Study to assess one (1) request for a new exemption to Annex IV of Directive 2011/65/EU for bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils (Pack 20) – Draft 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

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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 has been peer reviewed by Fraunhofer Institute IZM.

1.1. Background and objectives

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

- The scope covered by the Directive is now broader as it covers all electrical and electronic equipment (EEE; as referred to in Articles 2(1) and 3(1));
- The former list of exemptions has been transformed into 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 one request for a new exemption in this study.

1.2. Key findings – Overview of the evaluation results

The exemption request covered in this project and the name of the applicant concerned, as well as the final recommendation and proposed expiry date are summarised in the table below (Table 1-1). One request for a new exemption in Annex IV was included in the scope of this project. The reader is referred to the corresponding section 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
Requests for new exemption				
2019-4	Bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils	COCIR	Bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils	21 July 2023

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'une nouvelle demande d'exemption dans le cadre de la présente mission.

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

La demande d'exemption couverte dans le présent projet et le demandeur concerné, de même que la recommandation finale et la date d'expiration proposée, sont résumées dans le Tableau 2-1 ci-après.

Une demande de nouvelle exemption à l'annexe IV a été incluse dans la portée de ce projet. Le lecteur est invité à consulter la section correspondante 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
Demandes de nouvelles exemptions				
2019-4	Phtalate de bis-(2-éthylhexyle) (DEHP) dans les composants plastiques des bobines des détecteurs d'IRM	COCIR	Phtalate de bis-(2-éthylhexyle) (DEHP) dans les composants plastiques des bobines des détecteurs d'IRM	21 juillet 2023

3. Introduction

3.1. Project scope and methodology

The scope of the project covers the evaluation of one request for a new exemption. An overview on the exemption request 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 10 January 2020 and was planned for duration of eight weeks thus concluding 20 February 2020.

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

Information concerning the consultation was provided on the project website, including a general guidance document, the applicant's documents, a specific questionnaire and a link to the EU CIRCA website. Contributions were not made to the exemption.

Following the stakeholder consultation, an in-depth evaluation of the exemption began. The request was 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 evaluation of the exemption evaluated in the course of the project appear in chapter 5. The information provided by the applicant and by stakeholders is summarised in the first sections of the respective chapter. 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 applicant 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 specification 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/index.php?id=167

4. Links between the RoHS Directive and 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 manufacturing, use or placing on the market of chemical substances on the Union market. REACH, for its part, addresses hazardous substances through processes of authorisation (substances of very high concern) and restriction (substances of any concern):

- 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 Annex XIV of the REACH Regulation (Authorisation list): "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 a Member States or the European Chemicals Agency (ECHA) upon request of the Commission considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that it is not adequately controlled, it shall prepare a restriction dossier. ECHA has also the initiative to prepare a restriction dossier for any substance in the authorisation list if the use of that substance in articles poses a risk to human health and the environment that is not adequately controlled. The provisions of the restriction may be made subject to total or partial bans, or conditions for restrictions, based on an assessment of the risks and the assessment of the socio-economic elements.

The approach adopted in this report is that once a substance has been included into the Annexes related to authorisation or restriction of substances and articles under the REACH Regulation, the environmental and health protection afforded by REACH may be weakened in cases where an exemption would be granted for these uses under the provisions of RoHS. This is essentially the same approach as it has first been adopted

for the re-evaluation of some existing RoHS exemptions 7(c)-IV, 30, 31 and 40,[2] and in the following for the evaluation of a range of requests assessed through previous projects in respect of RoHS 2.[3] Substances for which an authorisation or restriction 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.

[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

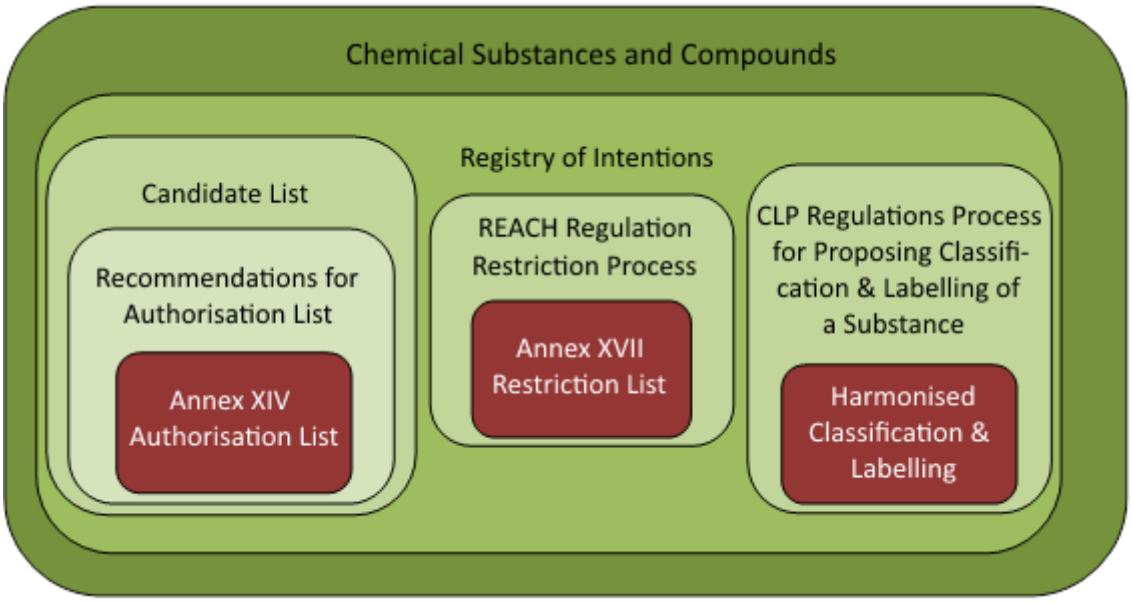
[3] Gensch, C., Baron, Y., Blepp, M., Deubzer, O., Manhart, A. & Moch, K. (2012) Assistance to the Commission on technological, socio-economic and cost-benefit assessment related to exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive), Final Report, Oeko-Institut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

