Department for Environment Food & Rural Affairs (Defra)

Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils

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Anthesis Consulting Group

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Executive summary

Background and Objectives

The European Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (2011/65/EU, RoHS 2[i]) permits exemptions to be sought. New and renewal exemptions are granted or extended at the discretion of the Commission and until 31st December 2020 have been automatically transposed into UK law as "The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012" (The RoHS Regulations)[ii]. With the United Kingdom's withdrawal from the European Union on 31st January 2020, and the end of the transition period on 31st December 2020, the UK regulation has been updated to reflect the rules for placing such equipment on the market in Great Britain and in Northern Ireland[iii] [iv].

Those exemptions which had already been transposed into UK law remain, but several exemption applications were still under review by the European Commission. Consequently, any new exemptions adopted by the European Union post 1st January 2021 that were submitted to the European Commission before 1st January 2021, require an independent review by Defra before the Secretary of State decides whether to apply that exemption to The RoHS Regulations. Amending regulations repatriate powers to the Secretary of State to consider exemption applications made for the GB market. They set out transitional arrangements for applications that were made to the European Commission before the end of the "transitional period".

Anthesis (UK) Limited (Anthesis) has been contracted by Defra, through award of contract No. 59661 to review the exemption adopted by the European Union on 11th August 2021 for Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils to be included in Annex IV, entry 46 of The Restriction of Hazardous Substances Directive (RoHS 2). This exemption is being considered under the "transitional provisions" mentioned above. The Anthesis review has primarily focused on the European Commission's reports [vi] [xi] considering *inter alia* alignment with UK REACH[v]; risk characterisation of the requested use; feasibility of alternatives paying specific attention to their availability in the GB market; and consideration of the socio-economic implications from a GB perspective.

Key Findings

The exemption request adopted in the European Union under RoHS 2 for the use of bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils (Annex IV, entry 46), should be adopted in Great Britain under The RoHS Regulations. A practically feasible and reliable substitute does exist, but as "*coils are very specifically designed, tested and adjusted to the MRI of the OEM*" [xi], they are not readily available from other suppliers. Therefore, without the exemptions, a supply gap would

arise until coils compatible with specific scanners are developed and approved. Based on the potential impact on health services and the environmental and financial impact in case hospitals would need to prematurely dispose and replace their MRI system, it can be concluded that the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits. There is no conflict with UK REACH, thus the exemption will not weaken environmental protections.

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1. Introduction

1.1 Adopted EU Delegating Act

On the 11th August 2021, a new entry to Annex IV was adopted by the European Union and was expected to be published in October the European Official Journal (however, at the time of writing this report has not yet been published). Directive 2011/65/EU has been updated as follows:

Entry:	Annex IV, entry 46
Exemption:	*Exemption for bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils*
Duration:	2.5 years
Member State adoption & publication:	Expected 31/10/2021
Member State application of provisions:	Expected 21/07/2021

The exemption was granted because the reliability of substitutes is not sufficiently ensured and the total negative environmental, health and consumer safety impacts of substitution are likely to outweigh the total environmental, health and consumer safety benefits.

1.2 Project scope and methodology

The Anthesis review has primarily focused on the European Commission's reports[vi] [xi], considering the exemption's alignment with UK REACH and the requirements laid out in The RoHS Regulations. The applications and additional information submitted by GE Healthcare[vii] and COCIR[viii] (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry) have also been consulted (available from the Öko-Institut website). The Anthesis review is supplemented with further research to confirm the applicability of the exemption request to Great Britain. It should be noted that Anthesis only has access to information in the public domain, it has not been able to assess any confidential information submitted during the European proceedings.

This report first summarises the exemption requests and the decision reached by the European Commission, Council and Parliament (Section 2). Section 3 reviews the exemption request within the context of Great Britain, considering:

- The risk characterisation of the requested use,
- The feasibility of alternatives, paying specific attention to availability in the GB market, and;
- Consideration of the socio-economic implications, from a GB perspective.

The Anthesis recommendation is given in Section 4.

2. Background to the Exemption

GE Healthcare submitted an application for an exemption for the use of 'Bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used to prevent damage to cable connections to MRI imaging

coils', on the 12th of September 2018. A second application, with a broader scope, was then submitted by COCIR on the 2nd of October 2019, for the use of 'Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils'.

Due to the similarities between the two requests, the Commission decided (upon discussion with GE Healthcare) to suspend the evaluation and finalise the assessment together with the COCIR application.

The GE Healthcare exemption request was discussed in the Member States' Expert Group meeting of 21st October 2019[ix], during which one expert highlighted a concern related to the exposure of vulnerable patients to DEHP within devices, however, it was also highlighted that the amounts of DEHP used are much lower in comparison to the amounts of DEHP used in other non-electrical applications. Both exemption requests were raised in the Member States' Expert Group meeting of 23rd February 2021 [x], however, no questions or comments were raised.

