devices (MD) (COCIR 2018a):

- Printed circuit boards (PCBs);
- X-ray tubes (including PCBs, cables, housing, etc.);
- Magnetic resonance imaging (MRI) coils;
- Detectors and components of detectors (e.g. radiation detectors); and
- Transducers with associated cables.

In the original application for exemption request, the applicant elaborates in detail about the market of Medical Devices (MD), describing how these are specialised, relative low volume equipment where each model is usually sold worldwide. This means that MD sold in the EU are identical to those sold in Asia and North America.

COCIR explains that many types of parts are removed from used MD during refurbishment, repair, servicing or maintenance (RRSM) and are reused for the same purposes in other MD (i.e. in RRSM of MD). Refurbished and reused parts and equipment are, according to COCIR, *"as good as new parts"* in addition to being available at lower costs to hospitals (COCIR 2018a).

As background regarding the use of recovered parts from MD, the applicant points out that the RoHS Commission Delegated Directive 2015/863 allows non-compliant spare parts to be used to repair non-compliant MD that were placed on the market before the entry in force of the restriction. This means that recovered parts containing phthalates can be used to repair, upgrade MD placed on the market before July 2012. About this COCIR clarifies that:

> *"RoHS amendment 2017/2102/EU Article 4.5 also allows non-compliant parts recovered from medical devices that were placed on the EU Market before 21st July 2014 to be used in medical devices to be placed on the market until 21 July 2024, but these dates however are applicable to the original six RoHS substances, not for phthalates which will not be restricted in Medical Devices until 21 July 2021." (COCIR 2018a)*

The applicant poses that parts that are produced for medical devices after 21 July 2021 will not contain the four restricted phthalates. However, recovered parts already in the market may contain these substances and according to the Commission Delegated Directive 2015/863, cannot be used to repair new devices. This represents a problem in terms of the availability of recovered parts for RRSM of old and new medical devices considering aspects provided in the application (COCIR 2018b):

- "*Manufacturers of the more complex types of medical devices that are frequently refurbished for reuse, usually have only one refurbishment centre worldwide where all used equipment is shipped and refurbished*".
- "*Parts recovered from equipment that was originally been placed on the EU market before 21 July 2014 are identical to parts from medical devices that were previously sold outside of the EU and so had not been previously been placed on the EU market.*"
- "*Parts from these two sources (EU and non-EU) cannot be kept separately.*"

COCIR elaborates on the fact that the impossibility to declare which of the parts are phthalate-free is explained by the procedures required by the chemical analytical methods available for this purpose. For these it is not possible to determine the presence of the four phthalates in every single component in a non-destructive manner[8] (COCIR 2018a).

Moreover, the information currently available along the supply chains does not provide a way to verify if (or which) phthalates were used in components prior to the restriction. According to the applicant, this is also due to the interpretation of manufacturers of the REACH regulation. As explained by COCIR:

> *"REACH Article 33 requires suppliers to inform recipients if these are present at >0.1% of the articles (based on a different concentration limit to RoHS), it was understood (explained in the original ECHA Guidance on substances in articles) that the term "article" referred to the complete assembly as supplied. Most of the times this meant that these substances were present at less than 0.1% in complex equipment and so suppliers did not have to communicate the content down the supply chain" (COCIR 2018b)*

In the application for exemption (COCIR 2018a), COCIR included a table illustrating in detail different scenarios in the RoHS status on parts recovered from medical devices and the possibility to use them for RRSM. According to the applicant, considering the context described above, after July 2021 it will not be possible to determine RoHS compliance of spare parts and used for RRSM activities and therefore, all unusable recovered parts will become waste.

[8] Chemical analysis of phthalates is described in standard EN 62321-8:2017, Determination of certain substances in electrotechnical products. Phthalates in polymers by gas chromatography-mass spectrometry (GC-MS), gas chromatography-mass spectrometry using a pyrolyzer/thermal desorption accessory (Py/TD-GC-MS).

Table 5-1: RoHS status of parts recovered from MD and RRSM use scenarios

Source of recovered part	RoHS compliance status of the recovered part	Medical device in which the recovered part is intended to be used for RRSM	Can the part be used and thanks to what?
MD sold outside of the EU before 21 July 2014	May contain all 10 RoHS substances	MD placed on the EU market before 21 July 2014	YES RoHS article 4.4
		MD placed on the EU market after 21 July 2014 and before 21 July 2021	YES RoHS exemption 31a
		MD placed on the EU market after 21 July 2021	NO NEW exemption 31a for phthalates needed, which clearly does not refer to "MD placed on the EU market" as per COCIR proposal
		New MD to be placed on the market between 22 July 2014 and 22 July 2024	NO RoHS article 4.5 as amended by Directive (EU) 2017/2102 does not allow for parts from non EU MD.
MD originally sold outside of the EU between 21 July 2014 and 21 July 2021	May contain phthalates	MD placed on the EU market before 21 July 2014	YES RoHS article 4.4
		MD placed on the EU market after 21 July 2014 and before 21 July 2021	YES Annex II of Commission Delegated Directive (EU) 2015/863
		MD placed on the EU market after 21 July 2021	NO NEW exemption 31a for phthalates needed
		New MD to be placed on the market after 22 July 2024	NO A new RoHS article 4.5 would be required for phthalates that does not limit to EU mMDs.

MD sold in the EU before 21 July 2014	May contain all 10 RoHS substances	MD placed on the EU market before 21 July 2014	YES RoHS article 4.4
		MD placed on the EU market after 21 July 2014 and before 21 July 2021	YES RoHS exemption 31a
		MD placed on the EU market after 21 July 2021	NO NEW exemption 31a for phthalates needed
		New MD to be placed on the market between 22 July 2014 and 22 July 2024	YES RoHS article 4.5 as amended by Directive (EU) 2017/2102
MD originally sold in the EU between 21 July 2014 and 21 July 2021	May contain phthalates	MD placed on the EU market before 21 July 2014	YES RoHS article 4.4
		MD placed on the EU market after 21 July 2014 and before 21 July 2021	YES Annex II of Commission Delegated Directive (EU) 2015/863
		MD placed on the EU market after 21 July 2021	NO NEW exemption 31a for phthalates needed
		New MD to be placed on the market after 22 July 2024	NO A new RoHS article 4.5 would be required for phthalates

Source: (COCIR 2018a)

Based on the above COCIR claims that in a scenario without this exemption and in order to ensure full compliance with RoHS, manufacturers should either:

- halt any refurbishment operations,
- sell refurbished equipment outside the EU, or
- not use any recovered part for RRSM in the EU in order to avoid the risk of unintentional non-compliance (COCIR 2018a).

This would entail a series of negative impacts which are described in sections 5.3.2 and 5.3.3.

5.3. Applicant's justification for the requested exemption

As justification for this amendment, COCIR contends that the overall negative health, safety and environmental impacts of manufacturing relevant parts and equipment anew are higher than using refurbished parts and equipment. This is further detailed in section 5.3.2.

The applicant claims that this new exemption is required for the same reasons that RoHS exemption 31a was required before the entry into force of restrictions for medical devices in 2014. As COCIR puts it:

> *"Similar to existing exemption 31a, this new exemption for the four RoHS-restricted phthalates will allow the reuse of recovered parts, regardless of where or when the medical devices they are originating from, were placed on the market. As already demonstrated for exemption 31a, and re-established again by the recent Waste Framework Directive, the environmental impacts of sending an old part to waste management and manufacturing a new replacement part always has a significantly higher overall impact than reusing the old part." (COCIR 2018a)*

The environmental arguments and socioeconomic impacts will be described in the next sections.

5.3.1. Substitution or Elimination of Bis-(ethylhexyl)-phthalate, Dibutyl-phthalate, Diisobutyl-phthalate and Benzyl-butyl-phthalate

According to COCIR, as that this exemption request relates to pre-existing components, only scenarios with and without this exemption can be compared in this case. Table 5-2 was included as part of the original application for exemption request in order to describe the different aspects considered in both scenarios.

Table 5-2: Comparison of scenarios with and without this exemption

With exemption	Without exemption
100% of recovered parts can potentially be reused	Most of the recovered spare parts cannot be used as the presence of phthalates is unknown and cannot be determined non-destructively (phthalate analysis is carried out by the method in EN 62321-8 which is solvent extraction from small particles of polymer followed by gas chromatography-mass spectroscopy).
Fewer new components will be manufactured and more MD will be refurbished.	Refurbishment of medical devices will have to use newly manufactured parts. However, this is not possible for older parts that have been discontinued and normally not economically-viable. Using new parts will be considerably more expensive than use of recovered parts and this will make refurbishment costs too high to be viable as an alternative to new equipment. Therefore, fewer MDs will be refurbished for reuse in the EU.
Less waste as 100% of recovered undamaged parts can potentially be reused	All unusable recovered parts will become waste as it is not possible to determine their compliance
All refurbished equipment can be sold in the EU or elsewhere	Unless new parts are used (if available and probably not economically viable), refurbished equipment will not be available in the EU, which will impact on EU hospitals
Greater availability of spare parts for repair, servicing and maintenance which will ensure shorter downtime of essential medical devices for EU citizens and avoid delays in urgent medical treatment. When medical devices are out of warranty, new spare parts may not be available and so could take up to 8 months to manufacture, if this is feasible at all)	Much lower availability of spare parts for repair of EU medical devices ensuring longer downtime of essential medical devices and delays in provision of urgent medical treatment to EU citizens

Source: (COCIR 2018a)

Regarding efforts to substitute, COCIR manifests that since the restriction of the four phthalates was published on 31st March 2015, manufacturers have been working to

determine whether parts and materials contain any of these four substances with the aim of replacing them wherever possible by 21st July 2021.

However, as is explained in the application, *"it is frequently not possible to determine from suppliers if these substances are present in any parts used in medical devices before March 2015 as this restriction had not been published and so there was no requirement from RoHS for suppliers to provide this information"* (COCIR 2018a).

COCIR also points out that "*all components of MD that are sold in the EU and which are placed in the global market will not contain DEHP, DBP, DiBP or BBP from 21 July 2021 at the latest*" (COCIR 2018a). As a result, the applicant claims that until this date less parts will contain DEHP, DBP, DiBP or BBP given that these substances are replaced by alternatives.

Referring to the progress in substitution on the overall concentration of the four phthalates in recovered parts, as part of its answers to clarifications questions, the applicant states that:

> *"…The "concentration" of parts likely to contain phthalates is therefore constant and homogeneous in the EU and globally. The "concentration" of such parts has already started to decrease as phthalates have been gradually phased out to meet the 2021 deadline and to meet national initiatives on green public purchasing. The fact that no exemptions for phthalates, except 2 very specific cases submitted by COCIR and a COCIR Member, have been submitted, proves that phthalates were being already substituted wherever possible well before 2018."* (COCIR 2019a)

In terms of availability of substitutes, it is highlighted that new parts are made by the same manufacturers as those of MD until production of one design ceases. In this case, sufficient stocks for warranty periods of 2-5 years are available. Moreover, the applicant points out that *"all substitutes must provide the same or better performance as the restricted phthalates in order to obtain Notified Body approval of medical devices as required by the Medical Devices Regulation" (COCIR 2018a).*

Based on these conditions, and considering the large overall negative environmental and health impacts that might result, the application submitted by COCIR marks the elimination or substitution options as not applicable for the case of RRSM in this context (COCIR 2018a).

According to the above, the consultants understand that the substitution of these four phthalates is technically feasible and is advancing in the MD industry. However, in the case of the use of recovered parts for refurbishment activities, environmental arguments and life cycle perspective should be given more relevance in the evaluation process.

5.3.2. Environmental arguments

As basis of the environmental arguments to support this exemption request, COCIR describes how parts that are recovered and refurbished remain within a "closed-loop". In this system, manufacturers make great efforts to collect their own used equipment from their clients so that parts recovered from devices can be used for RRSM and remain in a closed loop. The applicant adds that another reason why this is a closed loop system is because of the medical devices regulation which, on grounds of safety and performance aims to ensure that only approved parts are used. Figure 5-1 illustrates the flow of equipment and parts within the medical imaging sector.

The applicant claims that parts used for RRSM contribute to reduce the material flows of equipment and parts arriving at end-of-life (i.e. waste phase) prior to fulfilment of their full service life potential. Complementing this argument the applicant appeals to larger environmental impacts due to the unnecessary wasting of older parts and manufacturing of new ones in a scenario without this exemption.

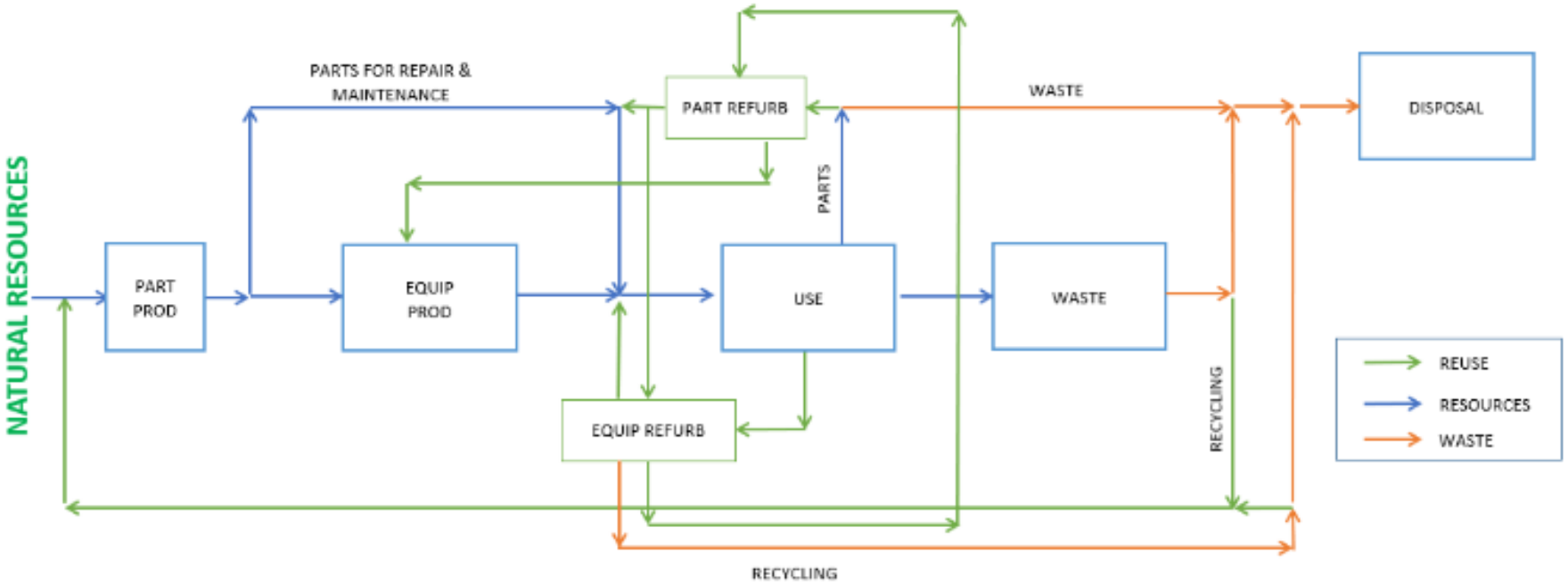
In its own words:

> *"Allowing all recovered spare parts to be reused, provides a net environmental and health benefit and is paramount to establish a proper circular economy business model. Life Cycle Analysis has been used to demonstrate that the overall health and environmental impact of reuse is less negative that the overall impact of disposal and manufacture of replacement parts." (COCIR 2018a)*

The applicant states that in the same way as Exemption 31a (published 12.02.16) this request for exemption is based on the basic principle of the EU Circular Economy recognizing that the environmental benefits of reusing parts are often higher than manufacturing a new part. According to COCIR, this also refers to the Waste Framework Directive which recognizes that life extension is always a better option than recycling or replacement with new manufactured products. As explained by the applicant:

> *"Exemption 31a, published in 12/02/2016 allows the use of recovered spare parts from medical devices to be reused for RRSM operations regardless of when and where the medical devices from which the parts originated and whether they were previously placed on the market in the EU or in a non-EU country. Exemption 31a recognized the principle that the environmental benefits of reusing part are always higher than manufacturing a new part. It is a basic principle of the EU Circular Economy, reconfirmed in the Waste Framework Directive in 2018: that reuse and life extension are always far better options than waste recycling and manufacturing of replacement new products".*

Figure 5-1: Flow of equipment and parts within the medical imaging sector



Source: (COCIR 2018a)

The application for exemption request (COCIR 2018a) also refers to environmental health and safety impacts which can be summarised as follows:

- Environmental and health impacts of manufacture of replacement parts that will cause emissions of global warming gases and hazardous substances and will consume resources and produce wastes.
- Comparative environmental and health impacts of DEHP, DBP, DiBP and BBP compared to the impacts of alternative plasticisers.
- Safety impacts related to reliability and diagnostic and treatment performance which can be put at risk by the non-availability of medical devices due to break-downs and delays.

To illustrate the impacts of manufacture of new parts in contrast to its reuse, COCIR presents results derived from a full life cycle Assessment (LCA) conducted by Zlamparet (2018) which compares the impacts of building new medical devices with the use of refurbished equipment in X-ray systems, PET, CT3 and MRI.

The original application included Table 5-3 which presents the percentage of three impact categories for refurbished equipment in contrast to 100% impacts of new equipment. With this COCIR intends to show that all impacts from refurbished systems are smaller than for new systems.

Table 5-3: Results of life cycle assessment comparison of new and refurbished MRI and X-ray systems (figures quoted the percentage of impact categories for refurbished equipment in contrast to 100 % impacts of new equipment)

Impact	Size of impact of refurbished system compared with a new system	
	MRI	X-ray system
Climate change	27%	3%
Human toxicity	32%	6%
Terrestrial ecotoxicity	28%	5%

Source: COCIR 2018 Application request for exemption

Referring to results from Zlamparet (2018) :

"This publication reports that 95% of MRI can be refurbished, 85% of CT and 65% of X-ray systems. The global energy saving from refurbishment of these three types of medical devices gives an annual life cycle energy saving of 211 MWh including energy saved by not making new parts when recovered used parts can be used." (COCIR 2018a)

In addition, COCIR provides LCA data about materials (e.g. PVC used as cable insulation in complex subassemblies and transducers, as well as printed circuit boards) that are used in replacements parts. With this the application offers comparative

information regarding the potential for impact reduction through use of refurbishment parts for RRSM.

COCIR estimates that about 2,200 tonnes of parts and 1,000 tonnes of equipment (total 3,200 tonnes) are refurbished and then reused in the EU annually. If it is assumed that *"90% of parts are PCBs (30% 1 or 2layer, 30% is surface mount devices and 30% ICs) and the rest is PCB cables (50% PVC and 50% copper wire)"* (COCIR 2018a), the presented LCA data serves as basis for understanding the impacts of manufacturing new parts. Using the VHK ecodesign impact data[9], the applicant calculates and presents these impacts in Table 5-4:

Table 5-4: Selected EU impacts on repair, maintenance and servicing medical devices in the EU without this exemption

Impact	EU total
Global warming impact	473,970 kg CO_2 eq
Heavy metals emissions to air	654 g Ni eq
Waste, hazardous/ incinerated	1,410 kg
Noon-hazardous waste landfilled	9680 kg

Source: (COCIR 2018a)

With this, the applicant supports its argument about the fact that not granting this exemption will imply a need for additional 2,200 tonnes of new parts with its associated impacts. Besides, according to COCIR, these results point out that the reuse of recovered parts for maintenance, repair and servicing gives significant reductions in many environmental and human impacts.