[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

inform interested parties of the substances for which the authorities intend to 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 June 2020, the consolidated version of the REACH legal text, dated 28.04.2020, 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:02006R1907-20200428. 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 exemption 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 the separate chapter in which the exemption evaluation is documented under the relevant section titled “REACH compliance – Relation to the REACH Regulation” (Section 5.5.1).

[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. Request 2019-4: "Bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector 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
RF	Radio Frequency
RoHS 2	Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment

5.1. Background

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) has submitted a request for *"Bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils"* to be added as exemption to Annex IV (COCIR 2019b).

Due to the similarity of another exemption request for "*Bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils*" submitted earlier already by GE Healthcare (2018),[8] it was decided

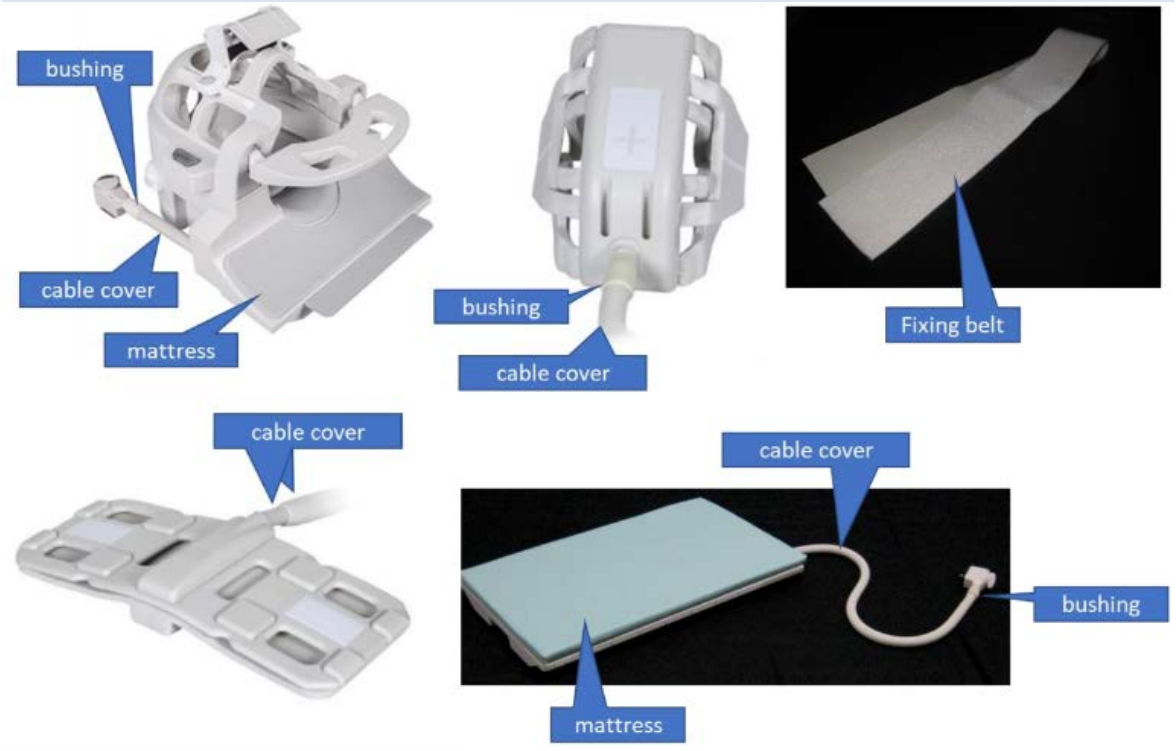
[8] The assessment of the GE Healthcare request has been assessed in the "Study to assess three (3) exemption requests relating to Annex IV to Directive 2011/65/EU: request for amendment of existing exemption 31a; request for a new exemption for bis-(ethylhexyl) phthalate (DEHP) in ion selective

in agreement with the EU COM and the applicant to suspend a final recommendation of that exemption request and to finalise the assessment together with the COCIR exemption request here at hand in order to gain additional information on the availability of substitutes and socio-economic aspects. The information provided by GE Healthcare is summarized and assessed in Gensch et al. (2020).

Information from GE Healthcare from their 2018 application as well as further answers on clarification questions will be provided in this assessment here at hand to allow a comprehension of how it coincides with this request.

COCIR (2019b) requests an exemption for the plasticiser bis-(ethylhexyl) phthalate (DEHP) applied in flexible polymers used in plastic components in MRI detector coils, which comprise bushing, cable covers (sheathing and insulation), fixing belt components and mattresses including their coverings in MRI detector coils. The following figure shows specific coils where the plastic components are indicated.

Figure 5-1: MRI coils showing cable cover, bushing and mattress locations



Source: (COCIR 2019b)

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)" Gensch et al. ((2020)). A final recommendation has been suspended, instead it was decided in agreement with the EU COM and the applicant to finalise the assessment together with the COCIR exemption request here at hand in order to gain additional information on the availability of substitutes and socio-economic aspects.