After the Öko-Institut and Fraunhofer IZM conducted their review[xi] of both applications and notifying the European Council and Parliament, the Commission adopted it as entry 46 in Annex IV of the RoHS 2 Directive and referred it to the WTO Committee on Technical Barriers to Trade (TBT) on 29th June 2021. The publication of the exemption request, in the Official Journal, is expected imminently due to the 22nd of July 2021 deadline in (EU) 2015/863 (the exemption will apply retroactively from this date) and the much-reduced commenting window by the WTO TBT of 15 days. [xii]

2.1 Exemption applied for

As explained above, two exemption requests have been submitted for DEHP with similar scope. GE Healthcare requested an exemption for the use of Bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used to prevent damage to cable connections to magnetic resonance imaging (MRI) coils. This application was submitted on the 12th September 2018 and requested exemption until January 2024.

A second applicant (COCIR) applied for an exemption for the use DEHP in plastic components in MRI detector coils on 2nd October 2019. COCIR originally requested that this exemption would be valid until January 2025, however during the evaluation, reduced it to two years stating that there 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)"[xi]. Whilst DEHP is used in both applications as a plasticiser in polyvinyl chloride (PVC), the COCIR application extends the scope of the exemption to different parts of the MRI coils.

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

According to GE Healthcare, the technical function of DEHP in the MRI devices is to enable flexibility of PVC in the strain relief mechanism for the point of connections between MRI equipment and cables.

Figure 1: *MRI Coil for the shoulder; the four strain relief boots are circled in red. Source: GE Healthcare Application.*

Over the coil's lifetime, there are about 30,000 repetitive bend cycles. Without the flexible strain relief mechanism, the lifetime of the MRI coil would be reduced as repeated flexing movement would lead to damage at the point of connection. Therefore, 'strain relief boots' are used at the point of connection, as shown in Figure 1 and 2. These boots are made of DEHP-PVC; DEHP enables the flexibility of PVC to ensure strain relief in connections, without disrupting the function of the MRI equipment or alter the image quality.

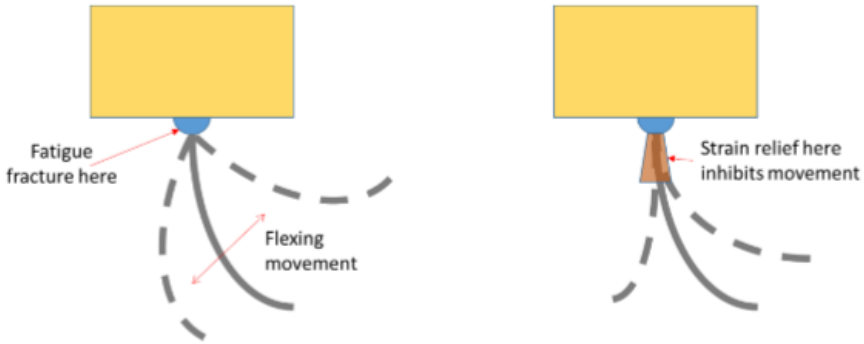

Figure 2: *The role of flexible strain relief in ensuring longevity of connections of wires to MRI equipment, taken from GE Healthcare Application.* [vii]

The COCIR application has a broader use, as DEHP is used in other parts of the MRI coils shown in Figure 3. These parts include cable covers, bushings, fixing belt and mattress covers. The purpose

of DEHP within PVC in each of these components is to act as a plasticiser (same as in case of the GE Healthcare application) that enables the flexibility required for components within MRI coils.

Figure 3: *Diagram from COCIR application showing functional uses of materials containing DEHP-PVC within MRI coils.* [viii]

2.2 Additional information considered

Legal considerations

Annex II of the RoHS 2 Directive specifies 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. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part".* COCIR explained in their answers to the Öko-Institut's questions that whilst faulty coils may be replaced, hospitals can always expand their capabilities by buying new types of coils for specific body parts. In this case these new and additional coils are not considered spare parts. COCIR further explained that the specific type of coil is plugged into the MRI scanner when it is being used and then disconnected and stored elsewhere, far from the MRI as they could interfere with image quality. Endorectal coils and full body coils vary in shape and function. While the spare part clause would allow replacement of dysfunctional coils, the exchange of coils with different ones, or the addition of new types of coil cannot be considered a "replacement".

2.2.1 REACH Authorisation, Restriction and SCIP Database

In accordance with the criteria laid out in Article 5 (1)(a) of RoHS 2, the ability to grant an exemption by adapting Annexes III and IV should not "*weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006*" (REACH). Therefore, the following section will consider any potential conflicts with (EU) REACH.