5.3.3. Socioeconomic impacts

COCIR describes a range of socioeconomic impacts related to increase in directs production costs and possible social impacts within the EU for a scenario where this exemption is not granted. COCIR explains that these implications result from the impossibility to use recovered spare parts which would lead to use newly manufactured spared parts

As presented in the original application, this would result in:

[9] Methodology for Ecodesign of Energy-related Products, MEErP 2011, Prepared for the European Commission, DG Enterprise and Industry, Unit B1 Sustainable Industrial Policy, contract SI2.581529, R. Kemna.

Increase in production costs since additional parts would need to be made to replace those that cannot be used.

Even though the COCIR manifests that it is not possible to estimate such costs, it is highlighted that repairing phthalates free equipment will be more difficult immediately after 2021 as warehouses of spare parts will be filled with parts likely containing phthalates-. Apart from the economic impacts for the healthcare and referring to the implications for circular economy, the applicant states that:

> *"What is even more relevant for COCIR is that the production of new parts will involve a higher environmental impact, as shown in the dossier, while reusing old parts is the way-to-go for a fully functioning circular economy"* (COCIR 2019a).

Higher costs for hospitals and clinics in EU that buy refurbished equipment and spare parts

To support this claims about economic impacts, the applicant describes:

> *"Many EU hospitals are able to buy the more expensive types of medical device because refurbished equipment is available at up to 50% discount that provides the medical diagnostic and treatment capability that they require. Without this exemption, the availability of such equipment would be very much diminished so that hospitals are unable to obtain this equipment with resultant negative health impacts on patients. If they were to buy new at the much higher cost, this will prevent them buying other medical equipment as their budgets are always limited and the non-availability of this equipment would have a negative health impact"* (COCIR 2018a)

According to the applicant's line of argumentation, the consultants understand that these impacts would result from the fact that new parts will have to be used to repair old and phthalate-free equipment. On additional information regarding this matter, COCIR explains that this would imply higher costs for hospitals already from 2022 (after the expiration of the 1 year warranty) and likely longer times that will reflect on patient treatment (COCIR 2019a).

Moreover, declaring that refurbished equipment costs normally 10-50% than purchasing a new one, the applicant suggests that impacts for healthcare could be linked to costs as well as the development of the refurbishment market. As COCIR puts it:

> *"The impact for healthcare could be estimated by multiplying the number of expected sales of refurbished equipment for the average cost of a new equipment, instead of the cost of a refurbished one (as such products will not be available)."*

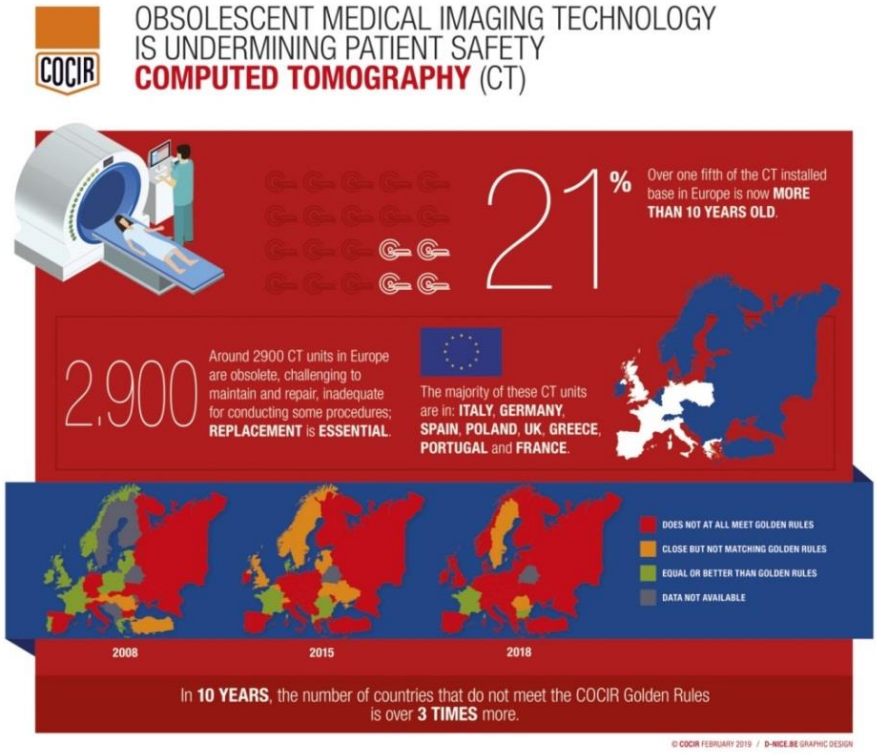
Longer downtimes when new parts have to be made before the device can be repaired

According to COCIR delays in availability of spare parts for faulty equipment has a direct impact on health of EU citizens due to delays in providing treatment. In this regard, the applicant states that repairs may be delayed if refurbished recovered parts cannot be used:

> *"[…] the global logistic created by manufacturers allows spare parts to be delivered worldwide to hospitals to RRSM medical devices to ensure the shortest possible downtime for the benefit of patients' health. Medical devices manufactured by COCIR's members are critical devices used in ER departments and other critical care facilities. "* (COCIR 2018a)

As part of their answers to the first round of clarification questions, COCIR provided infographics on the age profile of the installed base of medical imaging devices, which highlight a challenging situation regarding the obsolescence of the installed base of Magnetic resonance imaging (MRI), X-ray, Molecular imaging position emission tomography (MI-PET) and Computed tomography (CT) equipment. With this its intention is to evidence that *"refurbishment is a key element of the strategy to allow EU hospitals to renew their equipment in an affordable way"* (COCIR 2019a). An example for Computed Tomography is presented in Figure 5-2.

Figure 5-2: Infographic about obsolescent medical imaging technology- example Computed Tomography (CT)



Source: (COCIR 2019a)

Possible impacts on employment

COCIR considers the impact on employment to be negligible compared to all the others, in particular the impact on the access to medical devices in EU. As part of the answers to the first round of clarification questions, the applicant elaborated on this:

> *"Employment may not be affected significantly as refurbished equipment will continue to be sold outside of the EU, but EU hospitals will be forced to buy more new equipment, which should balance out any effects on employment"* (COCIR 2019a).

5.4. Stakeholder contributions

During the public consultation, solely **MedTech Europe**[10] submitted a contribution related to Ex. 31a (MedTech Europe 2019). The consultants understand the information provided in this contribution as supporting the request for exemption and providing additional information complementing COCIR's arguments.

This stakeholder opens its contribution with the following statement:

> *"MedTech Europe is of the opinion that the rationale applied for the exemption of reused spare parts containing the six RoHS 2 substances should be extended to spare parts containing phthalates. The extended exemption should cover all medical devices, including in vitro diagnostic medical devices (IVDs)."* (MedTech Europe 2019)

Arguments specifically related to question No. 2[11] of the public consultation questionnaire:

- Since high reliability is a prerequisite of the design, medical devices in the scope of RoHS Directive can have "extremely long lives".
- Therefore keeping these systems operational requires an uninterrupted stream of spare parts, which were designed with the system. Which mean that *"Changing the spare parts to be compliant with the RoHS regulation would be the same as redesigning the entire system in service"* (MedTech Europe 2019).
- Reusing instead of scrapping components from robust medical electrical equipment has benefits for the circular economy.

Considering the above, MedTech Europe expressed that extending Annex IV exemption 31a to include RoHS restricted phthalates will ensure maximum extended lives for medical devices and components that are still serviceable.

Supporting COCIR's request for exemption also including in vitro diagnostic medical devices (IVD) MedTech Europe offers the following arguments:

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10 European trade association for the medical technology industry including diagnostics, medical devices and digital health

11 COCIR requests the exemption for all medical devices, including in vitro diagnostic medical devices, and their accessories, but mainly provides supporting data for medical imaging devices. Please provide information and data to support the request for other than medical imaging devices falling under Cat. 8 of RoHS Directive Annex I.

- based on how long it takes to bring a new MD to the market (3 to 7 years and up to 10 for IVD), this contribution highlights that the above mentioned considerations should apply to all EEE medical devices (also those other than medical imaging).
- The fact that any change in material, including spare parts, that could compromise the reliability of the device could trigger its evaluation as a new device on an individual basis which would translate into time required to get approval from a Notified Body on an individual basis, both in Europe and any other regulated region.

For *in vitro* diagnostic medical devices, MedTech Europe refers to the fact that given that long lifespan (up to 20 years and more) of these systems, periodic refurbishment are carried out as part as normal repair and maintenance activities. For this reason, and considering that many of the equipment currently on the market were compliant at the time in which they were initially installed, it is often difficult to replace old parts with phthalate-free parts.

In this sense, this contribution expresses the need that spare parts are sufficiently available given the fact that product reuse, refurbishment and extension of lifetime are both environmentally and economically beneficial.

Besides, MedTech refers to the possibility that phthalate-containing parts might be required to ensure the performance of the equipment and associated reagents. If replaced by different parts, the extra testing and validation required in order to replicate performance exactly as originally specified, might result in delays and associated impacts to patients.

As part of this contribution, MedTech Europe provides numbers to support the relevance of this request for renewal. To show that the amount of spare parts placed on the market has been steadily growing, Table 5-5 provides number from one of its members which place spare parts on the market for analysers, flow cytometers and sample preparation devices.

Table 5-5: Weight of spare parts placed on the market for analysers, flow cytometers and sample preparation devices

Year	Weight of spare parts placed on the EU market (tonnes)
2014	0.115
2015	0.355
2016	3.625
2017	20.821
2018	31.105
Q1 2019	6.974
TOTAL	**62.996**

Source: (MedTech Europe 2019)

Further on, the MedTech Europe contribution reports numbers from a European member company which has avoided 40 tonnes of WEEE per years in the IVD business through the repair of service-parts.

As for other types of medical devices such as laser treatment systems for prostate enlargement, the contribution also offers concrete numbers from MedTech Europe members showing different results and costs reduction through reuse and refurbishment.

- From an installed base of 600 resonators in the EU, 2 refurbished ones are placed in the market per month. These are almost never scrapped and instead are refurbished and sent back out in an exchange pool,
- The difference between a refurbished and a new resonator is about 20,000 USD,
- Without access to non-RoHS compliant spare parts, this company would incur in costs of about 500,000 USD more per year in comparison to now.

5.5. Critical review

5.5.1. 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

With regards to **Annex XIV of the REACH Regulation**: DEHP, DBP, DiBP and BBP have been included in the SVHC REACH candidate list for the reason of being toxic for reproduction (Category 1B) in 2008 and have been added to Annex XIV in 2012. In July 2017, the four phthalates (DEHP, DBP, DiBP and BBP) have been additionally recognized for endocrine disrupting properties. Thus, these substances cannot be placed on the market or used after the 21 February 2015 (Sunset date), unless an authorisation is granted.

In the original request for exemption, it is however clarified that these substances are no longer used in the EU to manufacture parts of medical devices. As COCIR explains the parts have either already been made and are in use and will be reused in the future. Besides, parts may be manufactured outside the EU until 2021 (COCIR 2018a). Given that Annex XIV does not apply to imported articles and in the case of this request, manufacturers of MD represented by COCIR are considered not to manufacture its equipment in the EU. Thus the recovered spare parts containing DEHP, DBP, DiBP and BBP are imported as articles in the EU and in that case REACH Annex XIV is not applicable.

Additional references to DEHP, DBP and BBP are included in REACH Annex XVII:

- **Entry 51** in Annex XVII of the REACH Regulation stipulates that DEHP, DBP, BBP and DiBP shall not be used in concentrations greater than 0.1 % by weight of the plasticised material, in toys and childcare articles. Toys and childcare articles containing DEHP in a concentration greater than 0.1 % by weight of the plasticized material shall not be placed on the market.

  Whereas basically, this restriction concerning toys and childcare articles could apply to certain articles within the scope of Directive 2011/65/EU (RoHS 2), it is not in the scope of this requested exemption. Recovered parts for RRSM activities on medical equipment are not expected to be accessible to children under normal or reasonably foreseeable conditions of use.

  Furthermore entry 51, paragraph 3, contains the recent amendment of December 2018 that stipulates that the four phthalates that are restricted under RoHS (DEHP, DBP, BBP, DiBP individually or in any combination), shall not be placed on the market after 7 July 2020 in articles in a concentration equal to or greater than 0,1 % by weight of the plasticised material in the article. However, it is further stipulated that this paragraph shall not apply to medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof and shall not apply to electrical and electronic equipment within the scope of Directive 2011/65/EU. Thus, the restriction of entry 51 does not apply to the exemption here at hand.
- **Entry 30** of Annex XVII is also relevant (entry 30 refers to substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as toxic to reproduction category 1A or 1B) and DEHP, DBP, BBP, DiBP are listed in Appendix 6 that lists substances that have been found to be "Toxic to reproduction: category 1B (Table 3.1)/category 2 (Table 3.2)". According to entry 30, these four phthalates 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 30 of Annex XVII do not apply to the case of this RoHS exemption. The supply of spare parts recovered from and used for the repair or refurbishment of medical devices is in the consultants' point of view not a supply to the general public.

COCIR also mentions a registry of intentions under REACH: *"A restriction on materials with prolonged skin contact has been proposed. Most parts of medical devices do not have prolonged or frequent skin contact and so would be out of scope. If this restriction enters force in the future, any parts which have PVC that may be used with prolonged skin contact will not be reused."* (COCIR 2018a) The registry of intentions to which COCIR refers to has been decided and forms part of the amendment of entry 51 of Annex XVII. The prolonged skin contact is meant for plasticised material for use exclusively in the open air, which comes into contact with human mucous membranes or into prolonged contact with human skin. Thus, this does not apply to the present request.

No other entries, relevant for the use of DEHP, DBP, BBP and DiBP in the requested exemption could be identified in Annex XIV and Annex XVII (status September 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.

5.5.2. Scientific and technical practicability of substitution

Based on the aspects described in section 5.3.1 it can be followed that substitutes in the form of phthalate-free newly manufactured parts would be globally available after July 2021. The substitution of the phthalates being restricted step by step from July 2021 on is both scientifically and technically practicable or otherwise has been addressed in other exemption requests, e. g. in request 2019-1.

In the same way as it was considered by Gensch und Baron (2014) and described in detail in section 5.3.2, it is understood that the use of new parts for RRSM activities of MD would result in larger environmental, health and safety impacts are associated to the need of new materials and energy required for the manufacture of such parts.

In this regard, the consultants point out that the amendment to Annex II stipulated in Directive 2015/863/EU[12] authorizes the use of the restricted phthalates in "*cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of [...] medical devices, including in vitro medical devices [...] placed on the market before 22 July 2021*". This means that according to the RoHS Directive, the reuse of new spare parts containing phthalates for the repair of equipment already on the market is already possible without the requested exemption.

As stated in the previous evaluation report by Gensch und Baron (2014), this is further supported by the general intention of the Directive apparent in Recital 20: "*As product reuse, refurbishment and extension of lifetime are beneficial, spare parts need to be available*".

5.5.3. Reuse of refurbished parts

Provided that *"…reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer."* Article 4(5) allows the use of reused spare parts,

(a) recovered from EEE placed on the market before 1 July 2006 and used in equipment placed on the market before 1 July 2016,
(b) recovered from medical devices or monitoring and control instruments placed on the market before 22 July 2014 and used in EEE placed on the market before 22 July 2024;
(c) recovered from in vitro diagnostic medical devices placed on the market before 22 July 2016 and used in EEE placed on the market before 22 July 2026;
(d) recovered from industrial monitoring and control instruments placed on the market before 22 July 2017 and used in EEE placed on the market before 22 July 2027;

[12] COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances, see: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015L0863

(e) recovered from all other EEE that was outside the scope of Directive 2002/95/EC and which is placed on the market before 22 July 2019, and used in EEE placed on the market before 22 July 2029.

This means that, according to the RoHS Directive, the harvesting of spare parts containing phthalates from medical equipment placed on the EU market before 22 July 2014 as well as their refurbishment and use in EEE placed on the market before 22 July 2024 is already possible without the requested exemption. For in-vitro diagnostic medical devices different dates apply (2016 and 2026 respectively).

However, COCIR's request goes beyond this existing authorisation in two senses:

- First of all, the request extends the periods of the authorisation granted under Article 4(5) in the case of parts that contain phthalates, so that such parts can be harvested from medical equipment placed on the EU market after 21 July 2021 and used in any equipment throughout the validity of the exemption.
- Furthermore, as the exemption formulation is not limited to equipment placed on the EU market, it furthermore extends the pool of equipment from which parts that contain phthalates can be harvested, supporting the global practice of medical refurbishment: As the "refurbishment pool" of medical equipment is a global one, it would not necessarily be feasible to segregate parts according to where they were first placed on the market (EU or non-EU). For medical equipment it is also the general practice that one model is manufactured and marketed globally (as opposed to models marketed in certain geographical regions) and COCIR has specified in the past that only such models enter the "refurbishment pool". In this sense, the exemption supports the harvesting and reuse of parts containing phthalates from medical devices, regardless of where they were first placed on the market, increasing the availability of refurbished spare parts so that fewer newer components need to be manufactured.

As part of its contribution to the stakeholder consultation, MedTech Europe (2019) presented similar arguments stating that, in order to keep medical systems operation, an uninterrupted stream of spare parts which were designed with the system are required, and that *"Changing the spare parts to be compliant with the RoHS regulation would be the same as redesigning the entire system in service"* (MedTech Europe 2019).

However, from the consultants' perspective, this statement is only seen as partially correct, since the exemption request also allows the use of parts from old equipment in the repair and refurbishment of new equipment. Though in some cases of new equipment on the market, old parts cannot be used for refurbishment or repair (e.g., when the design or dimensions have changed), in other cases such use shall be feasible. Similarly it is expected that in some cases new parts compliant with the restriction of phthalates will be compatible with old equipment, whilst in others they will be incompatible.

Nonetheless, based on the information presented so far, the consultants can follow that, even though it is considered that newly manufactured parts may be RoHS-compliant, their use for repair of MD would lead to additional use of energy and resources. In this sense, given that the reuse and repair of spare parts is already

contemplated within various articles of the RoHS Directive, the substitution alternative is not understood as being beneficial in comparison with the use of refurbished parts in this case.

5.5.4. Environmental arguments and socioeconomic impacts

The applicant has provided detailed information on the broad range of environmental arguments including environmental, health and safety impacts (Section 5.3.2) as well as on socioeconomic impacts (Section 5.3.3) in a scenario where the exemption is not granted.

These sections offer sufficient evidence indicating that regardless of the availability of substitutes, this exemption is justified under Article 5(1)(a) of the RoHS Directive on adaptation to scientific and technical progress. The information submitted specifically addresses the premise that:

> *"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".*

Supporting environmental arguments of this request, the information provided by the applicant referring to environmental impacts and data comparing LCA of new and refurbished equipment is comprehensive and detailed. From the consultants' perspective, the reasons why not granting the exemption would lead to negative environmental impacts have been well clarified and supported with robust evidence.

As for the socioeconomic impacts in a scenario without the exemption, the applicant described the negative impacts derived from longer downtimes on treatments due to delays in availability of spare parts. In this regard, it could be argued that this consideration only applies to devices that would have been produced without the four restricted phthalates. This is because devices that have been placed on the market before July 2021 may also be repaired with phthalate-containing spare parts irrespective of this exemption. In the consultant's opinion, while this might be relevant from a product regulation perspective, it is not relevant from a RoHS point of view as RRSM activities can also be conducted if the spare parts are used parts.