COCIR requests a duration of the exemption of two years thus ending July 2023 (COCIR 2020).[9]

GE Healthcare (2018) requests an exemption for 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 (see the illustration of the plastic strain reliefs in the following figure). GE Healthcare (2018) requests the exemption until January 2024.

Figure 5-2: MRI coil for shoulder; the four strain relief boots are circled in red.

Source: *(GE Healthcare 2018)*

5.2. Technical description of the requested exemption

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 – located 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 are 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

[9] In the original application, COCIR (2019b) requested an duration until January 2025, thus of 3 ½ years. However in the clarification questionnaire (COCIR (2019a)), COCIR referred several times to a duration of the exemption of 2 years (e.g. "*an additional 2 years beyond 2021 are required…*"). COCIR (2020) explained the discrepancy between the dossier requested duration (2025) and the answers to the questionnaire (2023) that here are "*new information and developments of research. Companies are now more confident all the test and validation could be completed in 2 years (July 2023).*"

magnetic materials degrade the weak RF signals emitted by the human tissue resulting in distorted MRI images.

According to the applicant (COCIR 2019b), there are different plastic components in MRI coils that need DEHP as plasticizer in the polymer material. According to COCIR (2019b), the plastic components comprise four components; they are listed in the following with a short explanation of their function:

- **Cable cover**: Isolation of the patient from the cable to prevent thermal injury of the patient,
- **Mattress**: Positioning of the patient, isolation of the patient from metallic parts of the coil to prevent thermal injury of the patient,
- **Fixing belt**: Reduction of patient movement during the MRI scan,
- **Bushings**: Fixing both ends of cable cover to coil and connector.

The plastic component in the request of GE Healthcare (2018) comprise strain relief boots for the coil cable that 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 near 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. Over the coil's lifetime, there appear estimated 30,000 repetitive bend cycles. Thus, the strain reliefs are functionally not identical to the bushings as described by COCIR.

COCIR (2019b) points out a lifetime of the of the coils of at least 6 years, whereas GE Healthcare (2018) states that a coil has a lifetime of at least 8 years.

Across the range of components, COCIR (2019b) specifies the following requirements for the plastic components containing DEHP as a plasticiser:

- Easy fabrication by solvent and heat welding; formation of complex parts with defined quality,
- Mechanical properties: Besides durability, mechanical properties differ between the different components, e.g. good flexibility is important for cable covers, tensile properties are important for bushings, robust barrier to prevent burns is mentioned for cable covers and mattresses, electrical insulation is specified for cable covers and bushings.
- DEHP plasticized polymer is durable to sweat and sanitizing agents.
- Material needs to fulfil biocompatibility requirements for human skin contact according to ISO standard 10993 on "Biological evaluation of medical devices".
- Material must not have adverse effect on the image quality which implies the following requirements:
  - Low proton signal to avoid interfering with the MRI image,

- Low distortion of magnetic fields to avoid interfering with the magnets that align the protons in the body, and
- The material shall not build up electrostatic energy that could be released during imaging which would hamper the MRI causing distortion of the image.

5.2.1. Amount of bis-(ethylhexyl) phthalate (DEHP) in plastic components used under the exemption

The total amount of DEHP from both exemption requests of COCIR and GE Healthcare would account for annually 158 kg DEHP placed on the EU market.

COCIR (2019b) provides data from one manufacturer; accordingly 14 kg DEHP are placed through the requested exemption on the EU market annually. As basis for the information, COCIR provided on a confidential base the estimated average weight of each plastic component, an estimated average of DEHP in the material (that ranges from 2 to 30 %) and the quantity of shipment to EU in 2018 of each plastic component. The sum of the input parameters multiplied for each component resulted in the total amount of DEHP of 14 kg per year. The information provided by COCIR was considered plausible.

COCIR explained not to have additional data from other manufacturers apart from data already submitted by GE.

GE Healthcare indicated an amount of 144 kg DEHP in their plastic strain relief devices entering the EU market annually through application for which the exemption is requested (GE Healthcare 2019b). GE Healthcare confidentially provided as basis 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 information provided by GE Healthcare was considered plausible.

5.3. Applicant's justification for the requested exemption

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

COCIR (2019b) points out two options to identify alternatives to DEHP-plasticised components:

- "*Utilise a different plasticiser to DEHP for each of the material types; or*
- *Qualify an alternative polymer, which does not require a plasticiser such as DEHP.*"

As a third option, GE Healthcare (2018) mentioned the redesign of the coils eliminating the need for strain relief boots and thus the use of DEHP in plastic components.

As for an **alternative polymer**, COCIR (2019b) provides test results for three polymers: ethylene-propylene diene monomer rubber (EPDM), urethane rubber and silicone rubber in comparison to the polymers currently used in the plastic

components: CSM (chlorosulfonated polyethylene), CR (polychloroprene rubber) and NBR/PVC (acrylonitrile-butadiene rubber or polyvinyl chloride). However, the three polymers provided adverse effect on the image quality: *"Testing was undertaken to measure the proton signal of alternative polymer using field echo sequence with shot echo time with Table 4 detailing the "relative image intensity ratio" from the polymer versus air. The larger the ratio the more distortion to the MRI image with any increase in ratio of the alternative negatively impacting image quality and performance of the MRI."*

COCIR contends that the testing result as shown in the following figure *"[…] demonstrates that the currently identified potential alternative all have an increase in relative image intensity ratio. With EPDM and silicon rubber showing a significant increase affecting the image quality."*