At the time of the adoption and publication of Directive (EU) 2015/863, REACH Annex XIV included DEHP, due to its reproductive toxicant effects. There is an exemption for DEHP: 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.

Commission Regulation (EU) 2020/171 amended the Annex XIV entry and allows that even after the sunset date, the use of DEHP is allowed until 1st March 2023 in the following two cases:

- In the production of spare parts for the repair of articles where production ceased before the sunset date, if:
    - the substance was used in the production of those articles and
    - these cannot function as intended without those spare parts and
    - spare part cannot be produced without that substance
- Use (on its own or in a mixture) for the repair of such articles or complex products, where:
    - that substance was used in the production of those articles or complex products and
    - they cannot be repaired otherwise than by using that substance.

The applicants explained that hospitals purchase specific coils beyond repair and refurbishment, therefore, they still need the exemption.

Applications for Authorisation were received for DEHP for uses in EEE. None of the Authorisation applications submitted consider the use of DEHP in medical devices, due to the exemption afforded by Article 60 (of REACH). Article 60(2), which specifically exempts the need for Authorisation of use within medical devices, when the intrinsic properties of the substance identified has hazards that only affect human health.

Furthermore, Article 62(6) states that applications do not need to include risks to human health arising from medical devices. This is because the Medical Devices Regulation (EU) 2017/745, repealing Directives 90/385/EEC and 93/42/EEC and effective from 26th May 2020 and the in vitro Medical Devices Regulation (EU) 2017/746 repealing Directive 98/79/EC with effect from 26 May 2022, specifically identifies phthalates and assesses the risk of those uses.

In late 2014, DEHP was identified as a substance of very high concern (SVHC) for its equivalent level of concern, based on its potential for endocrine disruption properties for the environment. The Annex XIV entries for DEHP have yet to be amended, but the draft regulation was adopted on the 23rd November 2021 and will enter into force on the 20th day after its publication in the Official Journal. Once derogation for the use of DEHP in medical devices expires on 27th May 2025, further applications for Authorisation for DEHP might be expected, as Articles 60(2) and 62(6) will not provide full exemption for DEHP to be used in medical devices. In our opinion, even at that point, there will be no conflict between the exemption and EU REACH, as the substances are already incorporated into the articles when they enter the EU. Whilst the scope of Authorisation is to use substances on their own or in mixtures or incorporating them into articles within the EU. Indeed, if medical device items are imported as finished articles into the EU, then they would be exempt from needing an Authorisation.

Articles are typically regulated via restrictions (Annex XVII) and while DEHP is included in entry 51 of Annex XVII, it neither applies to EEE within the scope of RoHS 2 nor medical devices regulated by 90/385/EEC, 93/42/EEC, and 98/79/EC[xii]. Entry 51 was updated to its present form in December 2018 via the Commission Regulation (EU) 2018/2005. Based on its toxic to reproduction category 1B classification, entry 30 applies to DEHP, however, entry 30 restricts supply to the public.

The revised Waste Framework Directive mandated the European Chemicals Agency (ECHA) in 2018 to establish a database of articles that contain SVHCs in greater than 0.1% concentration. This database, called SCIP (**S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts), aims to provide transparency primarily for waste operators, to ensure safe recycling. The information is also accessible to consumers. The notification obligation for article suppliers entered into force on 5th January 2021, so it was not effective when the Öko-Institut prepared their assessment.

Any European medical device producer or importer must submit a SCIP-notification for the articles they place on the market, if they contain more than 0.1% of an SVHC. Therefore, while the exemption (in our opinion) does not weaken the environmental and health protection in the EU, as the SCIP notification requirement is not a restriction; it may cause an additional administrative burden for manufacturers.

2.2.2 Medical Device Regulations

The European regulatory framework ensures the safety and efficacy of medical devices and facilitates patients' access to devices in the European market. Medical devices within the EU are currently regulated by 1 Regulation and 3 Directives:

- Regulation (EU) 2017/745 on medical devices (MDR);
- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990);
- Council Directive 93/42/EEC on Medical Devices (MDD) (1993); and
- Directive 98/79/EC of the European Parliament and of the Council on in vitro Diagnostic Medical Devices (IVDMD).

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5th April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU will apply from 26th May 2022. The two new Regulations will progressively replace the existing directives after a transition period.

Regulation (EU) 2017/746 requires that medical devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances that may be released from the device. Devices from which such a release might cause a prolonged exposure may only contain substances that are CMR category 1A or 1B, endocrine disruptors or other SVHCs identified under REACH, where justified.