The scope 2015 review conducted by (Gensch et al. 2015) also details the impacts of the refurbishment of medical devices analysing its environmental and socioeconomic impact for three different policy options. These are aligned with the majority of the arguments presented by the applicant in the context of this request and therefore confirm its plausibility.

In the past, COCIR has contributed to consultations related to RRSM activities in the MD sector, by mentioning that a temporary discontinuation or limitation of such practices would result in a lower supply of second-hand (refurbished) devices with negative consequence for medical facilities and patients (Gensch und Baron 2014). For the evaluation of this exemption request, the information provided by COCIR (COCIR 2018a; 2019b; 2019b; 2019a) and MedTech Europe (2019) contribute to reinforce those previous arguments on which past recommendations have been based.

Based on the above, the consultants can establish that an exemption would be justified according to Article 5(1)(a) of the RoHS Directive.

5.5.5. Scope of the exemption

In the technical description of the exemption request, COCIR declares that this exemption is relevant to EEE in the scope of category 8; "*medical devices such as MRI, CT, PET, SPECT, ultrasound imaging, patient monitors, In vitro-diagnostic medical devices*". However, in section 1.a of the application (COCIR 2018a, p. 2), category 9 (i.e. monitoring and control instruments) was also marked in the list of relevant EEE.

To the question of whether this request should apply for EEE in both categories, COCIR clarified that even though they do not represent companies relevant to the category 9 and cannot supply information to support the necessity for the exemption, the decision to mark it as relevant was based on contact with a company which manufactures electron microscopes (COCIR 2019a).The applicant indicated that information regarding this category should be provided by relevant manufacturers during the public consultation.

On this topic MedTech Europe (2019) contributed to the stakeholder consultation and expressed that considerations from this exemption request evaluation should apply to all EEE medical devices (also those other than medical imaging). Regarding the application of this scope for EEE under Cat 9, no contributions from manufacturers of monitoring and control instruments were received in the process of this exemption request evaluation.

Even though the consultants understand that the relevance to both Cat8 and Cat 9 in the scope of this exemption is possible, the inputs and contributions considered for this evaluation do not sufficiently address the scope of Cat 9. Based on this, recommendations derived from this evaluation should be considered for Cat 8.

5.5.6. Conclusions

Supporting the arguments presented in this exemption request, the consultants recognise the relevance of the information summarised here. This is related to the general structure and interpretation of the RoHS Directive.

Article (3)(27) provides a definition for spare parts which reads:

> "'*spare part' means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part;*"

Directive 2011/65/EU refers to spare parts in two further articles:

Article 4(4) authorises the use of cables and spare parts for repair, the reuse, the upgrading of functionalities or the upgrading of capabilities of various product groups such as the following:

(a) EEE placed on the market before 1 July 2006;
(b) medical devices placed on the market before 22 July 2014;
(c) in vitro diagnostic medical devices placed on the market before 22 July 2016;
(d) monitoring and control instruments placed on the market before 22 July 2014;
(e) industrial monitoring and control instruments placed on the market before 22 July 2017;

Article 4(5) authorises the reuse of spare parts, provided that the reuse takes place in auditable closed loop business-to-business return systems, and that the reuse of parts is notified to the consumer. Items (b) to (d) are relevant to this exemption request (See section 5.5.3).

Based on these two articles the consultants understand the relevance of this exemption request for the RRSM activities of the Medical Devices manufacturers and healthcare providers across the EU.

As for the information presented and summarised throughout this evaluation report, it is concluded that COCIR's arguments are considered plausible and the exemption is technically and scientifically justified.

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

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

In terms of environmental impacts, the prevention of less than 2 tonnes per year of the four RoHS phthalates (DEHP, DBP, BBP and DiBP) present in about 3,200 tonnes of EEE waste per annum as consequence of not granting this exemption request should be weighed against the negative impacts from the new materials needed to manufacture and supply new parts to ensure the adequate functioning and upgrading the installed base of MD in the EU.

From the consultant's perspective, it can be followed that the use of recovered parts for RRSM activities in medical devices can be deemed as a beneficial practice. Therefore, in light of the information presented in this report, the consultants conclude that this exemption request is justified as the total negative environmental impacts caused by substitution outweigh the total environmental, health and consumer safety benefits thereof (third point, Article 5(1)(a)).

5.6. Recommendation

COCIR's arguments are considered relevant and well supported and the requested exemption is justified under the requirements of Article 5(1)(a). There are different options in the case the Commission agrees to grant an exemption on how to integrate the requested exemption in the current Annex IV:

(1) New exemption with the wording from the original request, independent from the existing exemption 31a.

"*Bis (ethylhexyl) phthalate, dibutyl phthalate, diisobutyl phthalate and benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer*"

In this case, the exemption is recommended to be valid for a 7 year period, starting 22.7.2022 and extending until 21.7.2029.

(2) Amendment of the existing exemption 31a with the new merged wording as proposed by COCIR (COCIR 2019a).

"Bis (ethylhexyl) phthalate, dibutyl phthalate, diisobutyl phthalate, benzyl butyl phthalate, lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer"

Here, specifying a validity period is more complex as detailed below.

On the one hand, it should be noted that COCIR has initially submitted the application marked as request for amendment of existing exemption in Annex IV suggesting that it could be combined with existing exemption 31a. However, since RoHS does not have an official procedure for amending an existing exemption, the application could be understood in terms of a new exemption. This would be supported by the fact that the arguments provided throughout the application refer to the four RoHS phthalates (DEHP, DBP, DiBP and BBP).

Should the exemption be granted through a renewal of Ex. 31a with an extension of the scope, it should be noted that the different EEE categories covered by the current Exemption 31a have different expiry dates. If all RoHS substances are to be addressed under a single exemption, extending the validity for the substances currently addressed under Ex. 31a would not be warranted as this has not been addressed in the current evaluation. This would result in the validity for the phthalates being limited according to the current validity, or to the splitting of the exemption to multiple entries in which the phthalates are addressed separately in relation to validity.

Besides, the information presented as part for this evaluation mostly addresses EEE under Cat 8, specifically medical devices other than in vitro diagnostic medical devices. Information on in vitro diagnostic medical devices was presented as part of the stakeholder contributions. As for granting the exemption for electron microscopes and their accessories, the consultants do not consider that the information provided throughout the process of evaluating the present exemption request offers sufficient information on the relevance of this scope for this type of EEE.

On the other hand, the consultants agree with the points highlighted by the applicant, regarding the alternative of merging two very similar exemptions (this and 31a) into a single one (COCIR 2019a). This would offer significant advantages considering that:

- Both exemptions are necessary to ensure repair and refurbishment activities;
- In the future, requesting the renewal of a single exemption would require less effort both from industry and the European Commission.

The consultants consider that this request from COCIR presents an exceptional case subjected to the existing legal procedures for the RoHS Directive. On these grounds a final recommendation for this option is not provided as it is considered to be beyond the scope of the present evaluation for exemption request. In this case, considerations about relevant aspects and implications derived from this request have been provided as input to a decision by the European Commission.

6. Request 2019-1: DEHP ion selective electrodes for point of care analysis

"Bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids"

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

XXwt %	Following a number, this formulation refers to the percent weight of a substances from a component or from the homogenous material within which it is contained, depending on used formulation.
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
BGA	Blood gas analysis
DEHP	Bis (ethylhexyl)-phthalate
EEE	Electrical and electronic equipment
EoL	End of life
ISE	Ion selective electrodes
IVD	In-vitro diagnostics
PoC	Point of care
RoHS	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment

6.1. Background

COCIR (2018b) has requested a new exemption for

„Bis (ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids"

The exemption is requested to be added to RoHS Annex IV and to be valid for the maximum validity period of 7 years for EEE in Category 8.

COCIR explains that medical personnel in emergency departments, intensive care units, neonatal units and in operating theatres often need to rapidly analyse various fluids of their patients, including pleural fluid[13], blood and dialysate[14]. These situations are referred to as "point of care" and analysis is usually needed within a few minutes. Point of care testing requires a much shorter time to obtain results compared to traditional laboratory testing. As explained by COCIR "*Point of Care (PoC) analysers are medical devices used in these situations where results of body fluid analysis are required in the shortest time possible in order to enable quick therapeutic intervention" (COCIR 2018b).*

These type of devices operate with disposable cartridges containing ion selective electrodes (ISE) and other chemicals used for analysis and measurements of ions in blood or other body fluids, as well as washing and waste disposal, aqueous quality controls and electronics.

Some ISE contain Bis (ethylhexyl) phthalate (DEHP)",

DEHP has been added to the list of restricted substances specified in Annex II of the RoHS Directive and shall be prohibited in medical devices covered by the Directive as of 22 July 2021[15]. An exemption is thus requested to allow further placing of cartridges on the market for use in PoC blood analysis devices, where these apply ion selective electrodes containing DEHP.

6.1.1. Amount of Bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes used under the exemption

COCIR estimates a total of 2.2 kilograms of DEHP entering the EU market annually through the application described for this exemption request. This amount of RoHS-restricted substance would therefore be avoided should the exemption not be granted.

Supporting this estimation the applicant details the general composition of the membranes as 29 wt % Polyvinyl Chloride (PVC), 70wt % DEHP and an ionophore that imparts specificity for the particular ion of interest (COCIR 2018b).

As part of the answers to the first Clarification Questionnaire, the applicant provides more information regarding average size and weight of one cartridge that contributes to understanding the dimensions of the products under the scope of this exemption. According to COCIR, the size of one cartridge is 29 cm x 26 cm x 20 cm and "*For one manufacturer the weight of a cartridge is 1.34 kg. Therefore each unit cartridge contains 0.00021 weight % of DEHP*" (COCIR 2019b).

COCIR also provided data referring to a scenario in which an exemption would not be granted, for details see section 6.3.2.

[13] Pleural fluid is defined as the fluid that is found between the layers of the pleura, the membranes of which line the cavity and surround the lungs.

[14] In the process of dialysis, dialysate is the fluid passing through the dialyser, used for drawing toxins out of the patient's blood stream.

[15] Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU

6.2. Technical description of the requested exemption

COCIR indicates that "*DEHP is used as a membrane solvent for the ion selective electrode (ISE) constituents"* (COCIR 2018b) that are used in PoC analysers to measure the concentrations of analytes such as partial pressure of carbon dioxide (pCO2), pH, concentration of sodium and potassium ions.

An important requirement of the functionality of ISE in this type of PoC analysers is the fact that they can analyse very small samples of whole blood. As highlighted by COCIR (2018b), this translates into reducing the need for blood transfusions and saving valuable time in emergency situations in comparison to central lab systems.

Regarding the component in which DEHP is used, COCIR describes that these ISE sensors "*are supplied to hospitals as components of disposable cartridges which contain the chemicals used for the analysis and carry out measurement, washing and waste disposal, aqueous quality controls and electronics*" (COCIR 2018b). In reference to the cartridges, COCIR describes that *„The measurement cartridge is a device that contains all the sensors used to make the measurements, liquid reagents to calibrate the sensors over its use-lifetime […]. The sensors are housed in a sensor module. The reagents are contained in foil laminated bags"*. (COCIR 2018b)

However, COCIR refers to the fact that ISE cartridges that contain DEHP are designed specifically for each type/model of instrument. Considering that *"many EU hospital already own or will buy before 21 July 2021 analysers that utilise ISE cartridges"*, new disposable cartridges must be compatible with PoC analysers already in the market.

Based on the above, the consultants understand that these cartridges containing DEHP are consumables of the PoC analysers, which are nevertheless to be considered as electrical and electronic equipment (EEE)[16]. They are disposed of after the chemicals used for the analysis have been consumed. In addition, these must be compatible with the type of analyser model that are already being used by hospitals in the EU. In this sense, the consultants understand that the exemption is at least in part concerned with the provision of such cartridges on the EU market, so as to ensure that devices already on the market can continue to be operated.

In its original application for exemption, the applicant lists the functions that the ‚DEHP cartridge is required to fulfil in the ISE cartridges of PoC blood analysers. These include:

> *„must be able to analyse whole blood directly,*
>
> *must not affect stability of membrane or electrodes during use or in storage,*
>
> *Cartridges must be compatible with analysers already on the market and in use within EU hospitals,*
>
> *Give analysis results within as short time as possible, ideally within one minute,*

[16] ISE cartridges are consumables with an equipment constituent meeting the specific definition of EEE in Article 3(1) and 3(2) of RoHS 2, comparable e.g. to printer cartridges, see FAQ 7.2. https://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf, last accessed 10.09.2019.

Change-over time to replace the used cartridges should be as short as possible, ideally less than 30 minutes."

As plasticiser, the substance must have the following properties:

"be liquid over a wide range of temperatures,

be compatible with, and solvate the other membrane components,

not induce phase separation,

not exhibit crystallization,

be lipophilic so it does not leach from the membrane during the use" (COCIR 2018b).

According to the applicant, this exemption request is requested for EEE in category 8, medical devices for in-vitro diagnostics (IVD) and relevant for devices used for *"chemical analysis of blood gases, electrolytes, metabolites, total hemoglobin, and hemoglobin derivatives in arterial and venous whole blood samples, dialysate and other body fluids such as pleural fluids"* (COCIR 2018b).

6.3. Applicant's justification for the requested exemption

Based on premises of technical unreliability of substitution alternatives, COCIR justifies the exemption with the argument that substitution is not technically practical. In the original application, COCIR declares that this exemption is needed because alternatives to DEHP have been found to give less accurate and incorrect test results and alternative methods to ion selective electrodes (ISE) take more time and may also provide inaccurate results.

6.3.1. Substitution or elimination of Bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes

Arguments for the justification of the need for this exemption in terms of substitution or elimination provided by the applicant address two levels: First, the level of substance substitution, regarding substances that could be applied as alternative plasticisers. Second, the technological level referring to elimination through the use of other methods or analysis devices or to elimination by developing an alternative design for the analysing cartridge.

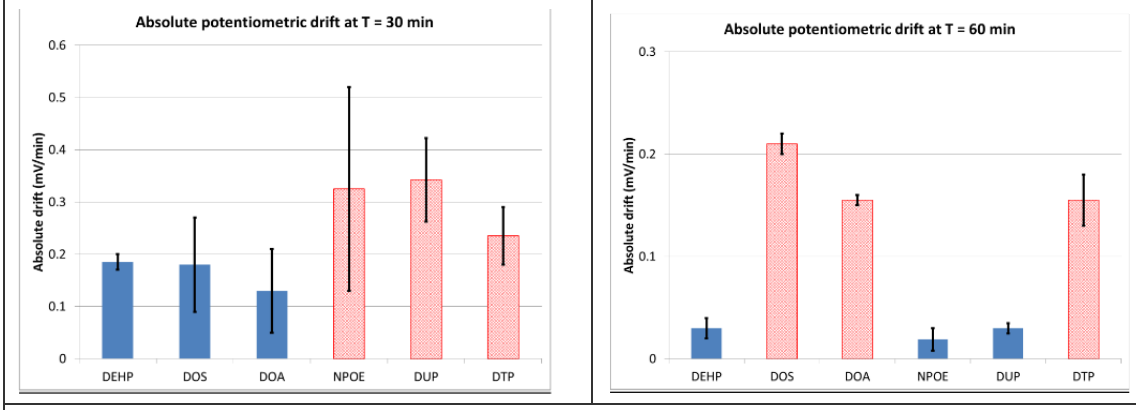
Substance substitution (Alternative plasticisers)

COCIR argues that attempts to replace DEHP with possible alternative plasticisers with similar properties have resulted in incorrect analysis translating into technical unreliability.

Regarding this, the applicant claims that several manufacturers of IVD ISE have attempted to replace DEHP with alternative substances with similar properties. The original application for exemption includes details about tests conducted with a range of plasticiser classes (ether, diester, phthalates). These tests were aimed at identifying a class which would yield sensors with the best balance and later life stability in terms

of potential (mV) drift[17] per unit timer. Sensors using nitrophenyloctylether (NPOE), dioctyl sebacate (DOS), dioctyl adipate (DOA), diundecyl phthalate (DUP), ditridecyl phthalate (DTP) resulted in unacceptable drift that cannot be used to give reproducible and accurate results.

Figure 6-1: Measured change in millivolts (mV) over the tested time period in minutes (mV/min) with measurements from several sensors



The above plots show the initial drift (mV/min) at T = 30 minutes and drift at T = 60 minutes after exposure to aqueous solutions for each of the tested plasticizers. DEHP exhibits the best balance of initial drift after one hour and reproducibility and is therefore the preferred plasticiser

Source: COCIR (2018b)

Based on the tests shown in Figure 6-1 of the original application for exemption, COCIR claims that *"research by manufacturers has shown that current models of analysers have to use the current design of ion selective electrode cartridges that contains DEHP"* (COCIR 2018). COCIR argues that alternatives to DEHP (substitution on the substance level) give less accurate test results than current ISE PoC analysers with DEHP.

Elimination on the Device Level (Alternative Analysis Methods and Devices)

Referring to alternative analysis methods, COCIR describes the range of currently available techniques and methods that could be used to measure the same analytes as done by PoC analysers.

The listed alternative methods are ion chromatography, flame photometry, atomic adsorption spectroscopy and glass pH electrodes for pH. Required time, materials, measurement procedure and calibration are clarified for each one of these methods. In addition, critical limitations pointing at reasons why they fail to perform the same

[17] Sensors Drift [mV/min]: Drift is a natural phenomenon for sensors. It affects all sensors regardless of the vendor. It is caused by physical changes in the sensor. Sensor precision often remains high. Drifting will affect the sensor's accuracy, causing it to be off target.
https://serverscheck.com/lab/sensor-drifting.asp

function as ISE PoC analysers, which perform up to the required time and sample sizes, are highlighted.

Ion chromatography for example, is a laboratory based technique that requires a skilled operator and the analysis time is much longer than with ISE. Similarly, flame photometry and atomic adsorption spectroscopy are also laboratory-based methods for which the samples should be prepared and separated before the analysis. On the other side, devices such as the glass pH electrode for pH, require more fluid to immerse the electrode, which may sometimes be more than is available from a patient. This represents a critical difference in contrast to the small samples required for ISE analysers. Further details can be viewed in the application (COCIR 2018b).

Further details as to alternative technologies are compiled in Table 6-1 below.