Figure 5-3: Assessed image intensity of potential alternative polymers

Current Polymer		Alternative Polymer			
Polymer	Intensity ratio	Polymer	Intensity ratio	Increase in ratio	% higher
CSM	7.1	EPDM	77.8	70.7	995.8
CR	5.5	Urethane rubber	6.9	1.4	25.5
NBR/PVC	2.2	Silicon rubber	12.6	10.4	472.7

Source: (COCIR 2019b)

Tests from GE Healthcare (2018) on nylon as alternative polymer failed in the mechanical requirements which is specific for their plastic strain reliefs of the GE Healthcare coils:

> *"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 lifespan 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."*

As for the **substitution of DEHP with an alternative plasticiser in polymer material**, COCIR (2019b) refers to tests as already presented by GE Healthcare (2018) in its exemption request on the plasticiser 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 assessing the relative image intensity ratio from the polymer versus air with PVC containing DEHT as plasticiser compared to PVC containing DEHP as plasticiser.

The tests were performed with two grades of PVC with different flexibility with DEHT respectively DEHP as plasticiser, which GE Healthcare (2018) characterises as having "*durometer value 65 and 90*": *"durometer is a measurement of hardness or flexibility. 65 durometers 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) presented the results of the measurements in the following tables, which are also included in the application of COCIR (2019b).

Figure 5-4: 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)*; (COCIR 2019b)

GE Healthcare (2018) interprets the above results as follows:

> *"The above results show that the DEHP-PVC material with durometer of 65 has a too strong 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) as well as COCIR (2019b) conclude from these tests that the PVC plasticisers have an impact on the image quality and in case of DEHT, it has a higher viscosity than DEHP and thus needs to be added in a higher concentration to the PVC formulation. GE Healthcare (2018) and COCIR (2019b) therefore exclude 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). GE Healthcare (2018) and COCIR (2019b) argue 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 **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."

The development of digital coils is also mentioned by COCIR (2019b), however rather as product innovation that is retarded if DEHP plasticized components need to be replaced.

To summarise the substitution efforts of COCIR and GE Healthcare, the tests with alternative polymers and one alternative plasticiser in PVC have not provided successful results to an extent that COCIR and GE Healthcare would continue with one of the tested alternatives.

GE Healthcare (2018) states in this regard that there is *"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."*

5.3.2. Environmental arguments

There were no environmental arguments brought forward by the applicants COCIR and GE Healthcare.

5.3.3. Socioeconomic impacts

COCIR (2019b) and GE Healthcare (2018) argue that there will be a negative impact on the EU healthcare if the exemption will not be granted: Particularly MRI coils cannot be purchased by EU hospitals because approved substitutes are not available (COCIR 2019b).

According to COCIR (2019b), MRI scanners generally can only use the original MRI manufacturers' coils. Also GE Healthcare (2018) in the original application states that "*GE MRI generally can only use GE's coils and this situation is the same for all manufacturers' coils.*" 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 2019d). GE Healthcare (2019d) further points out that this would also need a certain time of transition as e.g. validation of safety would be required. COCIR (2019a) states on the questions whether MRIs placed on the market could still be serviced with coils from other manufacturers that *"coils are specifically designed for one or more MRI models (depends on the technology). There are a few cases of 3rd party manufacturers that produce coils for specific MRI models. While some coils could be provided by such 3rd parties, hospitals would have no alternatives should they need to acquire new coils, or to replace old ones."*

COCIR (2019b) and GE Healthcare (2018) claim that without this exemption, many types of coils for specific body parts will no longer be available to EU hospitals. COCIR (2019b) explains this situation as follows:

> *"If hospitals are unable to buy the current wide range of MRI coils for their MRI scanners that they already own, the waiting times for receiving an examination are bound to increase and many patient's conditions would be more difficult to diagnose and treat as other less suitable methods would have to be used, if this is even at all possible. For example, a whole-body coil can be used to examine all parts of a patient's body, but the detail obtained for a small area such as a foot is significantly less than that which can be obtained by a dedicated foot coil. In addition, the time required to obtain a scan of a whole patient is much longer than a foot scan and this can cause delays in treating other patients, as MRI demand often exceeds their availability."*

GE Healthcare (2018) explains that *"currently there are more than 1,900 GE MRI scanners installed in European hospitals"*. GE Healthcare (2018) further calculates *"from online sources,*[10] *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*

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

treated using the most suitable diagnostic equipment." COCIR (2019b) provides updated estimations on the average number of patients receiving an MRI scan per year: *"A report from the Clinical Imaging board outlines that one MRI scanner typically treats around 7,300 patients per year (based on UK use in 2017)."* Based on these numbers, COCIR (2019b) specifies that *"over 2 million patients in Europe per year (based on the number of currently identified affected designs) […] could not be treated using the most suitable diagnostic equipment."* Thus, the sum of both estimations would result in 11 million patients affected by the exemption requests.