Furthermore, the Commission mandated a scientific committee to prepare a guideline specifically on phthalates, including a benefit-risk assessment of the presence of phthalates (including DEHP), considering the intended use of the device and available alternatives. This guideline may be consulted for the above-mentioned justifications[xiii].

2.2.3 Technical feasibility and availability of substitutes

There are several requirements that all components in MRI equipment must have due to the strict requirements associated with medical imaging and diagnosis. GE Healthcare states that the following characteristics are required [vii]:

- *"The polymer plus all additives including the plasticiser must be acceptable for use in medical devices. New materials must comply with biocompatibility requirements according to ISO 10993 "Biological evaluation of medical devices", before they can be used.*
- *Lifetime of at least 8 years of frequent use and without failures. This is on average equivalent to 30,000 repetitive bend cycles*
- *Must not affect MRI image quality, so must be non-magnetic and have a proton signal emission material / air ratio as low as possible, ideally <1.2, but must be <4.0 when within the imaging zone (i.e., strain reliefs that are attached to coils).*
- *Coil assemblies must not be damaged when a patient has to be rapidly removed from an MRI scanner in an emergency, for example, if they suffer a heart attack. This is important if coil assemblies have to be redesigned."*

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", and
- 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.

Also as stated in the COCIR application, the Medical Devices Regulation would not permit producing coils that are knowingly less reliable, and EU approval withdrawal could occur if substitutions that are less reliable are put in place.

In their application document [vii], GE Healthcare refers to several potential alternatives, and states that many of the strain relief boots sold in the EU are made using PVC containing DEHP. They also state that alternative materials used in such boots for other electrical equipment are not always

appropriate for medical devices due to additional requirements for approval for materials used in human skin contact in a medical setting. According to GE Healthcare, there are three potential options to avoid DEHP use in MRI coils, COCIR identified only the first two as potential options: an alternative polymer, alternative plasticiser or the redesign of the coil that avoided the need for strain relief.

Table 1: *Summary of suggested substitution mechanisms proposed in GE Healthcare and COCIR applications.*

	GE Healthcare	COCIR
Alternative polymers	Nylon has been suggested by GE Healthcare as an alternative to DEHP-plasticised PVC within the strain boots, however the applicant states that testing found nylon to be less flexible, and therefore reduced the lifetime of the part in comparison to DEHP-plasticised PVC.	COCIR also provides analysis of three potential alternative polymers (ethylene-propylene diene monomer rubber (EPDM), urethane rubber and silicone rubber), however, they state that these polymers led to reduced image quality, stating *"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."* Table 4 referred to by COCIR lists the alternative polymers as Ethylene-Propylene diene monomer rubber (EDPM), Food grade EDPM, Urethane rubber and silicone rubber, and assesses their advantages and disadvantages.
PVC using alternative plasticisers	GE Healthcare states that Diethylhexyl terephthalate-PVC is being considered as a potential alternative, however initial tests appear to suggest it does not perform as well as DEHP-PVC and inferior image quality could occur. Alternatives have not yet been approved and further testing of alternatives is required.	The COCIR application refers to the same testing as GE Healthcare's application included.
Avoid the need for strain relief boots by redesign	GE Healthcare refers to potential alternative designs of the coil that are under consideration. One of these is a digital coil design created by Phillips. However, at the time of the application, these innovations were	COCIR did not provide detail on new design options in their application.

	not commercially available, therefore, information on these developments remain confidential. [xiv] GE Healthcare estimated: "the market is 5-8 years away from implementation providing they make a commitment to pursue." [xiv] They also stated that every coil assembly would need to be redesigned and to go through the process of regulatory approval. GE Healthcare also state in their application that there are over 70 different coil designs (specific to different purposes and body parts) [vii].	

Both applicants provided a summary of the potential timelines that would be required for the testing stages of any alternative, which is summarised in Figure 4. These estimates vary slightly, due to the different applications and complexity of multiple components in the COCIR application, however both consider the substitution for only one coil. Replacing multiple coils would require more time.

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)

***Figure 4**: Summary table of COCIR and GE Healthcare's estimates for substitution timelines. Source: Öko-Institut and Fraunhofer IZM.* [xi]

COCIR also recognised in its application that if there are difficulties in testing, their estimated timeline of ~3 years could be extended as new materials would need to be identified, hence the extended exemption request until 2025. However, during the evaluation, they reduced it to two years stating that there 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)" [xi]. GE Healthcare estimated that the process would take around 4 years following the identification of a suitable substitution material.

The report by Öko-Institut summarises that neither GE Healthcare nor COCIR considered the alternative polymers or the alternative plasticiser they tested as feasible substitutes. However, they also concluded, that the fact that neither of the applicants requested the maximum of 7 years duration for the exemption, suggesting that both applicants have a concrete view on how to substitute DEHP in the plastic parts of the MRI coils.