Table 6-1: Comparison of operation characteristics and parameters for alternative analysis technologies

Method	Ions that can be analysed	Analysis time per sample	Limitations	Total elapsed time from taking sample to results	Analyse whole blood	Measure ion activity	No maintenance needed	Automatic calibration	Automatic quality control	Can analyse all analytes (Na+, K+, Ca2+, H+, pCO2, Cl-, Glu, Lac, pO2, total haemoglobin, hematocrit) simultaneous-ly	Positive ID of patient	Connection to hospital IT system
ISE PoC analyser	Na+, K+, Ca2+, H+, pCO2 (bicarbonate), Cl-, Glu, Lac, pO2, total haemoglobin, hematocrit	1 minute for all analytes simultaneously. It is important to note that measuring blood gases (pO2) and metabolites (glu, lac) together is critical for a full and rapid diagnosis of the patient.	All ions can be analysed simultaneously and rapidly from a very small quantity of fluid.	1 minute	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ion chromatography	Na+, K+, Ca2+, total CO2 (bicarbonate), Cl-	Whole blood cannot be analysed as it will block the small capillary and so additional time (at least 15 minutes) is needed to separate blood to extract the clear plasma that contains the ions (e.g. by centrifuge). Analysis requires calibration with at least at two standards (these contain for example all cations Na+, K+, Ca2+,) each standard taking typically 30 minutes.	Cannot measure ion activity. Anions and cations must be analysed separately, either by using two instruments or changing columns which will add at least one additional hour to the analysis time as the column has to equilibrate before it can be used. Ion chromatograph must be used by trained analysts and so are not suitable for	15 + (2 x 30) + 30 + 30 = ca. 2 hours for one sample, then >30 minutes for subsequent samples plus queuing time.	No	No	No	No	No	No	No	No

Method	Ions that can be analysed	Analysis time per sample	Limitations	Total elapsed time from taking sample to results	Analyse whole blood	Measure ion activity	No maintenance needed	Automatic calibration	Automatic quality control	Can analyse all analytes (Na+, K+, Ca2+, H+, pCO2, Cl-, Glu, Lac, pO2, total haemoglobin, hematocrit) simultaneous-ly	Positive ID of patient	Connection to hospital IT system
		Recalibration is advisable every 2 – 3 hours. Analysis time per sample is up to 30 minutes and in addition is data processing time of up to another 30 minutes. Note that Ca2+ ions take the longest time for analysis[18].	PoC locations. Samples therefore need to be taken from PoC facilities to these labs, where the samples join a queue, which can typically add 1 hour.									
Atomic adsorption	Na+, K+, Ca2+,	If a sufficient volume of blood is available, it can be centrifuged to obtain the clear aqueous phase, which will take about 15 minutes to separate the phases. Alternatively, acid digestion is an option but will take at least one hour (it also determines total calcium which is not the	Cannot measure ion activity This method is slow because whole blood cannot be analysed directly and only one ion is analysed at a time. These instruments are fairly large and require gas cylinders of acetylene and oxygen. These are very hazardous and	At least 2 hours including waiting time - 15 to 30 + 18 + (3x3) = 42 to 57 minutes	No	No	No	No	No	No	No	No

[18] See figure 4 in https://webcache.googleusercontent.com/search?q=cache:wI4xJ6tlCb8J:https://www.mdpi.com/2297-8739/5/1/16/pdf+&cd=1&hl=en&ct=clnk&gl=uk&client=firefox-b-d and figure 11 of https://www.unil.ch/idyst/files/live/sites/idyst/files/shared/Labos/Jackson_2000.pdf

Method	Ions that can be analysed	Analysis time per sample	Limitations	Total elapsed time from taking sample to results	Analyse whole blood	Measure ion activity	No maintenance needed	Automatic calibration	Automatic quality control	Can analyse all analytes (Na+, K+, Ca2+, H+, pCO2, Cl-, Glu, Lac, pO2, total haemoglobin, hematocrit) simultaneous-ly	Positive ID of patient	Connection to hospital IT system
		same as the concentration of the ISE method). Calibration of the spectrometer requires analysis of the ion at least at two concentrations so will take at least 6 minutes[19] per ion and sample analysis about 3 minutes per ion[20]. Total elapsed time for four ions is 15 to 30 + 18 + (3x3) = 42 to 57 minutes. In addition, time is required to set up the spectrometer and allow it to equilibrate (ca. 1 hour) before any analysis can be carried out.	are unsuitable in an emergency hospital environment. They can therefore only be used at a different location away from patients and untrained staff. Samples therefore need to be taken from PoC facilities to these labs, where the samples join a queue, which can typically add 1 hour.									

[19] It is good practice to flush out the instrument after each sample for about 10 minutes to avoid cross-contamination, so this time would be in addition per sample.
[20] https://www.sciencedirect.com/topics/materials-science/atomic-absorption-spectrometry

Method	Ions that can be analysed	Analysis time per sample	Limitations	Total elapsed time from taking sample to results	Analyse whole blood	Measure ion activity	No maintenance needed	Automatic calibration	Automatic quality control	Can analyse all analytes (Na+, K+, Ca2+, H+, pCO2, Cl-, Glu, Lac, pO2, total haemoglobin, hematocrit) simultaneous-ly	Positive ID of patient	Connection to hospital IT system
Flame photometry	Na+, K+, Ca2+,	Very similar to atomic adsorption spectroscopy, but can be quicker as Na+, K+ and Ca2+ can be analysed simultaneously, but has to be calibrated for each ion has to be separate taking about 18 minutes for three ions. Total elapsed include blood separation time is 15 + 18 + 3 = 36 minutes plus 1 hour equilibration time.	Cannot measure ion activity Flame photometry is a type of atomic adsorption spectroscopy and so analysis time is similar and the limitations described above are the same	1 - 2 hours = 15 + 18 + 3 = 36 minutes plus 1 hour equilibration time.	No	No	No	No	No	No	No	No
pH electrode	H+ only	Requires at least 10cm^3. This quantity will not always be available, for example very little blood can be taken from premature babies.	Measuring blood analytes, particularly pH, needs to be done at 37C (body temperature) and the system/sample controlled to +/- 0.1C for acceptable clinical performance. The electrode would need to be cleaned between each sample	Ca. 1 plus time for temperature equilibration and recalibration, probably 30 minutes per sample, although not likely to be sufficiently accurate	Yes	Yes	Yes	No	No	No	No	No

Method	Ions that can be analysed	Analysis time per sample	Limitations	Total elapsed time from taking sample to results	Analyse whole blood	Measure ion activity	No maintenance needed	Automatic calibration	Automatic quality control	Can analyse all analytes (Na+, K+, Ca2+, H+, pCO2, Cl-, Glu, Lac, pO2, total haemoglobin, hematocrit) simultaneous-ly	Positive ID of patient	Connection to hospital IT system
			to remove adsorbed proteins. The adsorption of proteins can cause the sensor to drift, requiring calibration. In addition, exposure of the sample to air will change the pH. Taking these together, a bench top pH electrode would not be capable of achieving the minimum +/-0.04 pH unit total analytical error expectation									

Source: COCIR 2019d, Personal communication by email submitted 2.10.2019

In reference to alternative methods, COCIR adds that "[…] *central lab systems use an indirect method of measuring these ions whereas blood gas systems measure them directly."* (COCIR 2018b).

COCIR argues that alternative methods to ion selective electrodes used in blood gas analysis devices (elimination on the technological level) have either been found to give less accurate and incorrect test results or require more time and are less reliable than ISE PoC analysers.

As for the possibility of elimination by developing an alternative analysis technique, in its original application for exemption COCIR poses that the "lab-on-a-chip" is the main focus of IVD equipment manufacturers (COCIR 2018b). Considering that this entails the development of a very different design, from mid-2018, the stages leading to the development of this alternative technology are expected to take between 8 and 10 years (see Table 6-2).

Table 6-2: Expected timescale for the development of alternative designs of analyser

Development phase	Elapsed time
Design of new miniaturised analysers and construction of prototypes	2 years from mid 2018
Testing to determine accuracy, adjustments to calibration. Establish manufacturing capabiltiy, site location and validation.	3 years
Clinical trials	1 year
Notified Body approval	6 months in EU, up to 2 years globally
Total elapsed time	**8 years (so by 2026)**
Support installed base of IVD analysers in EU hospitals	Current design of cartriges will be needed until **2030**

Source: *COCIR (2018b)*

As part of the answers to the first clarification questionnaire, COCIR provided further information about the work on this alternative which began before 2015. There they clarified that "*the "lab-on-chip" development is in feasibility phase and will take 8 to 10 years before complete replacement will be possible"* (COCIR 2019b).

Elimination on the Component Level (Alternative design or technology to the cartridge for ISE analyser)

Regarding the option of replacing DEHP in the current design, COCIR explains that different design for analyser cartridges that could substitute ISE cartridges containing DEHP is only expected to be available after 21 July 2021.

In their original application, COCIR explicitly claims that *"These analysers are planned to be sold in the EU until alternative technology is developed which is expected to be after 21 July 2021. Therefore this exemption will be needed for new analysers sold after 21 July 2021 as well as for consumable ion selective electrode modules that are supplied to hospitals in the EU to use with these analysers"* (COCIR 2018b).

This claim is based on the likely duration of the stages that would need to be carried out for this option. Timescales estimations for these stages are provided in the original application for exemption and include 7-8 years of technical development work as well as 2 years of subsequent regulatory path. Based on this, the total period could be up to 10 years.

Even so, COCIR highlights that "*modified ISE modules will however not be compatible with existing analysers that were designed with DEHP ISE modules and so an exemption would still be needed for these"* (COCIR 2018b). The consultants understand this to refer to reverse compatibility with devices already operating on the EU market. In this respect, in a later communication, COCIR (2019d) provided N estimation as to the lifetime of the analysers in which the ISE is applied: "*The average life-time of ISE PoC Analyzer is 9.7 years, with >50% of the install base older than 10 years*"

Considering that hospitals and clinics in the EU already using devices that require DEHP-membranes on its ISEs would need to obtain consumables until the analysers reach end of life, the applicant estimates that: *"cartridge consumables will be needed in the EU at least until 2030 and so this exemption will be needed for these until this date."* (COCIR 2018b)

6.3.2. Environmental arguments

Information provided in reference to the environmental aspects of this request for exemption address two main points: The end-of-life (EoL) treatment of the ISE cartridges, and the amount of WEEE generated in a forced substitution scenario, where current analysers are subject to premature obsolescence in the event that DEHP-based ISE cartridges would no longer be available for these to operate.

Regarding possible preparation for reuse, recycling or provisions for appropriate treatment of waste, in the original application, COCIR indicates that ISE cartridges cannot be recycled and are therefore sent for energy return. On this, it is added that after its use, ISE and membranes become bio-hazards so they are excluded from the WEEE Directive (COCIR 2018b).

In terms of environmental impacts, COCIR claims that *"without this exemption, hospitals would be forced to dispose of IVD analysers prematurely resulting in electrical equipment being disposed of before its normally expected end of life giving an increase in electrical waste" (COCIR 2018b)*. According to the applicant, the manufacture of substitute equipment to replace these, will also have environmental and health impacts.

In the answers to the clarification questionnaire, COCIR provided estimations about the possible amounts of waste generated through a forced substitution. This was

declared to be roughly > 1,000 t per year including all associated consumables and relates to the substitution of blood analysis devices already operating on the market. These estimations are based on (COCIR 2019b):

- an average weight of 16.6 kg per device of approximately 30,000 instruments currently placed on the EU market, which would generate around 500 tonnes of WEEE; and
- additional foreseeable generated waste which is based on a weight of 1.34 kg/cartridge of approximately 12 cartridges used per year per analyser.

The applicant also highlights the fact that even though these are theoretical calculations, these amounts of waste would be the result of avoiding a small amount of DEHP.

> *"There would be a large disposable cost for the >1000 t of waste as compared to preventing approximately 2.2 kg of DEHP from being placed on the market."* (COCIR 2019b)

In relation to the PoC analysis devices to be scrapped prematurely, COCIR furthermore estimates that "*Replacing these 500t by new devices would also lead to additional RoHS substances entering the EU market (e.g. lead in steel up to 0.35%, lead in aluminium with up to 1.5%, lead in copper with up to 4%). Assuming that 20% steel, 10% aluminium and 5% copper are being used, with a lead content of 0.35% in steel, 1.5% in aluminium and 4% in copper, the total weight of additional lead put on the market would be 2,100 kg (compared to a saving of 2.2 kg DEHP)*" (COCIR 2019b). This is data is compiled in Table 6-3 below.

Table 6-3: Estimation of the total weight of lead (Pb) entering the market through the replacement of PoC analysers currently in stock

Total Weight of EEE which need to be replaced [kg]	**500.000**
% Steel	20,00%
% Aluminum	10,00%
% Copper	5,00%
% Lead content in Steel	0,35%
% Lead content in Aluminum	1,50%
% Lead content in Copper	4,00%
Total Weight of Lead entering the market by products replacing the installed base [kg]	**2.100**

Source: *(COCIR 2019b)*

6.3.3. Socioeconomic impacts

Regarding the foreseeable socioeconomic impacts of the substitution, COCIR indicates an increase in fixed costs and possible social impacts within the EU. In the original application for exemption, COCIR further describes human health and economic impacts (See section 6.3.2 for environmental impacts).

The implications of a scenario where EU hospitals PoC units already using this type of cartridge analysers will not be able to obtain ISE module consumables include human health impacts:

> *"There will be serious implications if delays in obtaining analysis results occur or if they are not accurate. Any delay in treatment could, as a worst case, result in unnecessary deaths (although it is impossible to estimate a quantitative impact)" (COCIR 2018b)*

The economic impacts refer to the economic expenditures which hospitals and clinics in the EU will incur either by buying alternative analysers or by replacing them with new equipment. Besides, the applicant points at possible job losses if cartridges cannot be sold in the EU.

As part of the answers to the first clarification questionnaire and based on theoretical calculations, COCIR provided more specific estimations about these aspects (COCIR 2019b):

- "Approximately 30,000 instruments are [used; the consultants] in the EU and each uses 12 measurement cartridges/year and each cartridge can measure 500 samples [this; the consultants] yields approximately 180 [million; the consultants] measurements or 90 million patients (2 samples/patient) negatively impacted." (COCIR 2019b)
- "One manufacture estimates that approximately 158 million measurements are made per year and 432K [i.e. 432,000; the consultants] samples are measured each day world-wide. Assuming 50 % is in the EU and typically more than one sample is taken from each patient therefore roughly 40 million patients would be impacted for one manufacture. For 3 manufactures approximately 120 million patients would be negatively impacted per year" (COCIR 2019b).

To summarise, based on an estimate of approximately 30,000 instruments currently placed on the EU, it is estimated that between 90 and 120 million patients could be negatively impacted. These numbers consider the amount of measurement cartridges and samples per year reported and calculated from different manufacturers.

As for impacts on employment inside and outside the EU, COCIR refers to negative impacts along a range of industries e.g. manufacturing, supply chain, service, R&D, marketing, quality, regulatory, information technology, associated distributors, medical services and hospitals.

Clarifications from COCIR, regarding additional costs, estimate that hospitals would incur in unanticipated costs of more than 250 million in order to replace all systems currently placed on the EU market.

On this, COCIR points out that the overall impact to hospital infrastructure is similar to that described in Exemption 41, Section 7.4.5 of Gensch et al. (2019). These refer to hospitals across the EU conducting time- and money-consuming decision processes towards purchasing new blood analysers. Additionally, these impacts consider unanticipated investment costs of over 300,000 euros for one single hospital as well as further expenses from connecting the new instruments to existing information systems which are estimated at 20,000 euros. Finally, the need for training the staff on the new instruments would represent costs that could be measured in terms of number of employees and the hours invested per person. According to data from one German hospital, training their staff for just one hour could translate into 1,200 hours of unproductive work time (Gensch et al. 2019).

Despite providing detailed information about these aspects, COCIR clarifies that:

"This exemption is justified on the basis that substitution is not technically practical and does not rely on socio-economic issues to justify the maximum validity period" (COCIR 2018b).

Considering this, even though there is information about the socioeconomic impacts, the main focus of the justification for this exemption is on arguments of technical practicability of substitution.

6.4. Stakeholder contributions

During the public consultation, one contribution was submitted by **Radiometer Medical ApS,** who manufacture "acute care solutions in labs and at the point of care"[21]**.** Radiometer addressed the following arguments:

Radiometer agrees with the scope of the exemption and the wording proposed by COCIR. As evidence supporting this exemption request, Radiometer declares to have an ongoing project aimed to substitute the DEHP in ISE. This project has, however, not succeeded in the substitution so far.

As for alternatives that may cover part or all of the applicability range of DEHP, Radiometer claims that they cannot point today at a suitable substitute. No quantitative data about application specifications to support their view was provided in the contribution. In addition, this stakeholder declares that DEHP is used in all the relevant electrodes in the cartridges of their device so that it is not possible for them to make a partial substitution. On that matter it is indicated that their plan is to substitute DEHP before July 21, 2021.

About research initiatives currently looking into the development of possible alternatives this contribution states that:

> *"To Radiometer's knowledge the "lab-on-chip" technology will not be available in the foreseeable future"* (Radiometer Medical Aps 2019).

[21] See Radiometer Website: https://www.radiometer.co.uk/

In relation to their own PoC devices, Radiometer declares that the total amount of DEHP placed on the EU market as part of disposable sensor cassettes is about 35 g per year. Therefore, Radiometer considers the total of 2.2 kg DEHP provided in the estimation of COCIR in the original application as a reasonable estimation. (Radiometer Medical Aps 2019)

In quantitative terms, Radiometer estimates that as of January 1, 2019 a total of 7,800 of their analysers have already been placed on the EU market. This number is understood by the consultants to be mentioned as it clarifies the number of Radiometer devices that would need to be scrapped should cartridges no longer be available. Regarding possible additional waste to be generated in the event of a forced substitution the contribution includes the following statement:

> *"If accessories should not be available after 2021, the analysers cannot be used and must be scrapped. The amount of scrap from Radiometer equipment in this case is estimated to 73 ton"* (Radiometer Medical Aps 2019).

Finally, this stakeholder poses that in the event of a forced substitution, the main costs will be the replacement of all the impacted PoC equipment. In addition, Radiometer has estimated that total replacement costs, which include among others costs for equipment replacement and for training the staff on new equipment, to add up to € 130 million. It is highlighted that most of these costs will be allocated to the public sector apart from private hospitals and clinics.

6.5. Critical review

6.5.1. 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 criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The REACH regulation has been consulted in this respect: the first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

With regards to **Annex XIV of the REACH Regulation**: DEHP has been included in the SVHC REACH candidate list for the reason of being toxic for reproduction in 2008 and has been added to Annex XIV in 2012. In July 2017, DEHP has been additionally recognized for endocrine disrupting properties. Thus, DEHP as substance cannot be placed on the market or used after the 21 February 2015 (Sunset date), unless an authorisation is granted.

In the original application for exemption COCIR indicated that *"ion selective electrode membranes containing DEHP are manufactured outside of the EU and so only articles are imported into the EU and DEHP is not used as a chemical substance in the EU"*

(COCIR 2018b). Thus they are imported as articles in the EU and REACH Annex XIV is not applicable.

Additionally, DEHP is referred to in **REACH Annex XVII**:[22]

- **Entry 51** in Annex XVII of the REACH Regulation[23] stipulates that DEHP shall not be used in concentrations greater than 0.1 % by weight of the plasticised material, in toys and childcare articles. Toys and childcare articles containing DEHP in a concentration greater than 0.1 % by weight of the plasticized material shall not be placed on the market.
  Whereas basically, this restriction concerning toys and childcare articles could apply to certain articles within the scope of Directive 2011/65/EU (RoHS 2), it is not in the scope of this requested exemption concerning medical devices; the use of DEHP in ISE cartridges for PoC analysers is not related to applications in toys or childcare articles.
  Furthermore entry 51, paragraph 3, contains the recent amendment of December 2018 that stipulates that the four phthalates that are restricted under RoHS (DEHP, DBP, BBP, DiBP individually or in any combination), shall not be placed on the market after 7 July 2020 in articles in a concentration equal to or greater than 0,1 % by weight of the plasticised material in the article. However, it is further stipulated that this paragraph shall not apply to medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof and shall not apply to electrical and electronic equipment within the scope of Directive 2011/65/EU. Thus, the restriction of entry 51 does not apply to the exemption here at hand.
- **Entry 30** of Annex XVII is also relevant (entry 30 refers to substances in Appendix 5 or Appendix 6 and DEHP is listed in Appendix 6). According to entry 30, DEHP 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 30 of Annex XVII do not apply to this requested exemption.

COCIR also mentions a proposed restriction on DEHP for *"materials which have prolonged skin contact. However, hospital staff and patients can not touch the membranes as they are inaccessible inside the cartridge."* This proposal to which COCIR is referring to has been decided and forms part of the amendment of entry 51 of Annex XVII. The prolonged skin contact is meant for plasticised material for use exclusively in the open air, which comes into contact with human mucous membranes or into prolonged contact with human skin. Thus, this does not apply to the request here at hand.