COCIR (2019b) and GE Healthcare (2018) also claim that there are limited trained engineers available; thus there are strategic decisions to be made on whether to follow a substitution route or rather or a new product development route: "*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" (GE Healthcare 2018).* COCIR (2019b) concludes that *"it is clear that new medical device development could potentially give a more significant overall benefit than DEHP replacement."*

As examples for innovation, COCIR (2019b) specifies that the development of digital coils to replace analogue coil designs: *"One manufacturer claims that digital coils have better signal to noise ratio than analogue designs."* Another innovation according to COCIR (2019b) is the development of flexible and adaptive coils to adapt to different patient sizes while maintaining optimum image quality and multi-tuned coils to allow different imaging techniques without changing coils. COCIR (2019b) claims that these types of development *"would not be possible or would at best be delayed if the engineers were diverted to redesign existing products for compliance purposes, but without performance improvement, as would be the case with alternatives to DEHP in coils."*

5.3.4. Road map to substitution

Both applicants specify the same different stages for a substitution but estimate for the step of reliability testing a slightly different timeframe as shown in the following figure.

Figure 5-5: Stages for establishment of possible substitute and respective timeframe needed for completion of such stages

Phase	Elapsed time for one coil design	
	COCIR for plastic components	**GE Healthcare for strain reliefs**
Identify materials	Currently underway	Not known at present
Biocompatibility and other tests	Approx. 6 months per material being altered to DEHP free	Approx. 6 months
Reliability testing	6 months to a year	1-2 years
Verification and global approvals if needed	Up to 2 years	Up to 2 years

Source: *(GE Healthcare 2018)*, (COCIR 2019b)

The stage of verification and global approvals, GE Healthcare (2019b) explains that this comprises the verification of "*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. 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. According to the estimates by COCIR, substitution would take three years. However, both applicants add that *"the timescale for redesign of many different types of MRI coils would be much longer than for one coil, although only a representative selection of coil assemblies would need to be fully evaluated and verified. Manufacturers predict that as long as a suitable substitute material can be identified, full substitution of DEHP plastic with a DEHP-free material could be complete during 2022.However, if currently researched substitutes are discovered to be unsuitable, this exemption will be needed for longer, potentially up to 2025, to evaluate different alternatives*" (COCIR 2019b). GE Healthcare also 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).

5.4. Stakeholder contributions

There were no contributions submitted in the course of the stakeholder consultation covering the exemption request of COCIR, though other MRI manufacturers were contacted during the consultations and urged to provide a contribution.

The MRI manufacturer Philips provided feedback after the consultation was closed: Accordingly, Philipps (2020) also applies DEHP in cable strain reliefs and is currently working with their suppliers on a phase out: *"However a definite answer could not be given whether substitution will be completed by July 2021."*

A contribution of COCIR (2019c) during the stakeholder consultation held for the request of GE Healthcare, 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 (2019c) 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 (2019c) 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.”*

Canon Medical Systems Corporation (CMSC) also provided input during the evaluation of the request of GE Healthcare after the consultation had closed. CMSC (2019) stated that they use *“strain relief device for preventing cable connecting part damage as well as the cable cover for keeping a distance between and patient’s skin to prevent burns”* that contain DEHP and states that they are evaluating possible substitutes. 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) stated 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.*”

Last but not least, (Siemens Healthcare GmbH 2020) provided a statement explaining that *“the MRI coils of Siemens Healthineers had been designed without using DEHP from the beginning – therefore there was no need to qualify alternative materials (which might take years without a guarantee for success) and furthermore, no redesign activities were needed.*

Siemens Healthineers got notice that some coil manufacturers can currently only provide coils containing DEHP. Since the market is very small, there are no alternative manufacturers available for certain specialty coils. It would take several years to develop DEHP-free specialty coils which consequently means that valuable resources cannot be put into innovation to enhance healthcare.

In addition, MRI coils are always specifically designed to be used with specific MRI-devices – they cannot simply be replaced by DEHP-free-coils from other manufacturers without redesigning the device (which would anyhow be impossible for devices which are already placed on the market) and without redesigning available coils.

With the non-availability of such specialty coils and without having this exemption granted, the diagnostic quality will not be as high as possibly achievable, leading to ten-thousands of patients in the EU who will have decreased chances of high – quality diagnosis and timely treatment.

Therefore, Siemens Healthineers supports the renewal request as currently applied by the applicant, even so not being in the direct need for the technical exemption."

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 (EC) No 1907/2006"*. 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 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 Union 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**:[11]

- **Entry 51**, paragraph 1 and 2, in Annex XVII of the REACH Regulation[12] 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 this restriction concerning toys and childcare articles could apply to certain articles within the scope of Directive 2011/65/EU (RoHS 2), such articles are 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.

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

[12] 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

- Furthermore entry 51, paragraph 3, which is the most recent amendment of December 2018, stipulates that DEHP shall not 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 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. 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.

No other entries, relevant for the use of DEHP in the requested exemption could be identified in Annex XIV and Annex XVII (status May 2020). 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. Legal aspects – coils as spare parts

During the evaluation of another request for the renewal of exemption 27 on RoHS Annex IV for MRI equipment,[13] COCIR argued that coils are not spare parts according to Art. 4(4) of the RoHS Directive, which allows the use of *cables* or *spare parts* for the repair, the reuse, the updating of functionalities or upgrading of capacity for the following EEE relevant in the context of this exemption request: medical devices placed on the market before 22 July 2014.

Annex II of the Directive specifies the list of restricted substances and lists among others DEHP also stipulates in this respect that "*The restriction of DEHP, BBP, DBP and DIBP shall not apply to 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, and monitoring […] placed on the market before 22 July 2021*"

According to Art. 3(27), "*'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.*

[13] See the currently ongoing evaluation of the exemption request at https://rohs.exemptions.oeko.info/index.php?id=344

The functionality of EEE is restored or is upgraded when the part is replaced by a spare part".