Stakeholder Contributions

Several MRI manufacturers contributed to the stakeholder consultations, including Philips who stated that they are currently working with suppliers to phase out DEHP containing strain reliefs, however they were not certain at the time whether this would be possible before the restriction of phthalates in medical devices enters into force [xi].

Canon Medical Systems Corporation (CMSC) also provided input, stating that they also used equipment containing DEHP within the strain relief devices and were working on identifying possible alternatives. CMSC also referred to the potential development of digital wireless coils as an alternative, that would eliminate the need for a cable with strain relief. However, stated that they believe such equipment would take a long time to develop.

COCIR stated in the stakeholder consultation of the original GE Healthcare exemption request that a member was able to manufacture MRI coils that did not contain DEHP, due to an entirely different design that eliminated the need for DEHP as a plasticiser in PVC. This means that the substitution is technically practicable and reliable. However, they also state that this manufacturer supported the exemption request as they recognise the challenges associated with finding alternatives. This member is likely Siemens as they provided a contribution to stakeholder consultation directly, stating that they did not use DEHP as plasticiser within their MRI coils and so are not directly impacted by the restriction. However, they acknowledge the difficulty in designing new coils that does not contain DEHP and points out that these would not be compatible with the existing equipment.

2.2.4 Environmental considerations

The total amount of DEHP entering the EU market (via the two exemptions), is 158 kg annually. Both applicants provided confidential data to support their estimate, that were considered plausible by the Öko-Institut.

Neither applicant submitted any environmental considerations with their applications, though GE Healthcare provided estimates of the impact of premature waste generation when asked by the Öko-Institut via the clarification process. However, it has been established by the Öko-Institut, that even a forced substitution scenario would not lead to the premature replacement of coils (unless a hospital decides to immediately replace their MRI system, the coils could be used until end-of-life). It is not clear if any of the MRI scanners would need to be disposed or relocated to outside of the EU in a forced substitution scenario.

GE Healthcare states that the devices cannot be recycled and are instead either sent for energy recovery or landfill. During the incineration of PVC strain reliefs, copper, lead, gold, and other metals can be safely recovered from wires. COCIR indicated that MRI coils can be also returned to the manufacturer for refurbishment and reuse.

2.2.5 Socio-economic impacts

Human Health Impacts

Both applicants state that there will be a negative impact on healthcare in the EU if this exemption is not granted, as there aren't any approved substitutes, therefore hospitals will not be able to

purchase specific new MRI coils. GE explained that typically, coils are produced by the same suppliers as the MRI scanners, however, *"if products are not available and a market exists, suppliers will address the demand"* [xi]. However, this would need a certain transition period e.g., for approval. Both applicants claim that if the exemption is not granted, "*many types of coils for specific body parts will no longer be available to EU hospitals*." [xi] If hospitals cannot buy specific type of coils, this will reduce the ability for hospitals to diagnose specific conditions, as COCIR explains: *"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."* [viii]

Both GE Healthcare and COCIR submitted estimates for the number of patients that would be impacted if the exemption request is not granted.

- GR Healthcare calculated 9 million patients, based on 1,900 GE MRI scanners in Europe and typical treatment of 4,500 patients per year (estimate taken from 2004 data)
- COCIR estimated over 2 million patients potentially impacted based on 270 MRI scanners, each used to diagnose 7,300 patients per year (more recent UK data).

This amounts to a total of 11 million patients that would not be diagnosed with the most appropriate equipment, annually. Patients might be redirected to other hospitals, which would lessen the impact, but as COCIR stated there is already a long waiting list for MRI scans.

The COCIR application notes that there have been no reports of adverse effects to patients due to exposure to DEHP-PVC [viii]. A report by The Scientific Committee on Medicinal Products and Medical Devices concluded that no adverse impacts were found due to medical devices containing DEHP as a plasticiser, even in neonates or groups exposed to high levels of DEHP[xv].

Economic Impacts

It is not clear how probable it is that a hospital would need to replace their MRI scanner with a competitor's equipment, or how much of the existing equipment base would be affected. However, in such a case, the financial impact would be severe potentially leading to reallocation of funds, thus affecting other facilities at hospitals. Beyond the cost of the MRI scanner (COCIR states €1.5-3 million (£1,252,707-2,505,414[1], GE Healthcare indicated $1.2-3 million (£886,986-2,217,465[2])), there would be training needs, installation and potentially even adjustment of the building to the new system. GE Healthcare estimate $40,000 for training, assuming 10 MRI technicians and 40 hours' worth of work lost for at $100/hour.

