Department for Environment Food & Rural Affairs (Defra)

Use of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices (UK-2021-03)

Report prepared by: Pearl Nemeth

Report Approved by: Dr Richard Peagam

Date: 7th February 2022

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Anthesis (UK) Limited

Prepared for:

Graeme Vickery

Defra

Nobel House

17 Smith Square

London

SW1P3JR

Prepared by:

Pearl Nemeth

Anthesis (UK) Limited

Unit J, Taper Studios

175 Long Lane

London

SE1 4GT

Report written by:

Pearl Nemeth

+44 (0)7881 533 937

Pearl.Nemeth@Anthesisgroup.com

Email:

Website: www.anthesisgroup.com

Tel: 01865 250818

Company Registration: 08425819

Quality Assurance

Report checked by:

Paul Ashford, 20th October 2021

Report approved by:

Dr. Richard Peagam, 7th February 2022

+44 (0)7824 314 194

richard.peagam@anthesisgroup.com

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 requested. New and renewal exemptions are granted or extended at the discretion of the European Commission. Until 31st December 2020, these 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]. Due to 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].

The exemptions that had already been transposed into UK law remain, but several exemption applications were still under review by the European Commission during the transitional period. 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[iii] repatriate powers to the Secretary of State, to be able 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" [v]

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 DEHP, BBP, DBP and DIBP for use in spare parts recovered from and used for the repair or refurbishment of medical devices to be included in Annex IV of The Restriction of Hazardous Substances Directive (RoHS 2). This exemption is being considered under the "transitional provisions" mentioned above. The Anthesis review has focused primarily on the European Commission's report considering *inter alia* alignment with UK REACH[vi]; 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), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices (Annex IV, entry 47) should be adopted in Great Britain under The RoHS Regulations. There are existing scientifically or technically practicable substitutes, however, the total negative environmental, health and consumer safety impacts of substitution (i.e., manufacturing new parts) is likely to outweigh the total benefits and leads to the premature generation of waste. There is no conflict with UK REACH, however, there is a misalignment regarding the EU SCIP notification requirement, which is not mirrored in the GB legislative framework, thus it will be easier to circulate these old parts in the GB than in the EU. The financial impact to continue the present exemption is anticipated to be less than ±£5 million annual net direct cost to business (EANDCB).

Table of Contents

Disclaimer 2

Anthesis Consulting Group 5

Executive summary 5

Background and Objectives 5

Key Findings 6

Table of figures 7

1. Introduction 7

1.1. Adopted EU Delegating Act 7

1.2. Project scope and methodology 7

2. Background to the Exemption 8

2.1 Exemption applied for 8

2.2 Additional information considered 10

2.2.1. REACH Authorisation, Restriction and SCIP Database 10

2.2.2. Medical Device Regulations 12

2.2.3. Technical feasibility and availability of substitutes 13

2.2.4. Environmental considerations 13

2.2.5. Socio-economic impacts 14

2.3 Conclusion 14

3. Assessment to the Criteria laid out in Part 2, regulation 5 15

3.1 Links to UK REACH 15

3.1.1 Annex 14 (Authorisation) 16

3.1.2 Annex 17 (Restriction) 16

3.1.3 SCIP Database 17

3.1.4 Medical Device Regulations 17

3.2 Scientific and technical practicability of substitution 17

3.3 Environmental and socio-economic considerations 17

3.4 Exemption duration 19

4. Recommendation 19

5. Appendix 19

6. References 21

Table of figures

Figure 1: Timeline showing a comparison of the current legal situation regarding spare parts containing DEHP, BBP, DBP and DIBP, compared to the situation where the exemption request is adopted. 10

1. Introduction

1.1. Adopted EU Delegating Act

On the 11th of August 2021, a new entry to Annex IV of the RoHS 2 Directive was adopted by the European Union, which is expected to be published in the European Official Journal in October 2021. Directive 2011/65/EU has been updated as follows:

Entry: 47	Annex IV, entry 47
Exemption:	For the use of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices.
Duration:	7 years
Member State adoption & publication:	31/03/2022
Member State application of provisions:	21/07/2021

The exemption was granted because recovered spare parts are often collected for refurbishment and further distribution globally, and it is not feasible to distinguish spare parts by their market of origin and to determine the concentration of phthalates in a non-destructive way. Furthermore, the existing spare parts provisions do not cover spare parts recovered from outside the EU. Whilst the substitution is scientifically and technically practicable, the total negative environmental, health and consumer safety impacts of substitution (i.e., manufacturing new parts) is likely to outweigh the total benefits and leads to the premature generation of waste.

1.2. Project scope and methodology

The Anthesis review has primarily focused on the European Commission's report[vii] considering its alignment with UK REACH[vi] and the requirements laid out in The RoHS Regulations. The application submitted by COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry, the Applicant) has also been consulted (available from the Öko-Institut website[viii]). 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.