COCIR[14] explained during this evaluation that faulty coils may be replaced. Hospitals, however, purchase sets of coils according to the kind of examinations they need to perform, and they can always expand their capabilities by buying new ones for specific body parts. These new and additional coils are not replacements and Art. 4(4)(a) is not applicable. COCIR further explained that MRI devices are constructed to apply different coils. The specific type of coil is plugged into the MRI scanner when it is being used and then disconnected. The coils are stored elsewhere when not needed, far from the MRI as they could interfere with the image quality. Coils are very different in shape and function, from endorectal coils to full body coils.

While the spare part clause would allow replacing dysfunctional coils, the exchange of coils with different ones, or the addition of new types of coils cannot be considered a "replacement". Beyond the exchange of defect coils, coils cannot be considered as spare parts.

This aspect is also important for the exemption request here at hand because through the spare part provision new and additional coils with DEHP containing plastic components could have been serviced also if the exemption request is not granted.

5.5.3. Scientific and technical practicability of substitution

COCIR (2019c) stated in the consultation on the GE Healthcare request that one MRI manufacturer does not need the exemption for DEHP in MRI coils due to *"a totally different design with no need for a cable strain relief*". Therefore, it can be concluded that substitution of DEHP in MRI coils is technically practicable and reliable.

COCIR (2019c) as well as another MRI manufacturer, CMSC (2019), who also stated to use DEHP in plastic components of MRI coils, supported 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."*

From the information provided by COCIR, GE Healthcare (2018) and Phillips, it can be summarised that MRI manufacturers are still underway to identify suitable substitutes for the DEHP based plastic strain reliefs. The substitution tests of COCIR (2019b) and 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 taking into account the long service life of the coils.

[14] COCIR (2020): Answers to questionnaire 3, received via e-mail from Riccardo Corridori, COCIR, by Dr. Otmar Deubzer, Fraunhofer IZM, on 24 February 2020, document "Ex27_AnnexIV_Questionnaire-3_COCIR.pdf". Answers to questionnaire 3.

The road maps of COCIR as well as GE Healthcare show similar stages that are necessary to evaluate a suitable material once identified. COCIR (2019b) estimated that these stages will take three years, whereas GE Healthcare (2018) estimates that these stages will take four years. However, both estimates only cover the redesign of one coil. Substitution of a wider range of coils will take longer according to both applicants.

Taking into account that COCIR applies for an exemption duration until July 2023 and GE Healthcare until 01 January 2024, in the consultants' opinion the roadmaps suggest that both applicants have a concrete view on how to substitute DEHP in plastic components by one of the options: substitution by an alternative polymer, substitution with an alternative plasticiser or by a new development in the redesign of the coils. Both applicants, COCIR and GE Healthcare, did not request 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 both applicants are able to reach substitution in the requested timeline.

To summarise the status of substitutes, it is understood that DEHP can be replaced as plasticiser in plastic components of MRI coils and that one MRI manufacturer already places DEHP-free MRI coils on the EU market. The information provided by CMSC (2019) 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.

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 e.g. GE Healthcare starts from a different point in terms of coil design and material equipment than the manufacturer that has eliminated DEHP from MRI coils and needs additional time to complete substitution.

The feedback from COCIR and single MRI manufacturers such as GE Healthcare and Philips further suggests that MRIs placed on the market could not be serviced with coils from other manufacturers. After the consultation on the COCIR (2019b) request, MRI manufacturers were urged to provide information on the possibility to supply coils for other MRIs should the exemption not be granted. Philipps (2020) stated in this regard that "*due to regulation hospitals can only work with the MRI detector coils from the original manufacturer. Therefore, it would be a serious problem if such coils would not be available anymore.*" Also GE Healthcare explained 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." However, COCIR (2019a) clarified in this regard that *"while some coils could be provided by such 3rd parties, hospitals would have no alternatives should they need to acquire new coils, or to replace old ones."* It can be summarized from this feedback that MRI coils are very specifically designed, tested and adjusted to the MRI of the OEM and that coils cannot be supplied by another manufacturer. This might be for reasons such as technical adjustment but also in light of internal hospital regulation and supply organization. This means that though substitution may be possible, the availability of substitutes is not given considering the OEM specific supply with coils.

To conclude, though substitutes are in principle available and placed on the market, the substitutes are not readily available for the MRIs of all manufacturers (e.g. those requesting the exemption). The availability of substitutes is not given in this specific context.

5.5.4. Environmental arguments and socioeconomic impacts

The applicants 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, also lists MRI coils as being a relevant application for being returned to the manufacturer, refurbished and reused (COCIR 2018) (see in Gensch et al. 2020). 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).

As already specified above, the spare parts provision is not applicable to MRI coils (see section 5.5.2): The legal interpretation is that coils not replacing a defect coil cannot be considered a spare parts. Thus, it is not allowed supplying MRI devices in the current stock with new or additional DEHP containing coils unless they replace defect coils in MRI devices which were placed on the market prior to the date where restriction of DEHP applies to medical devices (22 July 2021).

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

As MRI manufacturers such as e.g. GE Healthcare will not be able to finish substitution by 22 July 2021, in consequence, the manufacturers concerned will not be able to meet the demand of coils if the exemption will not be granted.

The information provided by COCIR and 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; 2019c; COCIR 2019a; 2019b).