[22] See also the Appendix of this report at page 108.

[23] Please note that this entry has been amended quite recently:
COMMISSION REGULATION (EU) 2018/2005 of 17 December 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, valuation, Authorisation and Restriction of Chemicals (REACH) as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP);
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R2005&from=EN

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

No other entries, relevant for the use of DEHP in the requested exemption could be identified in Annex XIV and Annex XVII (status August 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.

6.5.2. Scientific and technical practicability of substitution

As justification of the exemption, COCIR offers arguments first and foremost based on the lack of reliability of the substitutes. COCIR's Members have attempted to comply with the substance restriction through efforts to replace DEHP with possible alternative plasticisers with similar properties. These efforts have concluded in incorrect analysis results which evidences technical unreliability for the intended application.

- COCIR (2018b) summarises the results from manufacturer's tests with alternative plasticisers detailing that NPOE, DUP and DTP exhibit unacceptable drift[24] and cannot be used to give reproducible and accurate results (See also section 6.3.1).
- Information from COCIR (2018b) intends to show that in contrast, DEHP exhibits the best balance between initial drift after one hour and reproducibility, and is therefore the preferred plasticiser out of all of the alternatives tested. This characteristic is seen as key for the technology to meet the needs of PoC environment as well as the short period of time needed to obtain analysis results.

The consultants understand that even though a broad range of RoHS compliant plasticisers exist and have been tested, the compatibility with the intended use of the sensors in PoC situations, makes time and precision of results a critical feature that needs to be ensured for the ISE application described by the applicant.

Looking into the initiatives of other producers of PoC blood gas analysis devices to substitute DEHP in the ISE of such devices, shows that at least a few manufacturers have difficulties to find alternatives.

- (COCIR 2019b) states that "*for 3 manufactures approximately 120 million patients would be negatively impacted per year*" in relation to the estimation of socio-economic impacts and the consultants thus conclude that three of the at least four manufacturers[25] of blood analysis devices have not achieved substitution and

[24] Sensors Drift [mV/min]: Drift is a natural phenomenon for sensors. It affects all sensors regardless of the vendor. It is caused by physical changes in the sensor. Sensor precision often remains high. Drifting will affect the sensor's accuracy, causing it to be off target.
https://serverscheck.com/lab/sensor-drifting.asp

[25] The consultants are aware from the review of exemption 41 of Annex IV for lead in blood gas analysis cartridges, that there are at least four manufacturers placing equipment in the EU market (Roche,

would need the exemption. This would suggest that one manufacturer may be compliant and would not need an exemption for DEHP[26].

- Radiometer Medical Aps contributed to the stakeholder consultation in full support of the request given that it uses DEHP in disposable sensor cassettes and that DEHP covers all the relevant electrodes at the sensor device. When asked about the status of ongoing research for substitution, Radiometer expressed that *"Our plan is to substitute before July 21, 2021"* (Radiometer Medical Aps 2019).

Technical information regarding the use of DEHP as plasticiser in ISEs was provided by Professor Mark Meyerhoff from the University of Michigan in the form of technical comments, following an inquiry by the consultants.

In his comments, Professor Meyerhoff explains in detail the scientific principles of the functionality of plasticisers in polymeric membrane-based ion-selective electrodes. In this document, he acknowledges that the nature of the plasticizer employed can play a significant role in the ion-selectivity exhibited by polymer membrane ISEs. In order to explain the criteria governing this selectivity, he elaborates on the two following processes (Meyerhoff 2019a):

(1) the single ion partition coefficients from aqueous phase of sample solution into organic phase of the membrane (primarily the plasticized PVC) (k_i and k_j; where $k_i = [i]^{org} / [i]^{sam}$ [27] and for j ions: $k_j = [j]^{org} / [j]^{sam}$. ; where "i" is the primary target ion and "j" is some potential interferent ion; and

(2) the formation constants of the ions to form a complex with the selective ionophore (L) in the plasticized membrane phase (i.e., K_f for rxn: $i_{org} + L_{org} <-> iL_{org}$ and $j_{org} + L_{org} <-> jL_{org}$).

Meyerhoff (2019a) explains that these two processes dictate the selectivity coefficient (K^{pot} observed with any given ionophore used to prepare polymer membrane ISEs), in accordance with the following equation[28]:

$$K_{i,j}^{pot} = \frac{k_j}{k_i}\frac{K_f^j}{K_f^i}$$

Based on these criteria, Professor Meyerhoff elaborates on how changing the plasticiser would affect selectivity:

Siemens, Instrumentation Laboratories and Radiometer). Abbot also manufactures PoC devices, but using single use cartridges in a hand held device and thus their equipment is irrelevant in respect of this comparison.

[26] From publicly available data, only two of the named companies are specified as COCIR Members and it can thus not be concluded if COCIR has full information on the compliance of all relevant actors or not. For detail see: https://www.cocir.org/about-cocir/members.html

[27] The consultants understand "sam" to be an abbreviation for sample and "org" to be an abbreviation for organic phase, whereas the equation is related to the analysed ion in the aqueous phase of the sample solution and in the organic phase of the membrane. "I" represent the target ion, whereas j represents other, potentially interfering ions.

[28] K^{pot} represents the selectivity coefficient. K_f is the binding constant of the ionophore, whereas K_i and K_j are the binding constants of the target ion and the interfering ion respectively.

> *"In most cases, the ratio of the formation constants of the ion with the ionophore dominate the selectivity term. Hence, changing plasticizer from one to another will not usually have dramatic effect, unless the dielectric constant of the plasticizer changes significantly. Such large changes in dielectric constant can cause exudation of the plasticizer or ionophore from the membrane phase, and also alter the solvation energy of the free ion within the plasticizer phase (k_i). If it makes the k_i value lower, but does not change the k_j value equally in the same direction, then the selectivity constant will increase, making the electrode less selective. (Meyerhoff 2019a)"*

Moreover, this expert's comments also consider possible exceptions in which changing the plasticisers would indeed affect selectivity:

> *"So, in most cases, I would expect that changing from DEHP to some other plasticizer that has a similar lipophilicity/dielectric constant is not going to dramatically change the selectivity and analytical performance of any ionophore-based ISE. The only exception could be in the case of polymeric membrane electrodes that utilize ionophores that are not especially selective in their binding constants (K_f values, above) with the target analyte ion over potential interferent ions. In such cases, if the plasticizer helps extract the target ion to a greater extent than interferent ions into the membrane phase, then the overall selectivity could be enhanced or vice versa."* (Meyerhoff 2019a)

On this, the document provides an example of DEHP use as plasticisers in certain Ca^{++} selective membrane electrodes that employ dialkyl-phosphate carrier type ionophores to obtain enhanced calcium ion selectivity. For these membranes it is considered that the electrode selectivity could be negatively impacted by altering the plasticiser. Even in this case, the substitution might represent higher costs but it is still not considered technically unfeasible.

As Professor Meyerhoff puts it: *"Given the rather small sizes and quantities of the membrane materials employed to create the ISE sensors employed in modern blood analyzers, this is not a particularly compelling argument not to change to an ionophore system (e.g., to ETH 1001) that does not require the use of DEHP"* (Meyerhoff 2019a).

Building on this, his comments conclude with the following statement on the practicability of DEHP substitution:

> *"For sure, all other ISE ionophore systems[29] (for Na^+, K^+, H^+, etc.) do not require the use of DEHP as the plasticizer to achieve the desired selectivity for measurement of the target ions in undiluted blood samples."* (Meyerhoff 2019a)

The consultants understand this to mean that even in the cases where ion selectivity could be affected by a change in the plasticiser (e.g. Ca^{++}), the constraints for DEHP substitution are rather economical than technical. Moreover, it is understood that for

[29] Besides Calcium ions

the following analytes, the application of DEHP as a plasticiser does not play a role in the ion selectivity of the polymer membrane ISE: Na^+, K^+, H^+.

From the content of these technical comments, the consultants conclude that substituting the plasticiser in an ISE in modern blood analysers would require technical re-design and calibration, but is in principle a feasible process. The status of substitution of the various manufacturers appears to depend on whether DEHP is used in ISE of a specific device to begin with and how far the efforts to substitute are (testing of plasticisers, redesign, recertification of device, etc.). In a later follow up communication with Professor Meyerhoff it was enquired about whether his technical comments are limited to the feasibility of substitution for blood analysers (Meyerhoff 2019b). The consultants wanted to clarify whether ISEs measuring a broader range of fluids represent larger technical difficulties of substitution. This, considering that the subject of this specific request for exemption, are ISE used in Point of Care devices which, besides whole blood samples, serum and plasma, also provide analysis for other body fluids (e.g. urine, cerebral spinal fluid, pleural fluid and dialysate).

To this, Professor Meyerhoff expressed that whole blood is surely the most complex matrix, but for sure other plasticisers can function effectively for all the relevant ISEs for reliable measurements in whole blood samples. Besides, he expressed scepticism about the impossibility of DEHP substitution under those conditions.

> *"I truly doubt that these other types of samples really would have some components that would make it impossible to use another plasticizer, other than DEHP, to make the polymeric membrane ISEs function with good accuracy/adequate selectivity"* (Meyerhoff 2019b)

With this, as a technical consultant on the electrochemical sensor technology with more than 30 years of experience, Professor Meyerhoff confirms his initial position about this exemption, by which he states that it is possible that all ISE sensors within other whole blood analysers can indeed be prepared without the need to employ DEHP in the sensing membranes.

COCIR were asked to comment on the input of Prof. Meyerhoff and provided the following input: the "*technical input on the ISE selectivity impact from changing plasticizers in sensor membrane formulations is correct. However this is only one requirement for a clinically useful blood analysis system.*

There are complex interactions between the sensor membrane formulations, internal electrolyte formulations, system calibration reagent surfactants, calibration reagent preservatives and compatibility with internal system materials used to house the sensors. The membrane formulations are specifically optimized to function within the system and all components that contact the sensors. All these aspects need to be addressed to yield a stable, reproducible and useful system.

In our exemption request we also noted that the system utilizes mathematical formulas (algorithms) that are specifically designed for each sensor (membrane formulation). Therefore it is the total integrated system (instrument, reagents, sensor formulation, algorithms) that is the complete system device which yields clinically acceptable performance and results.

Overall system stability and availability is very important to enable quick treatment of patients. In our exemption request we showed data that alternative plasticizers do not enable a stable system and will result in delayed treatment of patients. This delay can negatively impact patient outcomes. We also showed data that alternative plasticizers yield sensors with more variability. This can cause low quality clinical results leading to improper treatment of patients.

The conclusion of our data was the following; DEHP exhibits the best balance of initial drift after one hour and reproducibility and is therefore the preferred plasticizer. This has allowed the technology to meet the needs of the critical care environment in particular a short period of time to obtain results and a short time before first measurement with a new cartridge." (COCIR 2019d)

Though the consultants understand that various parameters may affect the time needed to develop a substitute for DEHP in this application, it can also be understood that at least one manufacturer expects complete substitution by July 2021. This leads to the conclusion that substitution is possible in the time frame available before the DEHP restriction is to come into force for medical devices, though it can also be followed that finding a compatible substitute may be more time-consuming for some manufacturers as it is a trial and error process.

As to the comparability of PoC devices with alternative blood analysis technologies, COCIR provide a comparison of the operation characteristics and parameters of alternative analysis technologies in Table 6-1. The comparison shows that the alternative technologies mentioned either do not provide the same functions (e.g. ion chromatography, atomic adsorption spectroscopy, flame photometry) or only cover part of the functions provided by the ISE PoC analysers (pH electrode). Furthermore, all technologies addressed in the table require a substantially longer time to provide results in comparison with the ISE PoC analyser (between 30 minutes to over two hours in comparison with the relatively short time period of 1 minute in which results are obtained with the ISE PoC analyser).

Referring to the use of alternative technologies for blood analysis, this review emphasizes that "point-of-care" equipment is used by medical practitioners to measure various blood parameters in proximity to where the patient is being taken care of (emergency rooms, intensive care units, and operation rooms). Thus the short time in which such devices provide results is of importance to allow rapid diagnosis and decisions as to further care. *"The alternative of sending blood samples to the central laboratory requires more time and also does not provide results for parameters unique to blood gas analysis devices (pH, pO2, pCO2, HCO3)"* (Gensch et al. 2019, p. 60).

6.5.3. Environmental arguments and socioeconomic impacts

Environmental arguments for this exemption request were provided by COCIR referring to the amounts of waste generated in possible scenarios in which an exemption shall not be granted.

The first aspect to be considered is the End of Life (EoL) treatment of the ISE cartridges after they have been used and discarded. In the original application, COCIR

details that since these cartridges are considered a bio-hazard, they cannot be recycled and are sent for energy return (see section 6.3.2).

In this regard, the consultants understand that a decision about granting the exemption would not modify the EoL treatment of such medical waste. Therefore, in terms of additional material flows containing DEHP that could lead to emissions and health risks in EEE waste management facilities, whether an exemption is granted or not shall not affect possible impacts in such facilities. In other words, not granting an exemption is not expected to lead to environmental benefits in the form of reducing such emissions.

The second aspect to be considered refers to the amount of WEEE that would be generated as result of premature obsolescence of the PoC analysers, which currently use ISE cartridges containing DEHP. The applicant provided information about the amount of waste that would possibly be generated highlighting the difference between > 1000 t of waste (from scrapped equipment and consumables, containing an estimated 2,100 Kg of Pb) compared to 2.2 kg of DEHP prevented from being placed on the EU market annually (see section 6.3.2).

In light of these estimations, the consultants enquired about the possibility of selling the stock of consumables outside the EU in the event that the exemption is not granted. Addressing this enquiry, COCIR provided additional information regarding the EU stock of cartridges for PoC blood analysis devices that would go to waste (COCIR 2019b):

> *"… each instrument uses a range of cartridges (1 -3), quality control materials and accessory consumables (e.g. syringes) all of which would be in stock. The cartridges would not be sold outside of the EU as there are other distribution centres which support the rest of the world. Manufacturing production and distribution centres are pre stocked based on forecast demand so all material is accounted for. In addition there is a limited shelf life so all stock would go to waste. Even if the manufacturer could sell outside of the EU the stock at the other centres would go to waste. Therefore millions of consumables would not be used and would become waste"* (COCIR 2019b)

In this case it could be argued that in a substitution scenario, it is possible for hospitals to stock up on cartridges to keep operating the PoC equipment to avoid premature obsolescence. According to information included in the review of Ex. 41, Annex IV for this type of sensors the expected shelf life is up to 9 months (Gensch et al. 2019, p. 58). Though the shelf-life may vary between manufacturers, COCIR also refer to a limited shelf-life. This means that the limited shelf life of consumables of this type would critically constrain this possibility and PoC devices will cease to be operational shortly after ISE cartridges containing DEHP are no longer available. Though this means on the one side that such devices may be scrapped prematurely, it is also assumed that as long as consumables are available (stocked) with a suitable shelf-life, that they would be used and not "go to waste" as suggested by (COCIR 2019b). As manufacturers are aware of the legislation, it is also assumed that restocking of manufacturer distribution points would be avoided after mid-2021 if the exemption is not approved, avoiding such stock going to waste.

Information provided by COCIR regarding the various socio-economic impacts that could result should the exemption not be granted is summarised in Table 6-4.

Table 6-4: Possible socioeconomic impacts in a scenario in which the exemption is not granted

Impact area	Detail	Estimations from COCIR (referring to three manufacturers)*	Consultants comments on information
DEHP avoided on the market and in the waste stream	DEHP not to be placed on the market through ISEs used in compatible PoC analysers.	2.2 kg of DEHP to be avoided on the market annually.	It is noted that the amount of 2.2 Kg DEHP to be placed on the market is an annual estimation, meaning that every year for which the exemption is needed shall result in an additional 2.2 Kg of DEHP being placed on the market. It is also noted that consumables are treated as medical waste and not as EEE waste. Therefore, the exemption will not affect the amount of restricted substances in EEE waste streams.
Generation of additional waste	Equipment subject to premature obsolescence and waste from consumables should ISE cartridges containing DEHP no longer be available.	>1000 tons of waste would be generated if ISEs containing DEHP are no longer available on the EU market. Around 500 tons of WEEE from scrapped obsolete PoC equipment (containing ca. 2,100 Kg of Pb) and the rest from millions of unused associated consumables at the end of shelf life.	It is not clear why COCIR considers that consumables would be scrapped ahead of their EoL. The PoC devices already on the market are expected to be RoHS compliant and could be used as long as consumables are available. As long as the consumables are compliant at the time placed on the market, they can be used afterwards. The shelf life of the cartridges is understood to be limited (assumed up to 9 months) and would suggest that the PoC device obsolescence would follow shortly after cartridges could no longer be placed on the market. However, this would suggest only the obsolescence of these devices - ca. 500 tonnes containing ca. 2,100 Kg of Pb.

Impact area	Detail	Estimations from COCIR (referring to three manufacturers)*	Consultants comments on information
Health impacts	EU hospital PoC units that use DEHP-ISE analysers will not be able to obtain DEHP-ISE module consumables and so will not be able to analyse patients' body fluids.	The impact will be felt directly by the end users in hospitals and clinics where these critical care devices could no longer be used. This will negatively impact patient care as proper treatment would not be given and put lives at risk. Based on estimations from analysers from 3 manufactures approximately between 90 and 120 million patients would be negatively impacted per year.	In the consultants opinion it needs to be assumed that manufacturers would communicate to facilities that the consumables shall no longer be available and thus that hospitals would prepare for this process and acquire new equipment. It is not clear if devices are available on the market at present that do not use DEHP, but at least Radiometer plans to be compliant by July 2021, when the restriction of DEHP for medical devices comes into force. As a minimum, health facilities would be expected to seek compliant equipment and acquire it as fast as possible. This unplanned investment may affect the general ability to provide patients with other services in light of limited budget, but it cannot be followed that medical facilities would not replace equipment as quickly as possible.
Economic impacts	Hospitals and clinics in the EU would need to buy alternative analysers if cartridges are no longer available in the EU.	There would be a large disposable cost for the >1000 t of waste as compared to preventing approximately 2.2 kg of DEHP from being placed on the market annually. > $250 million would be incurred by hospitals to replace all systems (decision process for new equipment, unanticipated invest-ment, new stocks of consumables, staff training, connection to internal system, etc.).	Where the cartridges use DEHP, the emissions and economic impacts on waste EEE treatment facilities should only be considered for 500 tonnes of obsolete devices. Where the cartridges cannot be placed on the market, there will be a decrease in respective treatment services – either the range of such services provided is to decrease or where new equipment will be bought, there will be decreases in other services that would be invested in were the exemption available. In this sense, the estimation of $250 million represents an estimation of the maximum decrease of services provided to patients. The impact on patients described above which is

Impact area	Detail	Estimations from COCIR (referring to three manufacturers)*	Consultants comments on information
			the result of this decrease is unknown in range. (See also comments on generation of additional waste and health impacts).
Impacts on manufac-turers	Manufacture of substitute equipment (if and when suitable designs are available) to replace non-compliant ones will have environmental and health impacts.		It can be followed that new manufacture to replaced devices reaching EoL early shall result in additional use of resources, i.e. in resources used not reaching their full potential. It is assumed that other environmental or health impacts of manufacture are controlled, as required by legislation of emissions of facilities, for example by the Industrial Emissions Directive where EU manufacture is concerned.
Employ-ment	Impacts on employment in total, in the EU and outside the EU	All functions and a range of industries would be negatively impacted e.g. manufacturing, supply chain, service, R&D, marketing, quality, regulatory, Information technology, associated Distributors, medical services and hospitals.	Assuming that at least one manufacturer shall be compliant by July 2021 (e.g., Radiometer), alternatives are likely to be available before the restriction comes into force and it is thus assumed that some negative effects on employment might be offset by the industry sector which has reached compliance.