This report first summarises the exemption request 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

On 17th July 2018, the Commission received an application for an exemption to allow spare parts containing > 0.1% DEHP, BBP, DBP and DIBP, recovered and used for the repair and refurbishment of medical devices, to continue being placed on the market in the EU.

The Commission launched a study to carry out the required technical and scientific assessment in November 2018, to evaluate the application for a new exemption. The study, conducted by the Öko-Institut, included an eight-week stakeholder consultation, during which one response was received, with the study being concluded in 2020.

The Commission consulted the Member States' expert group for delegated acts under the RoHS 2 Directive[i] on 23rd February 2021. The minutes from this meeting report that one Member State expert suggested having a general provision for spare parts in a closed-loop context, in Annex II, but as the Directive does not allow for such a provision, the proposal could not be accommodated[ix]. There was a reference made to the SCIP[1] database[x], but the minutes do not describe how this might have impacted the exemption request, if at all.

The application was submitted as an amendment to Annex IV entry 31a, however, as the RoHS 2 Directive does not have an official procedure to amend an existing exemption, the European Commission adopted it as a new exemption (Annex IV, entry 47) 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. [v]

2.1 Exemption applied for

According to the Applicant, DEHP, DBP, DIBP and BBP are added to polymers (including rubber), adhesives, sealants, paints, and lacquers for a variety of possible uses as listed:

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

[1] **S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts). Since the 5th of January 2021, article suppliers are required to notify articles containing substances of very high concern (SVHCs) above 0.1 % (w/w) to the SCIP database, to improve information in the value chain and specifically to assist waste operators.

- As a processing aid in polymer mouldings.

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

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

The Applicant explains that in the medical device market, there is already a rather mature recovery and distribution system for spare parts to be used for refurbishment, repair, servicing, or maintenance (RRSM). There are several reasons for this. Due to the high reliability requirements for the Notified Body approval of medical devices, as required by the medical devices regulations, medical equipment has a long lifetime. It is easier to recover parts, as they don't need re-approval, compared to producing new parts and it is also economically more viable. Manufacturing new spare parts (without phthalates) would also lead to longer downtimes for hospitals (new manufacture is estimated to take about 8 months), especially immediately after 2021, when most parts would still contain phthalates. Furthermore, manufacturing parts to old models that are already obsolete is not always possible. The well-established global collection and distribution system ensures fast allocation, thus short downtime for hospitals for these (often) critical medical equipment.

There are several legislations that already allow the use of spare parts under certain circumstances; however, the exemption request goes further in some respects. Article 4(5) of the RoHS 2 Directive (as amended by Directive (EU) 2017/2102) allows using spare parts recovered from medical devices placed on the market prior 2014, until 2024. Compared to this, the exemption would extend the period until which spare parts can be recovered from medical devices placed on the EU market from 2014 to 2028 and the period until the harvested spare parts can be used in the refurbishment from 2024 to 2028.

Directive (EU) 2015/863, that introduced the restriction of the four phthalates (DEBP, BBP, DBP and DIBP) in medical devices (categories 8 (Medical devices) and category 9 (Monitoring and control instruments including industrial monitoring and control instruments) from 21st July 2021, also allows that, spare parts (containing either of the four phthalates) placed on the EU market before July 2021 can still be recovered and used for repair and refurbishment of medical devices.

Neither Article 4(5) of the RoHS 2 Directive, nor Directive (EU) 2015/863 allows for spare parts to be recovered from medical devices not previously placed on the EU market. However, the Applicant states that, due to the complexity of the medical devices in question and their global supply chain, it is not always clear to medical equipment manufacturers whether a certain part was originally placed on the market in the EU or outside the EU, before or after 2021, when the phthalate restriction became applicable; and testing of the products is not possible in a non-destructive way.

Therefore, the applicants require the exemption as with the exemption, parts previously not placed on the EU market can be used and the period until which spare parts can be harvested would be extended from 2021 to 2028. This second criteria is more important for the non-EU

parts again, as those might still contain phthalates even if they were placed on the market after 2021.

The following figure aims to explain the difference between the status quo and the exemption application, i.e., the exemption would help medical device suppliers by:

- Extending the periods when spare parts potentially containing DEHP, BBP, DBP and DIBP can be recovered from medical devices for repair and refurbishment and,
- Allowing the recovery of spare parts from medical devices, that have not previously been placed on the EU market (thus potentially containing the restricted phthalates).