Table 5-1: 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 plastic components	158 kg of DEHP to be avoided on the market annually.	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. 388 kg DEHP.
Generation of additional waste	Coils are long-life devices of at least 6 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.	According to GE Healthcare, 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; According to GE Healthcare, 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 MRIs where the manufacturer does not reach to substitute DEHP until July 2021 might face shortage in supply of approved coils.	There are estimated 8,900 MRI scanners in the EU. One MRI scanner treats around 7,300 patients per year (based on UK use in 2017) according to COCIR. COCIR estimates over 2 million patients in Europe per year (based on the number of currently identified affected designs). Representing GE Healthcare MRIs	If new or additional coils can no longer be serviced for MRIs already on the market and for MRIs newly placed on the market after July 2021, it can be expected that coils that are not specific for the body part under examination would be used for the MRI scan. This would affect the quality of the image and thus of the diagnosis. It is understood that no competitors could fulfil a possible supply gap of coils in these cases.

Impact area	Detail	Estimations from GE Healthcare	Consultant's comments
		(currently more than 1,900 installed in the EU), more than 13 million patients per year in the EU could not be treated using the most suitable diagnostic equipment.	
Economic impacts	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. COCIR indicates costs of at least 1.5 million Euros and up to 3 million Euros for the most common models. According to GE Healthcare, costs for a single system may range $ 1.2 million to $ 3 million. 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 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. GE Healthcare has around 1,900 MRI 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: 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.

Impact area	Detail	Estimations from GE Healthcare	Consultant's comments
Impacts on manufacturers	Impact on the market share	A delay in the ability of GE Healthcare to supply MRI coils to support the already installed base of systems may result in loss of market share and reputation. 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, this customer relationship will no longer be accessible for more than 10 years.	In part this is understood as an impact to market structure of MRI manufacturers.
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 e.g. GE Healthcare to match the decreased demand for their 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; 2019c); (COCIR 2019a; 2019b)

In terms of impacts on the environment: Not granting the requested exemptions would avoid the placing on the market of 158 kg DEHP per year in plastic components of MRI coils of at least two manufacturers, accounting for ca. 388 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.

The consultants concluded above (see section 5.5.3) that MRI coils are very specifically designed, tested and adjusted to the MRI of the OEM and that coils cannot be supplied by another than the OEM manufacturer. Thus, there would be no compliant coils available in this specific context if the exemption was not granted and a supply gap of coils would appear.

According to Statista, a provider of market and consumer data, there were 17.4 MRI scanners per million inhabitants in the EU27 in 2016.[15] Thus there are estimated 8,900 MRI scanners in the EU.[16] GE Healthcare indicates to have placed on the market approximately 1,900 MRIs; the COCIR request is estimated to concern 270 MRIs. The exemption request therefore concerns in total a market share of at least 24 %, i.e. almost one quarter of all MRIs in the EU.

The consultant can follow that a supply gap in coils for a quarter of the European MRIs has effects on EU health care through a lower medical supply for patients caused by lower quality of the MRI scan because the specific body part coil could not be used or longer waiting times will apply for the MRI scan and diagnosis.

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 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* [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).

It is obvious that not granting the requested exemption shall result in a loss of business for manufacturers. As MRI systems are systems with very long life, GE Healthcare claims that this loss would not be reversible in the short term: *"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."*

5.5.5. Scope of the Exemption

Compared to the exemption request of GE Healthcare (2018), that only covered plastic strain reliefs, the request of COCIR (2019b) is wider in scope as the wording is more general on plastic components.

Questioned on the possibility to reformulate the exemption request by listing the specific plastic components or by listing specific categories, COCIR (2019a) argues

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

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

that if listing the four plastic components (cable cover, mattress, fixing belt and bushings) in the exemption formulation, *"the terms are not clearly defined (the exemption cannot provide any definition or guidance) and so may not be clearly understood by Market Surveillance Authorities, manufacturers or users […]. Apart from the indicated applications, there are no other uses of flexible polymers in MRI coils, therefore the generic wording will not open for any misuse of the exemption. The limited time requested as extension also contributes to ensure the quantities estimated in this dossier will be placed on the market (no loopholes)."*

According to GE Healthcare (2019d), any supply of coils by another manufacturer would *"require some time as there will be validation of Safety required by a NRTL such as Intertek for each coil chosen in each system it is applied to maintain ETL marking. […] If a new product to address the need needs to be developed, 3 years is typical for new product introduction."* (GE Healthcare 2019d). Taking into account the specific testing and approval requirements for medical devices and its materials, the consultant understands that a broader formulation of the exemption would not create a loophole for misuse by third party manufacturer.

As GE Healthcare requests the renewed exemption to be valid for six months longer than COCIR, it may be relevant to set a another expiry date for this kind of plastic components – plastic strain reliefs - compared to the rest of the components where the expiry date as requested by COCIR can apply. However, as the consultants understand from the information provided by manufacturer, bushings and plastic strain reliefs, though they might differ in the specific function (fixing of the connection versus prevention of overbending of the cable), cannot be separated by a definition and some stakeholders use the terms bushings and strain reliefs interchangeable.

This means that the bushings in COCIR's request would also be granted a longer duration than originally requested. If bushings covered by COCIR's request were brought onto the market for a longer duration, the amount of DEHP is however minor (in the range of some hundreds of grams) because the polymer of the bushing component is rather rigid and only requires the addition of DEHP at the lower end of the DEHP concentration range indicated in COCIR (2019b) at 2-30 %.