The economic impact on the manufacturers would be also significant, GE Healthcare indicated market share loss (especially considering the long lifetime of MRI scanners of around 30 years)

[1] https://www.google.com/intl/en/googlefinance/disclaimer/ (06/01/2022)

[2] https://www.google.com/intl/en/googlefinance/disclaimer/ (06/01/2022)

and reputation risk being the key impacts if they would not be able to supply the coils to the MRI scans already in place.

The GE Healthcare application states that potential substitution costs would make production costs economically unviable and state that: *"It would be unreasonable to significantly increase prices of coils to fund substitution research as EU hospitals all have limited funds and would not be able to buy coils that are considerably more expensive."*

Employment

GE Healthcare states that employment (manufacturing and supply chain included) will be impacted, however, does not provide further details on the extent. However, if a competitor can provide compliant coils, that might offset some of the negative effects on employment.

2.3 Conclusion

Based on the contribution from Siemens, stating that they eliminated the need for DEHP in MRI coils via an entirely different design with no need for cable strain relief, it can be stated that a practically feasible and reliable substitute does exist. However, as "*coils are very specifically designed, tested and adjusted to the MRI of the OEM*" [xi], they are not readily available from other suppliers. Therefore, without the exemptions, a supply gap would arise until coils compatible with the specific scanners are developed and approved. Furthermore, in some cases there are additional barriers to using other supplier's coils, e.g., if the hospital's internal regulations or the guarantee does not allow it.

Impacts on health services would also occur, i.e. potentially 11 million patients would not be diagnosed with the most appropriate equipment annually, if alternatives are not developed, tested, and approved, either by the applicants, or their competitors. Hospitals would face significant financial burdens if they need to replace their MRI systems, in additional to the environmental impact should current MRI systems would be disposed ahead of end-of-life; and manufacturers would face reputational risks and losses to their market share. Considering the long lifetime of MRI scanners, this impact would be long-term. The Öko-Institut estimated that the two exemption requests would affect approximately 24% of the MRI scanners in the EU. These socioeconomic impacts (particularly the possible health impacts) were considered significant enough to grant the exemption.

MRI producers are still in the process of identifying and testing possible alternatives, therefore, these two applications are essentially bridging the gap until the alternative is identified, tested, and approved. The fact that neither applicant requested the maximum duration for their exemption suggests that they have a clear view on how to substitute DEHP in the plastics components of the MRI.

Whilst GE Healthcare requested a longer exemption period, it was decided to extend this duration to both applications, as some stakeholders use the terms bushing and strain relief interchangeably, thus COCIR might inadvertently benefit from the longer exemption period of GE Healthcare. From the environmental impact perspective, there is little difference, as bushings are rather rigid, therefore, the concentration of DEHP tends to be lower. For practicality reasons the exemption was granted until 01 January 2024 with a scope covering both applications, following the conclusion that the reliability of substitutes is not sufficiently ensured and the total negative environmental, health and consumer safety impacts of substitution are likely to outweigh the total environmental, health and consumer safety benefits.

3. Assessment to the Criteria laid out in Part 2, regulation 5

Regulation 5 of The RoHS Regulations permits an exemption to be granted if the following are satisfied:

- The exemption does not weaken the environmental or health protection afforded by UK REACH; and
- The elimination or substitution of the material or component, via design changes or use of materials or components which do not include any restricted substances, is scientifically or technically impracticable.
- The reliability of substitute materials or components is not ensured; or
- The total negative environmental, health and consumer safety impacts caused by substitution of another material or component is likely to outweigh the total environmental, health and consumer safety benefits of that substitution.

The following assessment reviews each of these elements.

3.1 Links to UK REACH

On 1st January 2021, UK REACH [v] entered into force and substances manufactured or imported >1 tonne per annum (tpa) in Great Britain require registration, before being placed on the market.

To minimise disruption to businesses and supply chains at the end of the transition period, existing GB downstream users who were, at any time in the 2-year period before 1st January 2021, already a downstream user under EU REACH could submit a Downstream User Import Notification (DUIN). The deadline for the notification was 27th October 2021. This effectively defers their registration responsibilities for up to six years depending on the tonnage band and hazard profile of the substance. Consequently there is currently no publicly available database of all substances likely to be registered in Great Britain. The Government recently set out its intention to consult on extending the transitional deadlines for full registration[xvi]. A list of substances for which information has been submitted to the Health and Safety Executive (HSE) under Article 127B(4)(a) of the UK REACH Regulation (initial transitional data) was published in September 2021[xvii] This is not a verified list of registrations that were transferred into UK REACH from EU REACH under Article 127A (1) (transferred registrations), only a list of substances for which information has been submitted to the HSE under Article 127B(4)(a) of the UK REACH Regulation (initial transitional data).