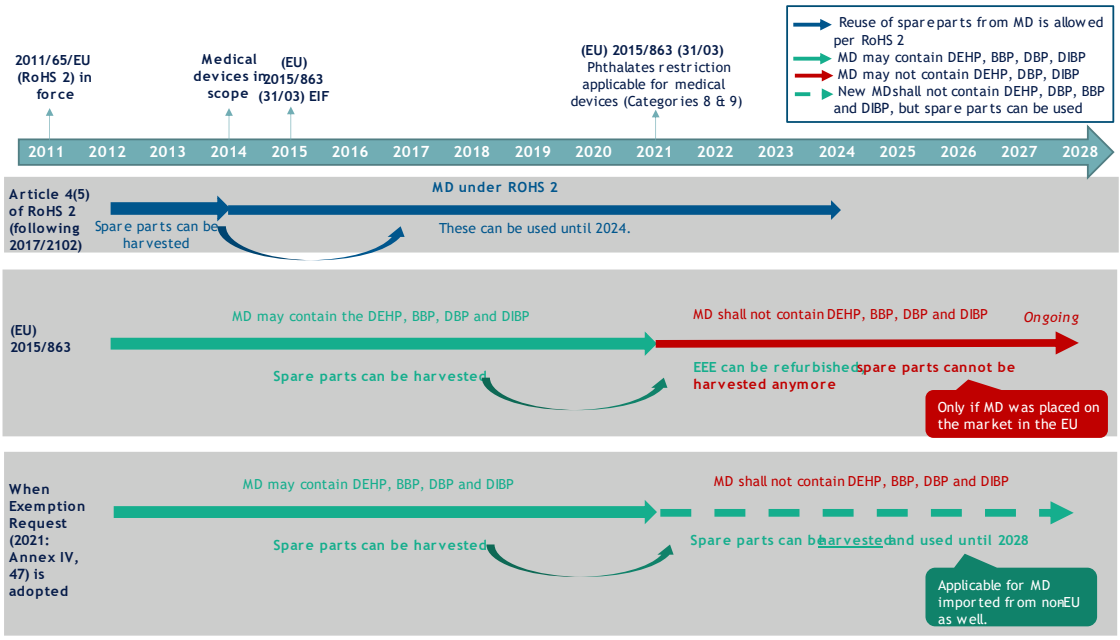

Figure 1: *Timeline showing a comparison of the current legal situation regarding spare parts containing DEHP, BBP, DBP and DIBP, compared to the situation where the exemption request is adopted.*

2.2 Additional information considered

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 look at any potential conflicts with (EU) REACH.

At the time of the adoption and publication of Directive (EU) 2015/863, REACH Annex XIV included these phthalates, due to their reproductive effects. There is an exemption for DEHP, BBP and DBP: 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. Applications for Authorisation were received for DEHP and DBP for uses in EEE. As no applications were received for either BBP and DIBP, these substances could not be placed on the market as the substances themselves or in

mixtures on the EU market for use on their own, in mixtures or used to produce articles in the EU after 21st February 2015 (so-called sunset date) as per (EU) No 143/2011 and (EU) No 125/2012.

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

- In the production of spare parts for the repair of articles the production of which ceased before the sunset date, where:
  - 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.

However, these do not apply for the current exemption as feasible alternatives exist for DEHP, BBP, DBP and DIBP.

None of the Authorisation applications submitted consider the use of phthalates in medical devices, due to the exemption afforded by Article 60 (of REACH). Article 60(2) 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, though, 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. In 2017, all four phthalates were further identified as SVHCs, owing to their endocrine disrupting properties for human health. The Annex XIV entries for these substances 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 the 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 (as the spare parts already exist), whilst the scope of Authorisation is to use substances own 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, this is the case for what placed originally on market outside the EU and now used as spare parts.

Articles are typically regulated via restrictions (Annex XVII) and although DEHP, DBP, BBP and DIBP are 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[xi]. Entry 51 was updated to its present form in December 2018 via the Commission Regulation (EU) 2018/2005. Based on their toxic to reproduction category 1B classification, entry 30 applies to each of the phthalates,

however, entry 30 restricts supply to the public. The supply of spare parts recovered from and used for the repair or refurbishment of medical devices must take place in a closed-loop business-to-business return system, i.e., they are not supplied to the general public.

COCIR also mentioned a registry of intentions under REACH: "A restriction on materials with prolonged skin contact has been proposed. Most parts of medical devices do not have prolonged or frequent skin contact and so would be out of scope. If this restriction enters force in the future, any parts which have PVC that may be used with prolonged skin contact will not be reused". Öko-Institut confirmed that the registry of intentions, to which COCIR refers, forms part of the amendment of entry 51 of Annex XVII so does not apply to the exemption request.