5.5.6. 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 in strain reliefs is possible because 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 MRI on the market. In contrast, other manufacturers such as GE Healthcare, CMSC and Philips are still in the process of testing and certifying an alternative for use in their equipment. COCIR and GE Healthcare have provided information to show the efforts of manufacturers into the search for a substitute. The consultants understand that even though substitution of DEHP is in principle possible in plastic components of MRI coils, e.g. GE Healthcare and CMSC need additional time to substitute DEHP in their coil portfolio.

Substitution as reached by one manufacturer however is not readily available on the market for all manufacturers' MRI scanners and their specific coils because coils are not compatible with other manufacturers' coils. According to COCIR, GE Healthcare and Philipps, hospitals having an MRI scanner are dependent of the OEM of their MRI for the supply of new or additional coils. Therefore, the availability of the substitute is understood not to be established.

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 the COCIR and GE suggest that a supply gap of coils may become relevant for the MRIs that would benefit from the exemption, which accounts for at least a 24 % of all MRIs in the EU. It is expected that patients might be affected by a delay in examination, possibly resulting in increased symptoms in some cases and might be affected with a lower quality of MRI scans if coils are used that are not body part specific; this entails a lower quality in diagnosis. In the consultant's opinion, these socioeconomic impacts, considered as possible health impacts of a substitution scenario are serious enough to justify granting the exemption.

5.6. Recommendation

Though it can be understood that some MRI coils are available that do not contain DEHP, it can also be understood that these would not be compatible with MRI of all OEMs. It can be concluded from this that for certain types of coils, substitutes are not yet available on the EU Market. As the types of coils for which this is the case may vary between various OEMs and possibly also between models of a certain OEM, it was not possible to demarcate a scope of coils for which the exemption is needed, as opposed to coils where substitutes exist.

Not granting an exemption would have the benefit of avoiding the placing of 388 kg DEHP on the market. However, it is also understood that in light of the lack of alternative coils for the full range of this application, substitution of DEHP containing coils at this stage would lead to negative impacts on the health of at least estimated 11 million patients (longer waiting times, lower quality of diagnosis and in both cases subsequent increase in symptoms). It is also possible that in some cases, environmental impacts in the form of MRI equipment scrapped ahead of its end-of-life may occur, though such impacts are assumed to be less common and thus not expected to have a significant range.

Though COCIR has requested a shorter duration until July 2023, the recommendation proposing an additional half a year for one joint expiry date is proposed for reasons of practicability and avoiding additional administrative burden. It is recommended to grant the exemption with the following formulation:

Exemption formulation	Duration
Bis-(ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils	01 January 2024

6. References

CMSC (2019): Personal communication by emails submitted 6 June 2019, 28 June 2019 and 19 July 2019.

COCIR (2018): Original Application for Exemption, Request for amendment of existing exemption in Annex IV for "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". submitted 17.07.2018. COCIR (ed.). Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/application_COCIR_RoHS17_ex_31a_Phthalates_in_reused_parts.pdf, last accessed on 22 Aug 2019.

COCIR (2019a): Answers to 1st Questionnaire Exemption 2019-4 (new request), Exemption for „Bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils.“. Oeko-Institut e.V. and Fraunhofer-Institut IZM (ed.). Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_20/Answer_Request_2019-4_COCIR_Questionnaire_Clarification_final_COCIRv3_20191219.pdf, last accessed on 29 Apr 2020.

COCIR (2019b): Original Application for Exemption, Request for a new exemption for "Bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils". submitted 02.10.2019. COCIR (ed.). Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_20/Application_COCIR_DEHP_in_MRI_coils_-_0102019.pdf, last accessed on 29 Apr 2020.

COCIR (2019c): Personal communication (1) by email submitted 23 July 2019.

COCIR (2020): Personal communication (2) by email submitted 22 April 2020.

GE Healthcare (2018): Original Application for Exemption, Request for new exemption in Annex IV for "Bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils. submitted: 12.09.2018. GE Healthcare (ed.). Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/application_GE_Global_Operations_RoHS_17_Application_Form_Strain_relief_DEHP_20180912.pdf, last accessed on 22 Aug 2019.

GE Healthcare (2019a): Answers to 1st Questionnaire Exemption Request No. 2019-2 (Clarification Questionnaire), Exemption for „DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils“. Oeko-Institut e.V. and Fraunhofer-Institut IZM (ed.). Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/clarification_GE_Ex_2019-2_RoHS17_1st_round_GE_Plastics_final_answers.pdf, last accessed on 22 Aug 2019.

GE Healthcare (2019b): Personal communication (2) by email submitted 1 August 2019.

GE Healthcare (2019c): Personal communication (4) Information provided on socio-economic impacts by email submitted 10.10.2019.

GE Healthcare (2019d): Personal communication (3) by email submitted 5 September 2019.

Gensch, C.; Baron, Y. (2014): 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), Report for the European Commission DG Environment under Framework Contract No ENV.C.2/FRA/2011/0020. Oeko-Institut e.V.; Eunomia Research & Consulting Ltd, 30 Sep 2014.

Gensch, C.; Baron, Y.; Moch, K.; López, V.; Deubzer, O. (2020): 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. http://rohs.exemptions.oeko.info/. Oeko-Institut e.V.; Fraunhofer-Institut IZM. Oeko-Institut e.V. and Fraunhofer-Institut IZM (ed.), 2020. Online available at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_17/RoHS_Pack-17_April_2020_final.pdf, last accessed on 29 Apr 2020.

Philipps (2020): Personal communication by email submitted 27 February 2020.

Siemens Healthcare GmbH (2020): Personal communication by email submitted 12 May 2020.

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 June 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).