DEHP is not listed, which means we do not have information that any companies would manufacture or import DEHP in greater than 1 tonne per annum, however, as explained above, currently no information is available to confirm this.

The Statutory Instruments for UK REACH also laid out transitional measures for the Authorisation and Restriction processes within UK REACH and these are discussed in the following section.

3.1.1 Annex 14 (Authorisation)

Substances included in Annex XIV of REACH were transposed to UK REACH, with effect from 1st January 2021. Currently, the substances included in UK REACH Annex 14 are the same as those in the EU equivalent Annex XIV and therefore, this includes DEHP due to its intrinsic hazard as toxic to reproduction.

The transitional arrangements provided for by UK REACH required GB-based holders of EU Authorisations, or GB downstream users relying on another's Authorisation, to confirm the Authorisation, to the HSE by 1st March 2021. Where an Authorisation decision was still pending from the EU, then other transitional measures exist. The HSE has initiated its first public consultation for an Authorisation application concerning DEHP. It concerns the extension of the Authorisation originally granted to Rolls Royce in 2014[xviii], but this is out of the scope of this report as it is not used in medical devices.

As noted above, applications for Authorisations would not be anticipated for medical devices all the while Annex 14 only includes DEHP for its reproductive toxicity and not as suspected endocrine disruptors for the environment.

The Candidate List (the list of substances of very high concern (SVHCs) is the precursor for including substances on Annex 14. The Candidate List was transposed on 1st January 2021 to UK REACH and includes those substances added to the List up to and including June 2020[xix]: thus, DEHP is included for its endocrine disrupting properties for human health and DEHP is also included as endocrine disruptor for the environment. If the Annex 14 entries are amended in UK REACH in a similar way to EU REACH, then medical devices containing DEHP will be in scope of Authorisation. As stated earlier, in our opinion even at that point there will be no conflict between the exemption and UK REACH, as the substances are already incorporated into the articles when imported, whilst the scope of Authorisation is to use substances on their own or in mixtures or incorporating them into articles within GB.

The UK REACH work programme for 2021/2022 states that the UK will present its first recommendation of priority substances to be included in Annex 14, but this does not include DEHP, as they focused on ECHA's 10th and 9th recommendations, whilst amending the Annex XIV entry for DEHP was included in the 8th recommendation[xx]. Therefore, at the time of writing the report, it is not known when the UK will move forward with updating Annex 14.

3.1.2 Annex 17 (Restriction)

REACH Annex XVII, as of 31st December 2020, was transposed to UK REACH and included all EU restrictions that had entered into force including any in their transitional period[xxi]. Thus, DEHP is included as entry 51 with the same conditions as the EU. The legislation allows for further restrictions to be imposed if relevant chemicals pose an unacceptable risk to human health or the environment. The UK Government announced its first plans for restrictions under UK REACH on 23rd March 2021[xxii], and has since created a Registry of restriction intentions[xxiii]. To date only 2 new restrictions are proposed, above and beyond those already transposed, and these do not concern either uses in scope of The RoHS regulations or DEHP.

3.1.3 SCIP Database

In November 2020, Defra confirmed that it will not transpose the SCIP provisions[xxiv], but was considering how to identify and track chemicals of concern in articles to reduce barriers to reuse and recycling. At that time, Defra indicated that the UK's approach will probably be communicated in its chemicals strategy, that was planned to be published in 2022. The notifications of SVHCs in articles according to article 7(2) exists but only applies above 1 tonne[xxv]. The Agency for UK REACH Work Programme 2021/2022 does not mention SCIP[xxvi].

This means that whilst the SCIP notification might create some additional administrative burden for manufacturers placing on the market MRI scanners and coils in the EU, in the UK, no such

requirements are foreseen (for the time being). It will therefore be easier to import articles containing DEHP on the UK market than to the EU.

3.2 Scientific and technical practicability of substitution

Based on the contribution from Siemens, stating that they eliminated the need for DEHP in MRI coils via an entirely different design that does not need cable strain relief, a practically feasible and reliable substitute does exist. However, as "*coils are very specifically designed, tested and adjusted to the MRI of the OEM*" [xi], alternatives are not readily available from other suppliers. Therefore, without the exemptions, a supply gap would arise until coils compatible with the specific scanners are developed and approved. Furthermore, in some cases there are additional barriers to using other supplier's coils, e.g., if the hospital's internal regulations or the guarantee does not allow it.