Source: *Summary from data presented in COCIR (2018) and COCIR (2019)*

Note: *COCIR Refer in their information to impacts related to three manufacturers, though it is not clear which manufacturers are meant. In relation to impacts on end-users, the previous review of Ex. 41, Annex IV also offered examples from typical German hospitals regarding the possibility of using other devices should the non-RoHS compliant cartridges no longer be sold within the EU. To support the critical review, it is noted that blood analysers used in German hospitals are usually from one vendor and one single model. This is done to facilitate standardization and harmonization in training and use procedures within the hospital staff (Gensch et al. 2019).

According to the information above, it is understood that even though stocking-up with consumables for the current compatible PoC analysers is an eventual possibility for hospitals, the limited shelf time would result in premature obsolescence of these

equipment (expected once the maximum shelf life of stocked cartridges is reached). Subsequently, it would be necessary to replace the PoC analysers with alternative RoHS-compliant PoC equipment, which would lead to unexpected financial and operational challenges for the end-users (both for hospitals and staff). These challenges translate into negative health impacts and delays in health services for patients.

The consultants' understanding of considerations in terms of the environmental and socioeconomic arguments provided for this exemption are summarised as follows:

- The EoL waste treatment of cartridges for PoC blood analysis equipment is not understood to be affected by the compliance of the ISE sensors with the substance restriction. Discarded cartridges are managed as medical waste and treated by energy recovery regardless of whether the ISEs contain DEHP or not. In this sense, whether an exemption will be granted or not shall not affect possible emissions related to the treatment of waste in WEEE facilities - the restriction of the DEHP cartridges on the market shall not have a benefit in terms of possible DEHP emissions at EEE waste management facilities.
- Considering the limited shelf life of consumables for PoC analysers and the design compatibility between cartridges with specific devices, an eventual premature obsolescence of the equipment currently on the market (ca. 30,000 instruments) is unavoidable, should the exemption not be granted. In this respect, it is not that additional waste shall be generated, but rather that the waste of such devices shall be generated prematurely. Considering COCIR's estimation that the "*life-time of ISE PoC Analyzer is 9.7 years, with >50% of the install base older than 10 years*" and considering the limited shelf-life of cartridges, suggests that early obsolescence of equipment is to affect a large part of the equipment in stock.
- Though the amount of 2.2 kg DEHP to be avoided annually should the exemption not be granted is to be viewed as a benefit for the environment/health, this scenario shall also result in ca. 500 t of waste being generated of devices scrapped early in light of the unavailability of ISE consumables on the EU market, i.e. in a cost in terms of resource use. It is not straightforward to determine if the benefits of avoiding DEHP justify the costs of the early scrapping of materials such as aluminium, steel and copper contained in the PoC devices.
- In order to replace the scrapped PoC obsolete equipment, around 2,100 kg of lead would enter the EU market through new devices replacing the installed base. It is noted that such impacts are expected anyway when new devices will be placed on the market and in this sense, this is viewed as an acceleration of an impact expected in the further future.
- Costs for hospitals and other health providers represent the main negative economic impacts.

6.5.4. Scope of the Exemption

Following the initial review of the exemption request application, and in light of the information made available, an effort was made to detail the range of body fluids falling under the scope of the requested exemption. In its original application, COCIR specifies that the exemption is "for point of care analysis of ionic substances in human body fluids" (COCIR 2018b). However, based on the information presented in the

exemption application, analyses are currently only performed on the following fluids: blood samples, pleural fluids and dialysate.

In this respect, in the first round of clarification questions, COCIR was asked to provide a complete list of body fluids of relevance to this type of ISE measures, to which they listed the following: (COCIR 2019b):

- Whole Blood
- Serum
- Plasma
- Urine
- Cerebral Spinal Fluid
- Pleural fluid

Additionally, it was clarified that although dialysate is not a body fluid, the instrument and sensors are also used to measure this in cases of patients undergoing lifesaving dialysis. Therefore, according to the applicant, other body fluids and dialysate also need to be included within the scope of the exemption.

In this case, the consultants consider that the initially proposed scope of this exemption to be too narrow to cover all application areas and would propose to add dialysate fluids to the formulation. The following formulation, which was agreed with the applicants, should be used should an exemption be granted:

„Bis (ethylhexyl) phthalate (DEHP) in ion selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids."

6.5.5. Conclusions

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

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

In the review of this request for exemption, in relation to scientific and technical progress, it can be understood that alternative plasticisers are available on the market. Professor Meyerhoff claims that other plasticisers can function effectively for all the relevant ISEs for reliable measurements in whole blood samples.

Nonetheless, COCIR puts forward that some producers, have conducted tests with alternative plasticisers, but have not yet found and implemented a substitute suitable for the reliability and time requirements of results provided by PoC analysers. COCIR has provided sufficient information to show that efforts with alternative plasticisers have resulted in unreliable results, which do not meet the time standards and

replicability required for the intended use in PoC situations. Nevertheless, Radiometer declares that a substitution would be achieved in their PoC analysis devices before 21 July of 2021, when the DEHP restriction shall apply to medical devices under the scope of RoHS. The consultants thus question the need for an exemption with the maximal duration as requested by COCIR. Seeing as Radiometer expects to achieve substitution by 2021 confirms that substitution is possible, and also considered reliable, though it can be followed that the time needed to achieve compliance may vary from manufacturer to manufacturer to some degree.

In terms of environmental impacts, where substitution is achieved, there is no information as to the identity of the substitute used, and thus the comparison of the negative impacts of the alternative substances with that of the use of DEHP is not feasible at the substance level on the base of the publicly available information. It is noted that Radiometer intend to apply the substitute before 21 July 2021. This is understood to mean that in the recertification of the cartridges it has not been found that the use of the substitute would "*compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons*", as placing such devices on the market would not be allowed according to Directive 3/42/EEC concerning medical devices (Annex I, Essential Requirements, 1.1, stipulating the conditions to be fulfilled for a medical devices to be placed on the Union market).

Nonetheless, additional environmental and socio-economic aspects are of relevance. These relate to a substitution scenario in which DEHP can no longer be used and include socio-economic impacts (Article 5(1)(a) sentence four). They do not refer directly to the environmental comparison of the DEHP-based cartridges and their substitutes (compliant cartridges or alternative technologies).

Environmental impacts include:

- It is expected that the annual placing on the market of 2.2 kg DEHP could be avoided as a consequence of not granting this exemption request. Seeing that as of July 2021, at least one manufacturer is expected to be compliant, this annual amount would decrease. This decrease will further continue as additional manufacturers become compliant. This impact is understood to be of absolute nature - expected in an exemption scenario and prevented where the exemption is not granted, however it is not expected to have an actual benefit. Despite the fact that DEHP is to be placed on the market, it is understood not to lead to impacts that are not acceptable in the use phase (as this would not be allowed through the Medical Devices Directive) nor to impacts in the waste management of EEE, seeing as all analysis cartridges (with DEHP or without) are to be disposed of as medical waste. In other words, as the exemption scenario is not expected to result in actual negative impacts, vice versa it cannot be assumed that a substitution scenario will result in benefits (prevention of impacts).
- In contrast, not granting an exemption shall lead to negative impacts from resulting premature waste flows and new materials needed for manufacturing and placing new devices on the market. This is related to the approx. 500 tonnes of WEEE from scrapping PoC equipment subject to premature obsolescence, but also a similar amount of materials required to manufacture new equipment prematurely

in replacement of the ones that can no longer be operated, also containing other restricted substances such as lead (2,100 kg of lead foreseen). In this case, the impacts are not absolute but considered only as an acceleration of impacts expected anyway. Though premature scrapping of equipment is to be understood as an impact, however, under an exemption scenario, the equipment would be expected to be scrapped at the end of its service life (approx. 10 years) and it can be expected that some of the analysers in the EU stock shall be newer and some older.

It is not straightforward to weigh the prevention of 2.2 kg of DEHP being placed on the market against the acceleration of impacts related to premature obsolescence of the existing stock (500 tonnes) and premature manufacture and placing on the market of new equipment produced from various resources and containing about 2.1 tonnes of lead.

A further indication for a weighting of the amount of 2.2 kg of DEHP being placed on the market by this exemption request, is to consider the tonnages of DEHP brought on the market by all applications:

- DEHP is registered under REACH for manufacture and use in the EU in a tonnage band of 10,000 – 100,000 tonnes per annum.[30] This does not include the import of DEHP in articles.
- The European PRODCOM statistics on the production of manufactured goods contains an entry for the group 'dibutyl and dioctyl orthophthalates'[31] to which but not exclusively DEHP belongs; thus, the total volume for the EU28 of 281,379 tons in 2018 that even exceeds the tonnage band for DEHP indicated by the registration dossier cannot only be ascribed to DEHP.

Though the RoHS Directive does not foresee a threshold for total amounts per year of restricted substances to be considered in exemption requests, a comparison of amounts of DEHP applied in total might support the socio-economic impacts. Against the amounts of DEHP for all applications ranging from 10 000 to 100 000 tons per year of DEHP manufactured and/or imported in the European market per year,[32] the amount 2.2 kg of DEHP can be considered a minor amount that has to be weighed against the following impacts on health:

In terms of **impacts on health**, it can be followed that not granting the exemption would also result in a significant impact on healthcare facilities currently using ISE PoC analysers that contain DEHP. In such cases, devices currently on the market are expected to become non-operational shortly after ISE cartridges containing DEHP are no longer available. Such devices would need to be replaced relatively quickly after cartridges can no longer be placed on the market and could no longer be operated. This would mean that health facilities would not be able to operate the equipment over intended lifetime (loss of benefits related to past investments) and would also need to liquidate sufficient funds to allow purchasing compliant equipment relatively quickly

[30] ECHA Registered Substance Database: Entry for Bis(2-ethylhexyl) phthalate; https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15358

[31] PRODCOM Code 20143410.

[32] As a substance; this does not cover the import of DEHP in articles.

and to train staff on how to use it. Such investments would not have been planned and could affect the range of other services to be provided by such facilities. COCIR estimates that the overall impact to hospital infrastructure is similar to that described in Exemption 41, Section 7.4.5 of Gensch et al. (2019). In this report, an estimation was made for a single hospital of medium size and referred to unanticipated investment costs of over 300,000 euros for new equipment; another 20,000 euros for connecting the new instruments to existing information systems and costs related to the training of staff on the new equipment estimated at 1,200 hours of non-productive work (Gensch et al. 2019).

The first two Article 5(1)(a) criteria are not considered to be fulfilled, seeing as substitutes shall exist by the time the DEHP restriction comes into force for medical devices (22 July 2021) and are considered reliable.

In terms of Article 5(1)(a) third criteria, in past evaluations, fulfilment has been based on a comparison of health and environmental impacts of the RoHS substance in a specific application and impacts of its direct substitute (substance or technology to substitute the initial application). In the current case, the comparison cannot be based on a direct substitute but perceives the general scenario of substitution (i.e., impacts referred to are not tied to the available substitute but to a scenario in which DEHP can no longer be used. Assuming the European Commission can follow this interpretation, this criteria could be observed as fulfilled, i.e., meaning that "*the total negative environmental, health and consumer safety impacts caused by*" the substitution scenario in which DEHP cannot be used "*are likely to outweigh the total environmental, health and consumer safety benefits thereof*."

Article 5(1)(a) also specifies that "*decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account [...] the socioeconomic impact of substitution*".

In this regard, the non-availability of cartridges, subsequently leading to early EoL of devices already on the market, is expected to lead to various socio-economic impacts including environmental impacts (early obsolescence, premature manufacture of new EEE) and particularly to high costs for replacement of the devices by medical facilities which shall subsequently lead to health impacts, i.e. impacts on the range of services provided. Though not granting an exemption shall reduce the amount of DEHP to come on the market, this scenario should be weighed against:

- the premature obsolescence of ISE PoC analysers in stock;
- the accelerated use of resources for manufacturing new equipment (including ca. 2.1 tonne Pb); and
- the burden of compliance for health facilities that is expected to affect the quality and range of health services and thus to affect the health of patients.

To summarise, in the current case, it is observed that DEHP technologies shall be available in July 2021, when the DEHP restriction comes into force for medical devices. These substitutes are, however, not compatible with analysis devices of all manufacturers. Not providing an exemption, however, will lead to certain environmental and health impacts: Though the placing of DEHP on the market would be avoided, it would result in ca. 500 t of analysis devices being scrapped prior to

their end-of-life and in a use of around 2,100 kg of lead in the manufacture of devices to replace those scrapped early. It will also result in a decrease in health services to patients, either directly where analysis devices are not available to provide the services currently available at facilities or through funding being allocated from other services towards purchase of new analysis devices. Though it cannot be quantified, this is expected to have an impact on patient health that shall differ from case to case. It is also noted that avoiding the placing on the market of DEHP is not expected to have an actual environmental benefit, seeing as ISE are considered medical waste and sent to incineration, regardless of whether they contain DEHP or not.

It is observed that at least one manufacturer shall be compliant with the DEHP restriction as of July 2021, meaning that developing alternatives is feasible, even if other manufacturers may require additional time to complete this task. Should the exemption be granted, it is recommended to provide a validity of 7 years from the date of approval. Should a request for renewal of the exemption be made, the status of compliance of other manufacturers should be asserted to conclude whether the range of expected impacts would still warrant a renewal.

6.6. Recommendation

Seeing as Radiometer expects to achieve compliance by 22 July 2021 for ISE PoC analysis devices, it is concluded that after this date or in close proximity to it, the first two main Article 5(1)(a) criteria shall no longer be fulfilled for the requested exemption: substitutes shall be available and reliable. Assuming that the third Article 5(1)(a) criteria applies to the scope of a substitution scenario and not just the impacts of the actual substitute, this criterion can be considered fulfilled. Socio-economic aspects also support the exemption, seeing as not granting an exemption is expected to result in the early obsolescence of analysers of other manufacturers already on the market. Translating into socio-economic costs of a no-exemption scenario, particularly those expected for health facilities, and the impact related to the early scrapping of devices currently operating in the EU stock, are seen as significant.

It is further recommended to grant the exemption requested by COCIR for a duration of 7 years from the date of approval.

In this case, the exemption should be granted with the following formulation:

Exemption formulation	Duration
Bis (ethylhexyl) phthalate (DEHP) in ion selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids	7 years

7. Request 2019-2: DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils

"Bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils"

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

CMSC	Canon Medical Systems Corporation
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
DEHP	Bis-(ethylhexyl) phthalate
DEHT	Diethylhexyl terephthalate
EoL	End of life
MRI	Magnetic Resonance Imaging
PVC	Poly Vinyl Chloride
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment

7.1. Background

GE Healthcare has submitted a request for the addition of the above mentioned exemption to Annex IV.

Magnetic Resonance Imaging (MRI) is a medical imaging technique used to examine the human soft tissue. In MRI, the patient is exposed to a strong magnetic field and radio waves. The human tissue then emits weak radio frequency signals that are received by antennas - the coils - in close proximity to the part of the human body that is examined. The received signal is used to generate detailed three-dimensional images of the human body, including e.g. muscles, blood vessels and internal organs.

There is a number of different coils depending on the specific part of the body that is scanned e.g. shoulder, head, hand, knee, foot, breast etc.

One of the essential characteristics of the coils and the electronic circuitry that is connected to each coil is that the materials used must be non-magnetic because any magnetic materials degrade the weak RF signals emitted by the human tissue resulting in distorted MRI images.

GE Healthcare (2018) requests an exemption for the plasticiser bis-(ethylhexyl) phthalate (DEHP) in coil cable strain relief devices made of PVC. These devices, also called strain relief boots, should prevent the flexible cables that connect the MRI coils with the image processing system from fracturing by repeated bending. GE Healthcare states that so far no reliable alternative material could be identified.

The applicant requests the exemption until January 2024.

An example of a coil and the strain reliefs at the cable is shown in the figure below.

Figure 7-1: MRI coil for shoulder; the four strain relief boots are circled in red.

Source: *(GE Healthcare 2018)*

7.2. Technical description of the requested exemption

According to the applicant (GE Healthcare 2018), the strain relief boots for the coil cable are needed because the coil cable where attached to the rigid coil body or other rigid electrical components, will flex repeatedly in use when the coil is located to the patient's body. The cable needs to be protected for extensive flexing movements in order to prevent the electrical insulation and the internal copper wires from mechanical fatigue fracture by repeated bending. This failure mode is prevented by the flexible plastic components, the strain reliefs boots, so *"that the wire can flex for sufficient times without fracture during the expected lifetime of the equipment. By reducing the angle of movement of the wire where it connects to the rigid connector […], this greatly extends the lifetime of the cable and its connection."*

GE Healthcare (2018) summarises that a coil has a lifetime of at least 8 years of frequent use which results in a mechanical requirement of the strain reliefs to withstand 30,000 repetitive bend cycles.

Bis-(ethylhexyl) phthalate (DEHP) is a plasticiser in flexible PVC polymers, which provides certain flexibility to the strain relief boots for cables of MRI coils. GE Healthcare (2018) explains that the choice of the material thus also of the plasticiser for the strain reliefs is led by the requirement that *"the materials used for coils, including cables and strain reliefs do not adversely affect image quality"* and that *"choice of polymers and additives in polymers can affect image quality if these have strong proton signals."* GE Healthcare (2018) summarises the requirement as follows: the plastic material *"must be non-magnetic and have a proton signal emission material / air ratio as low as possible, ideally < 1.2, but must be < 4.0 when within the imaging zone (i.e. strain reliefs that are attached to coils)"*.

According to GE Healthcare (2018), another requirement for the strain reliefs besides the technical practicability and reliability in terms of image quality and fatigue fracture prevention, is that the material needs to fulfill biocompatibility requirements for human skin contact according to ISO standards on biological evaluation of medical devices.

7.2.1. Amount of bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used under the exemption

In its original application (GE Healthcare 2018), the applicant states that the amount of substance entering the EU market annually through application for which the exemption is requested would be at 40 kg DEHP annually. However, according to confidential information on the details of the estimations, a correction was agreed with the applicant (GE Healthcare 2019b): GE Healthcare provided as bases for the estimation the number for coils, which are annually placed on the EU market, multiplied with the number of four strain reliefs and the average weight of the strain relief resulting in the total amount of PVC used for the strain reliefs; multiplied with a conservative assumption for the DEHP concentration. The corrected amount of DEHP in plastic strain relief devices used under the exemption which is placed on the EU market by GE Healthcare annually is 144 kg DEHP. This amount concerns only the amount put on the EU market by GE Healthcare.

7.3. Applicant's justification for the requested exemption

7.3.1. Substitution or elimination of bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices

GE Healthcare (2018) explains that there are three options for substituting or eliminating DEHP in strain reliefs e.g.:

- Substitution by an alternative polymer,

- Substitution by PVC with an alternative plasticiser,
- Elimination of the need of strain relief boots by redesign of the coils.