Several entities of GE registered medical devices with the MHRA including GE Healthcare Coils, a Division of USA Instruments Inc. Siemens Healthcare Diagnostics Inc, Philips Medical Systems and Canon Medical Systems Corporation also submitted registrations. The database does not specify the type of equipment supplied to the UK in all cases; however, it can be assumed that some of these companies would be affected by the two exemption requests (as they either applied or contributed with comments during the European evaluation process). Whilst Siemens stated their coil design does not require DEHP, this doesn't mean that their product can be used by hospitals who own MRI scanners produced by different manufacturers.

3.3 Environmental and socioeconomic considerations

As the UK was a member of the EU during the period of research conducted by the Öko-Institut, the data described in the report would have included GB. Therefore, the environmental and socioeconomic considerations are likely to reflect the GB situation as well. However, based on published statistics relating to the number of MRI scanners per million inhabitants, it is possible to estimate the number of MRI scanners in GB and the number of MRI scanners impacted by the two exemption requests.

Table 2 shows an estimate of the number of MRI scanners placed on the market by GE Healthcare and the companies represented by COCIR in GB, based on the methodology used in the Öko-Institut's report. GE Healthcare placed 1,900 MRI scanners on the EU market, COCIR members represented 270 of these, equating to 24% of all the MRIs in the EU. If we assume that they have similar market share, that means about 100 MRI scanners would be impacted by the two exemptions in GB.

Table 2: *Estimates of the number of MRIs within GB, based on the proportions of GE Healthcare and COCIR MRI scanners in the EU.*

	EU27 Estimates (Methodology from Commission's Report) [xi]	**Great Britain Estimates (based on Commission's methodology)**
MRI Devices per million inhabitants (2016)[xxvii]	17.4	7.2
Number of Inhabitants	512 million	60 million [xxviii]

Estimated number of MRI Scanners	8,900	432
GE Healthcare MRIs in EU	1,800 (20.2%)	87.2 (assuming 20.2%) *
COCIR MRIs in EU	270 (3.0%)	13 (assuming 3.0%) *

**Estimated based on the proportions of population.*

Environmental Impacts

The total amount of DEHP entering the EU market, via the two exemption requests is estimated to be 158kg annually. Based on the above, it can be estimated that about 7.63kg of DEHP would enter the UK if the two exemptions are extended to GB.

It has been established by the Öko-Institut, that even a forced substitution scenario would not lead to the premature replacement of coils. MRI coils can be also returned to the manufacturer for refurbishment, but this is something that is possible anyway as there is a derogation for spare parts, irrespective of whether the exemption requests are granted.

As explained above, it is not clear how many MRI scanners would need to be disposed prior end-of-life, in a forced substitution scenario.

Human Health Impacts

Based on the estimates described above in Table 2, we can calculate the potential impacts on health services within the UK. Assuming 100 MRI scanners are impacted by the exemption already on the UK market and using the statistics provided by COCIR, i.e., that one MRI scanner typically can be used to diagnose around 7,300 patients per year, approximately 730,000 patients might be affected per year by being treated without the most suitable diagnostic equipment.

Economic Impacts

It is estimated that there are around 400 MRI scanners in the UK, 100 of these could be impacted by the two exemptions (assuming similar market share), however, it is not possible to judge how many of these would need to be replaced prematurely due to the exemption not being granted.

The economic impact on the manufacturers would be also significant (e.g. market share loss and reputational risk, if they would not be able to supply the MRI coils to the meeting their existing clients' needs). Several entities of GE registered medical devices with the MHRA, including GE Healthcare Coils a Division of USA Instruments Inc. Other companies that submitted comments to the stakeholder consultation, also registered medical equipment with the MHRA in the UK: Siemens Healthcare Diagnostics Inc, Philips Medical Systems, Canon Medical Systems Corporation. The database does not specify the type of equipment in all cases; however, it can be assumed that some of these companies would be affected by the two exemption requests.

To further assess the impact on hospitals in GB and their planned actions to overcome the potential supply gap, Anthesis have contacted the, the Royal College of Radiologists and the National Institute for Health Research but received no further information.

3.4 Exemption duration

In the EU, both exemptions were granted until 01 January 2024, as there are not enough reliable alternatives and the total negative environmental, health and consumer safety impacts of substitution are likely to outweigh the overall environmental, health and consumer safety benefits.

4. Recommendation

If the exemptions are not extended to GB, there could be a significant financial impact on hospitals and negative impacts on health services more generally. Furthermore, the potential environmental impact would be also significant, should any of the existing MRI systems need to be disposed ahead of their expected end-of-life. Therefore, it can be concluded that the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits, therefore, it is recommended to extend the exemption, Annex IV, entry 46 granted under RoHS 2 in EU-27 to Great Britain. As the EIF of the restriction of DEHP is aligned with the EU, it is reasonable to adopt the exemption and with the same application date.

5. Appendix

6. References

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