As for an **alternative polymer**, GE Healthcare (2018) explains that there are several types of polymers that have good biocompatibility but they do not have the same flexibility as DEHP-plasticised PVC; GE Healthcare (2018) presents in its application data from tests with nylon and summarises the results as follows:

"The strain reliefs were flexed and began cracking at 4000 cycles. Testing was continued to 15,000 cycles and the strain reliefs developed cracks through their body; In the estimated useful 8 year life-span of a coil, conservative estimates indicate a need for at least 23,000 cycles. This is based on 200 working days per year for 8 years and an estimated 14 scans per day. Some health care providers if specialized or running multiple working shifts will incur a greater number of cycles sooner. No observable cracks during the normal lifespan is required for ability to adequately clean the device between patient uses and to maintain an acceptable appearance."

GE Healthcare (2018) concludes from the tests that nylon as tested alternative polymer would not be suitable.

As for the **substitution DEHP with an alternative plasticiser in PVC**, GE Healthcare (2018) presents test with diethylhexyl terephthalate, DEHT, which was chosen due to the chemical structure similarity to DEHP. GE Healthcare (2018) conducted tests on the impact on image quality by MRI proton signal intensity measurement by measuring the relative image intensity ratio from the polymer versus air.

The tests were performed with two grades of PVC with different flexibility, which GE Healthcare (2018) characterises as having "*durometer value 65 and 90*": *"durometer is a measurement of hardness or flexibility. 65 durometer is a material that is easily flexed and 90 durometer is much firmer and almost rigid. Due to higher plasticizer content in the flexible material, it creates a greater proton signal."* (GE Healthcare 2019a).

GE Healthcare (2018) explains that the different PVC grades are used in parallel: "*The more flexible versions are used for the strain reliefs furthest away from the patient and the less flexible material is used to attach the cable to the coil itself."*

Furthermore, the tests on the MRI proton signal intensity measurement were made "*within a range of "flip angles" because not only is image intensity important, but contrast between materials is also important (intensity and image contrast both vary with flip angle)."* (GE Healthcare 2018)

GE Healthcare (2018) presents the results of the measurements in the following tables.

Figure 7-2: Results from the measurements of relative image intensity ratio from the polymer versus air for two different PVC grades durometer 65 and 90

Table 1. Results for more flexible materials, durometer value 65

Flip angle	1	2	3	4	5	6	7	8	10	15
DEHP ratio	10	17	17	17.1	15.7	15.1	13	12.4	9.9	6.2
DEHT ratio	10.8	19.4	19	21	19.9	18.4	15.4	15.2	11.4	7.4
Increase in ratio	0.8	2.4	2	3.9	4.2	3.3	2.4	2.8	1.5	1.2
% higher	8.0	14.1	11.8	22.8	26.8	21.9	18.5	22.6	15.2	19.4

Table 2. Results for less flexible materials, durometer value 90

Flip angle	1	2	3	4	5	6	7	8	10	15
DEHP ratio	1.6	2	1.7	1.9	1.8	1.8	1.5	1.4	1.1	1
DEHT ratio	1.8	2.4	2.5	2.5	2.3	2.1	1.8	1.8	1.5	1.1
Increase in ratio	0.2	0.4	0.8	0.6	0.5	0.3	0.3	0.4	0.4	0.1
% higher	12.5	20.0	47.1	31.6	27.8	16.7	20.0	28.6	36.4	10.0

Source: *(GE Healthcare 2018)*

GE Healthcare (2018) summarises these measurements as follows:

> *"The above results show that the DEHP-PVC material with durometer of 65 has too strong a signal for use close to the imaging zone as the relative image intensity values are more than 4.0. This material is therefore only used at least 30 cm away from the imaging zone where it has no detrimental effect. The results of the 65 durometer material with diethylhexyl terephthalate-PVC show that this has an even higher image intensity than DEHP-PVC, which indicates that it could give inferior imaging performance to DEHP-PVC. Results with the less flexible 90 durometer material also show that diethylhexyl terephthalate-PVC gives a higher proton signal intensity than DEHP-PVC. Although all values from the 90 durometer material are within the 4.0 ratio limit, they are mostly higher than the ideal 1.2 limit with both materials (except at flip angles of 15°), but values are much closer to the 1.2 ideal ratio with DEHP-PVC than with diethylhexyl terephthalate-PVC. Diethylhexyl terephthalate-PVC is again therefore inferior to DEHP-PVC so could affect image quality under the most demanding imaging conditions."*

GE Healthcare (2018) concludes from these tests that the PVC plasticisers have an impact on the image quality and in case of DEHT, it has a higher viscosity then DEHP and thus needs to added in a higher concentration in the PVC formulation. GE Healthcare (2018) therefore excludes other plasticisers for PVC that are more viscous than DEHP because they are *"likely to have stronger MRI signal intensity (as higher concentrations would be needed) and so would also be less suitable than DEHP."* GE Healthcare (2018) argues that the viscosity values of the two most commonly used

substitutes for DEHP – DiNP (diisononyl phthalate) and DiDP (diisodecyl phthalate) - are higher than DEHP and thus would not be suitable for substitution.

As for an **alternative coil designs without strain reliefs**, GE Healthcare (2018) refers to the development of digital coils:

> *"This substitution option is much more complex than replacement of an additive in a polymer as the entire coil assembly has to be redesigned. GE makes over 70 different coils, which is a typical number for most coil manufacturers, and every coil assembly would need to be redesigned, fully tested including repetitive bending, proton image intensity measured, biocompatibility, etc. and also tested with patients before re-approval under the Medical Devices Regulation can be obtained from an EU Notified Body as well as approval in other countries outside of the EU. As every coil design is different, redesign would need to be carried out mainly sequentially and so for over 70+ coils, this would take many years and could not be completed by July 2021."*

To summarise the substitution efforts of GE Healthcare, tests with one alternative polymer and one alternative plasticiser in PVC have not provided successful results to an extent that GE Healthcare would continue with one of the tested alternatives: *"There is however, uncertainty over the material substitution option as it is not known whether a suitable material can be identified that meets all of the criteria listed in section 4C. The alternative option of coil redesign is also uncertain as this work has only recently started."*

7.3.2. Environmental arguments

There were no environmental arguments brought forward by the applicant.

7.3.3. Socioeconomic impacts

GE Healthcare (2018) argues that there will be a negative impact on the EU healthcare if the exemption will not be granted: *"If hospitals are unable to buy the current full range of coils, diagnosis and treatment times will be longer and some alternative method that have to be used may be less effective."* (GE Healthcare 2018)

GE Healthcare (2018) explains that *"currently there are more than 1900 GE MRI scanners installed in European hospitals"*. GE Healthcare (2018) further calculates *"from online sources,[33] one MRI scanner typically treats around 4,500 patients per year (this is old and conservative data from 2004, the number is higher today)."* and concludes on "*more than 9,000,000 patients in Europe per year who could not be treated using the most suitable diagnostic equipment."*

GE Healthcare (2018) claims that the great variety of coils designed for specific body parts will not be available.

In the original application, GE Healthcare (2018) states that "*GE MRI generally can only use GE's coils and this situation is the same for all manufacturers' coils."*

[33] GE Healthcare therefore refers to the following link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2645123/

However, in the further exchange of clarification questions, the applicant later adds that basically hospitals can source coils from other suppliers arguing that "*if products are not available and a market exists, suppliers will address the demand*" (GE Healthcare 2019e). GE Healthcare (2019e) further points out that however this would also need a certain time of transition as e.g. validation of safety would be required.

The case sketched by GE Healthcare (2018) in the original application that *"another potential impact on healthcare could be the forced adoption of a less performing material, e.g. inferior image quality or shorter lifetime"* is however relativized by the applicant himself by stating that *"producing coils that are knowingly less reliable is not permitted by the Medical Devices Regulation and could result in withdrawal of EU approvals."* (GE Healthcare 2018)

GE Healthcare (2018) also claims that there are limited human resources available; thus there are strategic decisions on whether to follow substitution or new developments ("*Medical device manufacturers are aware that the availability of trained engineers is limited and employers can choose whether these work on substitution or on new product development.")*

7.3.4. Road map to substitution

GE Healthcare estimates the following timeframe for the different stages as shown on the following figure.

Figure 7-3: Stages for establishment of possible substitute and respective timeframe needed for completion of such stages

Phase	Elapsed time for one coil
Identify materials	Not known at present
Biocompatibility and other tests	Approx. 6 months
Reliability testing	1-2 years
Verification and global approvals if needed	Up to 2 years

Source: *(GE Healthcare 2018)*

Asked for details on the stage of verification and global approvals, GE Healthcare (2019c) explains that they *"need to show biocompatibility of the new material to ISO 10993 to manage risk for the reasonable worst case as applied to the patient, user, operator, maintainer or bystander. Biocompatibility is reported in Verification records detailed in the Technical File supporting CE marking. Regulatory Affairs at GE must make any necessary updates to registrations affected. Additional work must be done to insure reliability of multiple flexures of the strain relief for customer satisfaction and the proton signal testing above for management of image quality. The technical verification and reliability test efforts take approximately 40 weeks to complete followed by the external registration time."*

To summarise the different stages, from the point that GE Healthcare identifies a suitable material, the development of a substitution will take four years. Based on the estimations provided in the figure above, GE Healthcare assumes that *"the timescale for redesign of over 70 MRI coils would be much longer than for one coil although only a representative selection of coil assemblies would need to be fully evaluated. GE Healthcare predicts that as long as a suitable substitute material can be identified, full substitution of DEHP-PVC with a DEHP-free material could be completed by January 2024." (GE Healthcare 2018)*

7.4. Stakeholder contributions

Contributions were not submitted regarding this exemption in the course of the stakeholder consultation though other MRI manufacturers were contacted and urged to provide a contribution.

Subsequent to the consultation, the consultant received feedback from one MRI manufacturer, Canon Medical Systems Corporation, CMSC (CMSC 2019), as well as the European Coordination Committee of the Radiological, Electromedical and Health-care IT Industry, COCIR (COCIR 2019).

The MRI manufacturer CMSC provided feedback after the consultation was closed: CMSC (2019) supports the request for exemptions and states that they also use strain relief device that contain DEHP and are developing substitutes for it. However, CMSC suggests that *"GE has developed MR coils that are more flexible than existing products in the market, and request exemption for a specified part where flexibility is strongly required."*

CMSC (2019) explains that they do not have a similar MRI coil and that their strain reliefs called bushings rather *"fix both ends of the cable case covering the cable to the coil connector part."* CMSC does not conclude on whether their bushings and the strain reliefs of GE Healthcare are functionally identical and if the scope of exemption also covers their products. Besides the bushings/strain relief device for preventing cable connecting part to damage, CMSC also mentions cable cover for keeping a distance between and patient's skin to prevent burns to contain DEHP and states that they are evaluating possible substitute. CMSC states that *"as GE described in the exemption request form it is essential to satisfy both the impact on the MRI image and the mechanical quality for preventing the properties the damage caused by the bending of coil."* CMSC did not further specify the technical requirements.

Generally, CMSC (2019) states that *"it is presumed that each company uses appropriate devices to the characteristics of such own device, such as shape, property, or using part. We have recognized that the use of phthalates including DEHP as plasticizers in these devices is generally [the common case]."*

As strategy for substitution, CMSC (2019) points out that *"the final solution is not to use the strain cables and the strain relief devices. One of the means is a digital wireless coil. It is necessary to resolve the impact of radio waves on MRI image quality and the compliance with radio law/regulations in each country. Therefore, we have thought that it takes more time to apply it to all products."*

COCIR (2019) provided additional information on practices from different MRI coil manufacturers and communicated that one member company stated not to need DEHP in MRI imaging coils due to *"a totally different design with no need for a cable strain relief. Only one of their coils (a very old design) has a cable strain and this cable strain relief is without DEHP."* Still, COCIR (2019) stresses that this manufacturer supports the exemption request from GE *"as they know the challenge on finding an appropriate substitute for this type of application."*

COCIR (2019) argues that *"there are many possible alternatives to DEHP and companies have to test several before finding one that is suited (unless they are extremely lucky)."* COCIR further argues that *"this process takes considerable time as not only the new plastic part/cable has to be tested for mechanical, physical resistance and properties, biocompatibility, safety etc., but it also has to be tested during imaging, to make sure image quality is not affected negatively (and that happens a lot with alternatives), as described in GE's exemption request."*

7.5. Critical review

7.5.1. 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.

With regards to **Annex XIV of the REACH Regulation**: DEHP has been included in the SVHC REACH candidate list for the reason of being toxic for reproduction in 2008 and has been added to Annex XIV in 2012. In July 2017, DEHP has been additionally recognized for endocrine disrupting properties. Thus, DEHP as substance cannot be placed on the market or used after the 21 February 2015 (Sunset date), unless an authorisation is granted.

It is understood that the applicant of the request here at hand supplies the PVC material for the cable strain reliefs from outside the EU. As Annex XIV does not apply to imported articles into the EU, REACH Annex XIV is not applicable here.

Additionally, DEHP is referred to in **REACH Annex XVII**:[34]

- **Entry 51** in Annex XVII of the REACH Regulation[35] stipulates that DEHP shall not be used in concentrations greater than 0.1 % by weight of the plasticised material, in toys and childcare articles. Toys and childcare articles containing DEHP in a concentration greater than 0.1 % by weight of the plasticized material shall not be placed on the market.

Whereas basically, this restriction concerning toys and childcare articles could apply to certain articles within the scope of Directive 2011/65/EU (RoHS 2), it is not in the scope of this requested exemption. The plastic strain reliefs to be used for the MRI coils are not expected to be accessible to children under normal or reasonably foreseeable conditions of use.

Furthermore entry 51, paragraph 3, contains the recent amendment of entry 21 of December 2018 that stipulates that DEHP be placed on the market after 7 July 2020 in articles, individually or in any combination of the other phthalates that are also restricted under RoHS (DBP, BBP, DiBP) in a concentration equal to or greater than 0,1 % by weight of the plasticised material in the article. However, it is further stipulated that this paragraph shall not apply to medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof and that it shall not apply to electrical and electronic equipment within the scope of Directive 2011/65/EU. Thus, the restriction of entry 51 does not apply to the exemption at hand here.

- **Entry 30** of Annex XVII is also relevant (entry 30 refers to substances in Appendix 5 or Appendix 6 and DEHP is listed in Appendix 6). According to entry 30, DEHP 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 30 of Annex XVII do not apply. The supply of DEHP in plastic strain reliefs is in the consultants' point of view not a supply of DEHP as a substance, mixture or constituent of other mixtures to the general public. DEHP is part of an article and as such, entry 30 of Annex XVII of the REACH Regulation would not apply.

GE Healthcare also mentions a registry of intentions under REACH: *"A restriction on materials with prolonged skin contact has been proposed. Strain relief boots of MRI coils will not have prolonged or frequent skin contact and so would be out of scope. Medical staff is instructed to route cables and the associated strain reliefs away from patients' skin."* The registry of intentions to which GE Healthcare is referring to has been decided and forms part of the amendment of entry 51 of Annex XVII. The prolonged skin contact is meant for plasticised material for use exclusively in the open

[34] See also the Appendix of this report at page 40.

[35] Please note that this entry has been amended quite recently:
COMMISSION REGULATION (EU) 2018/2005 of 17 December 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, valuation, Authorisation and Restriction of Chemicals (REACH) as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP);
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R2005&from=EN

air, which comes into contact with human mucous membranes or into prolonged contact with human skin. Thus, this does not apply to the request of GE Healthcare.

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

7.5.2. Scientific and technical practicability of substitution

Based on the COCIR (2019) statement that one MRI manufacturer has eliminated DEHP in MRI imaging coils due to *"a totally different design with no need for a cable strain relief*", it can be concluded that substitution of DEHP in MRI coils is technically practicable and reliable.

However, COCIR (2019) as well as another MRI manufacturer, CMSC (2019), who also uses DEHP in plastic components of MRI coils, support the request of GE Healthcare stressing the challenge to identify a suitable alternative: *"This process takes considerable time as not only the new plastic part/cable has to be tested for mechanical, physical resistance and properties, biocompatibility, safety etc., but it also has to be tested during imaging, to make sure image quality is not affected negatively (and that happens a lot with alternatives), as described in GE's exemption request."*

The information provided by CMSC (2019) additionally shows that every MRI manufacturer has a singular approach for designing the coils e.g. CMSC points out that the coils by GE Healthcare provide a higher flexibility than the coils manufactured by CMSC and determines the need of cable strain reliefs.

From the information provided by GE Healthcare (2018), it can be summarised that the applicant is still underway to identify a suitable material for the plastic strain reliefs. The substitution tests that GE Healthcare (2018) show the challenges for scientific and technical practicability of substitution – which comprises the material requirements of biocompatibility and weak proton signal emission in order not to adversely affect image quality - as well as for reliability which comprises e.g. the fatigue fracture prevention of the coil cable taken into account the long service life of the coils.

The tests that applicant (GE Healthcare 2018) provides comprising of one alternative polymer and one alternative plasticiser in PVC are presented in detail. The consultant understands that material research is sensitive with regards to market competition. This understanding is e.g. based on the COCIR statement that another manufacturer does not reveal the plastic composition for confidentiality reasons: *"This member company also stated that the used plastic blend is confidential and cannot be shared with competition (also, some of this companies coils are patented, so designs cannot be copied by their competitors)."*

In the road-map that shows the stages that are necessary to evaluate a suitable material once identified, GE Healthcare (2018) estimates that these stages will take

four years. Taking into account that GE Healthcare applies for an exemption duration until 01 January 2024, in the consultants opinion the roadmap suggests that GE Healthcare has a concrete view on how to substitute DEHP in plastic strain reliefs by one of the options: substitution by an alternative polymer, substitution by PVC with an alternative plasticiser or elimination of the need of strain relief boots by redesign of the coils. The duration of the exemption was requested by the applicant until 01 January 2024 is not the maximum duration of an exemption of Annex IV. The date where restriction of DEHP applies to medical devices is 22 July 2021. In the consultants view this shorter duration supports the estimation that the applicant is able to reach substitution in the requested timeline.

Thus, the consultant concludes that the evidence that one manufacturer does not need the requested exemption shows that substitution is possible. However, it is further understood that GE Healthcare starts from a different point in terms of coil design and material equipment then the manufacturer that has eliminated DEHP from MRI coils and needs additional time to complete substitution.

7.5.3. Environmental arguments and socioeconomic impacts

The applicant did not provide any environmental arguments, so this issue is not considered further. One point to note here is that the exemption request on the amendment of the existing exemption 31a by COCIR, which is also covered by this report, also lists MRI coils as being a relevant application for being returned to the manufacturer, refurbished and reused (COCIR 2018). Refurbishing practices such as mentioned by COCIR have already been recognized by the consultant as being beneficial to the environment in light of the extended use of products and parts (Gensch und Baron 2014).

Except for refurbished coils brought on the market, any new or additional coils placed on the market by GE Healthcare would require the exemption to be requested.

As GE Healthcare will not be able to finish substitution by 22 July 2021, in consequence, GE Healthcare will not be able to meet the demand of specific coils if the exemption will not be granted. The information provided by GE Healthcare regarding the various socio-economic impacts that could result should the exemption not be granted is summarised in the following table (GE Healthcare 2018; 2019d).

Table 7-1: Possible socio-economic impacts in a scenario in which the exemption is not granted

Impact area	Detail	Estimations from GE Healthcare	Consultant's comments
DEHP avoided on the market and in the waste stream	DEHP not to be placed on the market through the GE Healthcare plastic strain reliefs	144 kg of DEHP to be avoided on the market annually.	This amount results from the plastic strain reliefs of GE Healthcare only. DEHP from plastic components of other manufacturers are not taken into account. This amount would be relevant throughout the validity of the exemption should it be granted, accounting for less than 2.5 years and thus for approx. 360 kg DEHP.
Generation of additional waste	Coils are long-life devices of 8 years plus extension through repair. A worst case would be if the MRI is scrapped or need to be relocated to a non-EU market.	Weight of a typical 1.5 T cylindrical superconducting MRI scanner is on the order of 4,500 kg; a 3.0 T scanner may weigh up to 7,500 kg; coils weighing 4 – 10 kg; A typical MRI System uses a set of 8 MRI coils weighing a maximum of 80 kg, in sum a potential net electronic waste of 4,500-7,500 kg per MRI system.	Coils already on the market would usually not be disposed of prior to their intended end-of-life; thus there would be no additional waste from coils if the exemption would not be granted. It is not clear how probable the worst-case scenario might be; it depends on whether MRI manufacturers providing compliant coils can take over the supply of MRI scanners.
Health impacts	EU hospitals with GE Healthcare MRI might face shortage in supply of approved coils.	Currently there are more than 1900 GE MRI scanners installed in the EU One MRI scanner typically treats around 4,500 patients per year (old and conservative data from 2004). Thus, more than 9,000,000 patients per year in the EU who could not be treated using the	To begin with, it is understood that coils on the market could be serviced. As coils have a service life of 10 years and above, it is assumed that for MRI on the market before July 2021, coils could usually be serviced. Thus, in the consultants' view, this aspect applies only to cases where the coil can no longer be serviced for MRIs already on the market and for MRIs newly placed on the market after July 2021 and requiring new coils. It is also possible that in some cases, new coils may be needed for

Impact area	Detail	Estimations from GE Healthcare	Consultant's comments
		most suitable diagnostic equipment.	MRIs already on the market. It is not clear whether and how fast competitors could fulfil a possible supply gap of coils in these cases. In any case this aspect is thus assumed to affect a smaller share of patients and not all 9 million patients specified by GE. In the consultant's opinion it needs to be assumed that manufacturers would communicate to health care facilities that GE Healthcare MRI coils would no longer be available and thus that hospitals would prepare for this process; possibly they would need to acquire new equipment as fast as possible as an unplanned investment; this may affect the general ability to provide patients with other services in light of limited budget. In summary, some patients may be affected where they could not be treated using the most suitable diagnostic equipment (significantly less than 9 million), whereas in other cases patients may be affected in light of changes in medical facility investments that affect the range and quality of supplied services (it is not clear how many coils would be affected and thus what the range of budgetary shifts and impacts may be).

Impact area	Detail	Estimations from GE Healthcare	Consultant's comments
Economic impacts	Hospitals and clinics in the EU would need to buy coils from other manufacturer. Worst case if a health care facility replaces the whole MRI system	In a worst-case scenario where the MRI system is replaced with a competitor's system, there will be a large capital cost including: the new MRI system, training, installation labour and potential changes to the building to accommo-date the new scanner. Costs for a single system may range from $ 30,000 to $ 100,000 to accomplish a change-over in addition to the cost of the system in the range of $ 1.2 million to $ 3 million, training costs and down time when no scanning can be performed. If a hospital or clinic has 10 MRI technicians to retrain at 40 hours each, 400 hours of labour will be utilized in training with an estimated cost to the hospital or clinic of $ 40,000 for training assuming labour cost with overhead of $ 100/hour.	It is not clear whether and how fast competitors could fulfil a possible supply gap of coils. Possible impacts are addressed under the comments for "Health impacts" above. It is not clear how probable the worst-case scenario might be and to how many MRIs it would apply; it depends whether MRI manufacturers providing compliant coils can take over the supply of MRI scanners. Currently GE has around 1900 MRIs scanners on the market and it is possible that some of these would be affected, though it is not clear if only a few units or a certain share of devices. Adding up the costs specified, as of 15 October 2019, for one MRI, costs could be in the range of: (27,200 to 90,660 Euro) + (1.1 to 2.7 million Euro) + 36,260 Euro = 1.16 - 2.82 million Euro per MRI If this applies to only 1 % of the GE MRIs (= 19 devices), it would make up for between 22 and 53.6 million Euro. Though such costs would only affect the facility in which the MRI is to be replaced, in the specific facility this would require a shift in budget in this order and affect the provision of other health services.
Impacts on manu-facturers	Manufacture of compliant coils would have impact on the market share	A delay in the ability of GE to supply MRI Imaging coils to support the already installed base of systems may result in loss of market share and reputation for GE.	It is understood that an early replacement of coils is only expected in a small share of cases where they cannot be serviced in the 2.5 years period of the exemption. Where this is to be the case, though GE shall be affected negatively,

Impact area	Detail	Estimations from GE Healthcare	Consultant's comments
		If a hospital or clinic in the EU installs a competitor's MRI equipment with a life of 30 years, applied typically in the original installation for at least 10 years, we essentially have given up that customer relationship for the foreseeable future of 10 years and unique technologies GE offers will no longer be accessible to their patient population.	manufacturers that can replace coils shall be affected positively, setting of at least part of the total costs. In part this is understood as an impact to market structure of MRI manufacturers. It is not clear in how many cases "unique technologies GE offers will no longer be accessible to their patient population" and to what degree this shall affect the heath of such patients
Employ-ment	Impact on employment in total, in the EU and outside the EU	If market share is decreased, adjustments in employment are expected at GE to match the decreased demand for our products thus affecting employment.	Regarding possible effects on employment among MRI manufacturers, assuming that at least one manufacturer shall be compliant by July 2021, some negative effects on employment might be offset in the industry sector which reached compliance.

Source: *Summary from data presented in (GE Healthcare 2018; 2019d)*

In terms of impacts on the environment: Not granting the requested exemption would avoid the placing on the market of 144 kg DEHP per year by plastic strain reliefs in GE Healthcare MRI coils, accounting for ca. 360 kg for the duration for which the exemption is requested. As for the additional waste generated if the requested exemption is not granted, it is understood that an early replacement of coils would not take place as the coils would be used for the expected long service life of at least 8 years.

It should be noted that the information focuses on GE Healthcare and does not provide an overview on the whole MRI market. According to Statista, a provider of market and consumer data, there were 17.4 MRI scanners per million inhabitants in the EU27 in 2016.[36] Thus there are estimated 8,900 MRI scanners in the EU.[37] Based on these estimations, GE Healthcare has a market share of about 20 %.

[36] https://de.statista.com/statistik/daten/studie/182664/umfrage/kernspintomographen-anzahl-in-europa/

[37] Taking into account 512 million inhabitants in the EU27.

From the contributions of other stakeholders it is obvious that one manufacturer has substituted DEHP in the MRI coils whereas another MRI manufacturer uses DEHP in other plastic components for MRI coils. The market shares of these manufacturers are not known.

The consultant concludes that there is uncertainty if the exemption is not granted whether a supply gap of coils would appear. GE Healthcare explains that *"for new MRI coils, a hospital or clinic would go to the OEM of the scanner,"* though other suppliers can also provide coils: *"Approval and safety testing of a MRI coil from another supplier without the DEHP limitation is possible. Testing, adaptation of the connection to the system and software changes in the system to allow the coil average 6 -12 months. This assumes that the supplier has already solved the DEHP problem and has an existing product they are able to adapt. Development of a completely new product generally takes 3 years."* Additionally, GE Healthcare explains that *"3rd party sources offer coils in anything from the "as-is" condition to refurbished [consultants addition: coils]. Many of these 3rd party sources do not adhere to the same standards as the OEM. They range from independent persons' trading equipment on eBay to established 3rd party repair facilities with highly skilled professionals."* It is noted that, should a supply gap of coils become relevant, the time frames specified above suggest that only in some cases other suppliers would be able to fulfil the gap in the 2.5 year period for which the exemption has been requested, seeing as development of a new coil generally takes 3 years. Thus, it is basically possible that compliant manufacturers shall not always be able to close such supply gaps in the relevant timeframe, leading to impacts on patients. However, it was not possible to reach certainty on this point.

Additional waste would incur if a whole MRI system, the MRI scanner and the respective coils, would be replaced if supply gaps for specific coils occur, which would sum up to an amount of potential net electronic waste of 4,500-7,500 kg per MRI system. For such a worst case scenario, GE Healthcare also provides estimated costs for a hospital that replaces the whole MRI system that range between 1.1 million Euro and 2.7 million Euro plus e.g. training costs (*"If a hospital or clinic has 10 MR technicians to retrain at 40 hours each, 400 hours of labour will be utilized in training with an estimated cost to the hospital or clinic of $40,000* [36,260 Euro as of 15 October 2019] *for training assuming labour cost with overhead of $100/hour* [90.6 Euro]."). As specified above, this would account for a sum of 1.16-2.82 million Euro per MRI, though it is not clear how many such cases are to be expected, especially in light of the short period for which the exemption is requested (replacing an MRI, sometimes requiring a renovation of the medical clinic to allow the installation is not necessarily a process that all facilities affected would embark on should it be known that the shortage is only temporary).

The consultant can follow that any potential supply gap in coils for GE Healthcare MRIs has effects on EU health care through a lower medical supply for patients caused by e.g. longer waiting times until the MRI scan and diagnosis. According to GE Healthcare, there are currently more than 1,900 GE MRI scanners installed in the EU; based on a conservative assumption that one MRI scanner treats around 4,500 patients per year, more than 9,000,000 patients per year in the EU could potentially be affected by a supply gap of coils. It is not clear how many of these would be

affected, seeing as most coils already on the market can be serviced, and thus the number of affected patients is assumed to be significantly smaller.

It is obvious that not granting the requested exemption shall result in a loss of business for GE Healthcare affecting its general market share in the EU. As MRI systems are systems with very long life, GE Healthcare claims that this loss would not be reversible: *"A delay in the ability of GE to supply MR Imaging Coils to support the already installed base of systems may result in loss of market share and reputation for GE. If a hospital or clinic in the EU installs a competitor's MRI equipment with a life of 30 years, applied typically in the original installation for at least 10 years, we essentially have given up that customer relationship for the foreseeable future of 10 years and unique technologies GE offers will no longer be accessible to their patient population."*

7.5.4. Scope of the Exemption

CMSC, as another MRI manufacturer, stated that their coils contain additional plastic components that use DEHP, e.g. cable covers for keeping a distance and preventing burns to the patient's skin, mattresses or fixing belts. The manufacturer confirmed by itself that "*the scope of the exemption is different from that of GE and is wide.*"

In the following, it was communicated by the industry that another related request is under preparation.

7.5.5. Conclusions

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

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

From the available information it is observed that substitution is possible seeing as at least one manufacturer has substituted DEHP by a different design of coils that eliminates the need of plastic strain reliefs. This solution is also assumed to be reliable, as otherwise it would not be applied. In contrast, other manufacturers such as GE Healthcare and CMSC are still in the process of testing and certifying an alternative for use in their equipment. GE Healthcare has provided information to show their efforts into the search for a substitute. The consultants understand that even though substitution of DEHP is in principle possible in plastic strain reliefs for MRI coils, GE Healthcare and CMSC need additional time to substitute DEHP in their coil portfolio.

Though the GE Healthcare equipment may have specific characteristics, such as a higher flexibility, than existing products in the market, it has not been shown that an advantage over other equipment is a result of the use of DEHP.

The identity of the substitutes used by one of the manufacturers for DEHP is not known, it cannot be concluded whether the total negative environmental, health and consumer safety impacts caused by substitution outweigh the benefits thereof.

The Directive specifies in sentence 4 of Article 5(1)(a) that "*decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account the availability of substitutes and the socioeconomic impact of substitution.*"

The aspects presented by GE suggest that in cases where a supply gap of coils is to become relevant, that it may not be possible to close this gap within the 2.5 years for which the exemption has been requested in all cases, as development of a new coil generally requires 3 years. It is not clear how many coils would be affected in this respect, nor the subsequent number of patients to be affected (delay in examination, possibly resulting in increased symptoms in some cases).

GE provides information as to socio-economic impacts of a no-exemption scenario:

In terms of environmental impacts, the prevention of DEHP (ca. 144 kg per annum or 360 kg assumed that GE Healthcare shall achieve compliance by 01 January 2024) is mentioned on the one hand, while on the other, some scrap may be generated where coils cannot be serviced and need to be scrapped. There may be cases where an MRI cannot be operated in lack of suitable coils.

In terms of health impacts related to a potential supply gap of MRI coils for GE Healthcare MRI scanners there are two cases.

- If the requested exemption is not granted where other MRI manufacturers or 3rd parties shall be able to cover the supply gap, this may result in medical facilities needing to shift budget from otherwise planned acquisitions. In this case, the range and/or quality of services provided by the facility will be affected, resulting in delays in services for patients.
- If the requested exemption is not granted and other MRI manufacturers or 3rd party suppliers of coils cannot cover the supply, a certain share of the MRI scanners in the EU would be affected where the health care facility wants to acquire new or additional coils. Where an acquisition is however not possible in the 2.5 year period for which the exemption is requested, patients could expect delays in health services.

The potential impacts on healthcare can also be considered as "*additional*" impacts, seeing as should the exemption be granted they would not be expected to occur. The range of impacts is not clear. Granting the requested exemption would prevent the potential impacts on health care facilities as the GE Healthcare MRI scanners could continue to be equipped with coils as usual.

It is not clear how to weigh the environmental impacts against health ones, particularly in relation to impacts expected to be "*additional*" which could not have been conclusively assessed to what extent and in which time frame it would occur.

It was decided in agreement with the EU COM and the applicant to finalise this assessment together with the very similar exemption request for "*bis-(2-ethy]hexyl) phthalate (DEHP) in plastic components in MRI detector coils*", submitted to the Commission in October 2019, as further analysis of the availability of substitutes and socio-economic aspects can be conducted and additional data may be gained..

7.6. Recommendation

Due to the similarity of the exemption request for "*bis-(2-ethy]hexyl) phthalate (DEHP) in plastic components in MRI detector coils*", it was decided to merge both requests. The assessment will be finalized in the "*Study to assess one (1) request for a new exemption to Annex IV of Directive 2011/65/EU for bis-(2-ethy]hexyl) phthalate (DEHP) in plastic components in MRI detector coils*" (Pack 20).

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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 (**)	-

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)	
12. Lead chromate molybdate sulphate red (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8	21 Nov 2013 (*)	21 May 2015 (**)	-
16. Chromium trioxide EC No: 215-607-8 CAS No: 1333-82-0	21 Mar 2016 (*)	21 Sep 2017 (**)	-
17. Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid EC No: 231-801-5 CAS No: 7738-94-5 Dichromic acid 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 (**)	

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)	
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.

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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	By 19 November 2012, in accordance with Article 69, the Commission shall ask the European Chemicals Agency to prepare a dossier conforming to the requirements of Annex XV in order to assess whether the use of cadmium and its compounds in plastic material, other than that listed in subparagraph 1, should be restricted. 2. Shall not be used 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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	5. For the purpose of this entry, 'cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface. Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications: (a) equipment and machinery for: — food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] — agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] — cooling and freezing [8418] — printing and book-binding [8440] [8442] [8443] (b) equipment and machinery for the production of: — household goods [7321] [8421 12] [8450] [8509] [8516] — furniture [8465] [8466] [9401] [9402] [9403] [9404] — sanitary ware [7324] — central heating and air conditioning plant [7322] [8403] [8404] [8415] In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited. 6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below: (a) equipment and machinery for the production of: — paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] (b) equipment and machinery for the production of: — industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431] — 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:

Designation of the substance, group of substances, or mixture	Conditions of restriction
	— articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. 8. Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C. 9. By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons. 10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in: (i) metal beads and other metal components for jewellery making; (ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including: — bracelets, necklaces and rings, — piercing jewellery, — wrist-watches and wrist-wear, — brooches and cufflinks. 11. By way of derogation, paragraph 10 shall not apply to articles placed on the market before 10 December 2011 and jewellery more than 50 years old on 10 December 2011.
28. 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.	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:

Designation of the substance, group of substances, or mixture	Conditions of restriction
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.	— either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'. 2. By way of derogation, paragraph 1 shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.
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.	
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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1. 5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather. 6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part. 7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.

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): Bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 EC No 204-211-0 Dibutyl phthalate (DBP) CAS No 84-74-2 EC No 201-557-4 Benzyl butyl phthalate (BBP) CAS No 85-68-7 EC No 201-622-7 Diisobutyl phthalate (DiBP) CAS No.: 84-69-5 EC No.: 201-553-2	1. Shall not be used as substances or in mixtures, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material, in toys and childcare articles. 2. Shall not be placed on the market in toys or childcare articles, individually or in any combination of the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material. In addition, DiBP shall not be placed on the market after 7 July 2020 in toys or childcare articles, individually or in any combination with the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material. 3. Shall not be placed on the market after 7 July 2020 in articles, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material in the article. 4. Paragraph 3 shall not apply to: (a) articles exclusively for industrial or agricultural use, or for use exclusively in the open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin; (b) aircraft, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft; (c) motor vehicles within the scope of Directive 2007/46/EC, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles; (d) articles placed on the market before 7 July 2020; (e) measuring devices for laboratory use, or parts thereof; (f) materials and articles intended to come into contact with food within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EU) No 10/2011(*); (g) medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof; (h) electrical and electronic equipment within the scope of Directive 2011/65/EU; (i) the immediate packaging of medicinal products within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC; (j) toys and childcare articles covered by paragraphs 1 or 2. 5. For the purposes of paragraphs 1, 2, 3 and 4(a),

Designation of the substance, group of substances, or mixture	Conditions of restriction
	(a) 'plasticised material' means any of the following homogeneous materials: — polyvinyl chloride (PVC), polyvinylidene chloride (PVDC),polyvinyl acetate (PVA), polyurethanes, — any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings, — surface coatings, non-slip coatings, finishes, decals, printed designs, — adhesives, sealants, paints and inks. (b) 'prolonged contact with human skin' means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day. (c) 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children. 6. For the purposes of paragraph 4(b), 'aircraft' means one of the following: (a) a civil aircraft produced in accordance with a type certificate issued under Regulation (EC) No 216/2008 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, signed on December 7, 1944 , in Chicago; (b) a military aircraft. (*) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).'
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: -	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
CAS No: 13864-38-5 (e) Phenylmercury neodecanoate EC No: 247-783-7 CAS No: 26545-49-3	
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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm 2 per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size. 8. By way of derogation, paragraph 7 shall not apply to: (a) jewellery articles covered by paragraph 1; (b) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Directive 69/493/ EEC; (c) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/ 87) unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500 ° C; (e) keys and locks, including padlocks; (f) musical instruments; (g) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) 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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	--- (*) 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).
67. Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) CAS No 1163-19-5 EC No 214-604-9	1. Shall not be manufactured or placed on the market as a substance on its own after 2 March 2019. 2. Shall not be used in the production of, or placed on the market in: (a) another substance, as a constituent; (b) a mixture; (c) an article, or any part thereof, in a concentration equal to or greater than 0,1 % by weight, after 2 March 2019. 3. Paragraphs 1 and 2 shall not apply to a substance, constituent of another substance or mixture that is to be used, or is used: (a) in the production of an aircraft before 2 March 2027. (b) in the production of spare parts for either of the following: (i) an aircraft produced before 2 March 2027; (ii) 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 4. Subparagraph 2(c) shall not apply to any of the following: (a) articles placed on the market before 2 March 2019; (b) aircraft produced in accordance with subparagraph 3(a); (c) spare parts of aircraft, vehicles or machines produced in accordance with subparagraph 3(b); (d) electrical and electronic equipment within the scope of Directive 2011/65/EU. 5. For the purposes of this entry 'aircraft' means one of the following: (a) 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.

Designation of the substance, group of substances, or mixture	Conditions of restriction
	(*) 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 April 2020, 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)).