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 (including spare parts) they place on the market, in the event that they contain more than 0.1% of an SVHC. Recovered parts do not require SCIP notification if they were originally placed on the market in Europe. However, the Applicant claims that due to the global nature of the collection and distribution of used spare parts, there is no way of knowing the origin (EU or non-EU) of the collected spare parts. It is also not possible to determine the concentration of the SVHC in a non-destructive way. Furthermore, the Applicant specifically states that at the time of submission, i.e., in 2018, there was insufficient information available in the supply chain to verify if DEHP, DBP, BBP or DIBP were used in concentrations greater than 0.1% prior to the introduction of the restriction via Directive (EU) 2015/863. 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 form a practical barrier to refurbishment and maintenance with spare parts potentially containing the restricted phthalates, even when the exemption would allow it.

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, considering the intended use of the device and available alternatives. This guideline may be consulted for the above-mentioned justifications[xii].

2.2.3. Technical feasibility and availability of substitutes

Substitution is scientifically and technically practicable, in fact, the Applicant states that the number of parts containing the restricted phthalates "has already started to decrease as phthalates have been gradually phased out to meet the 2021 deadline and to meet national initiatives on green public purchasing. The fact that no exemption (requests) for phthalates, except 2 very specific cases submitted by COCIR and a COCIR Member, have been submitted, proves that phthalates were being already substituted wherever possible well before 2018.".

Despite the availability of the alternatives, the Applicant reasoned that the exemption should be granted by giving more relevance to the environmental benefits of using spare parts. The application aims to make sure immediate availability of spare parts (that can be legally used for repair and refurbishments) after the 2021-restriction enters into force.

2.2.4. Environmental considerations

The Applicant argues, that as the exemption request relates to pre-existing components, there are two meaningful scenarios that can be compared to assess the environmental impacts of the exemption:

- One where parts are used again (but potentially contain phthalates)
- One where new phthalate-free parts are produced, and the old ones are (prematurely) disposed.

According to the Applicant, this second scenario might also lead to fewer medical devices being refurbished, as some older parts might have been discontinued or it is simply not economically viable to manufacture a new part for refurbishment.

The Applicant confirmed that the collection and refurbishment take place in the required closed-loop business-to-business return systems, as manufacturers make great effort to collect their own parts and because the Medical Device Regulation requires that only approved parts are used.

COCIR argues that "Allowing all recovered spare parts to be reused, provides a net environmental and health benefit and is paramount to establish a proper circular economy business model."

COCIR provided full LCAs to support their claims and estimated that an additional 2,200 tonnes of new parts would need to be produced if the exemption was not granted. Based on the extensive information on the environmental impacts that were provided by the Applicant, the Öko-Institut considered the exemption justified under the Article 5(1)(a) of the RoHS Directive on adaptation to scientific and technical progress.

2.2.5. Socio-economic impacts

Due to the restriction on phthalates, any returned parts that contain phthalates could not currently be legally used for refurbishment. COCIR highlighted that the most significant socioeconomic implications of this would be the higher cost of producing new spare parts not containing the restricted phthalates (it did not estimate what these might be); and these not being immediately available after 2021 which would lead to longer downtime of essential medical devices and delays in urgent medical treatment. In their own words: "[…] the global logistic created by manufacturers allows spare parts to be delivered worldwide to hospitals to RRSM medical devices to ensure the shortest possible downtime for the benefit of patients' health. Medical devices manufactured by COCIR's members are critical devices used in ER departments and other critical care facilities".

Furthermore, consequently, refurbished equipment would not be available in the EU, even though "refurbishment is a key element of the strategy to allow EU hospitals to renew their equipment in an affordable way"[xiii] .

Whilst there was no monetary estimation provided and there were a few assumptions in the argumentation that could not be substantiated, the Applicant provided a broad range of arguments on the health and socioeconomic impacts.

During the stakeholder consultation, there was one submission made by MedTech Europe, and this reinforced the above arguments. MedTech Europe also provided concrete estimation for the potential cost reduction through reuse and refurbishment, illustrated in the case of a specific type of medical device, resonators:

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

The application provided sufficient evidence on the benefits for the European health system, along with the environmental benefits of not needing to produce new parts. It should be also recalled, that even without the exemption, it is possible to use parts containing phthalates originally placed on the market before July 2021 as per Directive (EU) 2015/863 (31/03).

2.3 Conclusion

The evaluation of the exemption application concluded that the negative environmental and health impacts of substituting refurbished parts containing DEHP, BBP, DBP and DIBP with new phthalate-free refurbished parts, are likely to outweigh the total environmental and health benefits. However, to ensure a high level of protection for the environment, health and consumer safety, reuse should take place in auditable closed-loop business-to-business return systems and the reuse of spare parts should be notified to the customer.

It was concluded that the exemption is consistent with REACH and thus does not weaken environmental and health protections, therefore, the exemption was granted. As noted above the SCIP notification requirement (that entered into force in 2021) might now provide a barrier to use spare parts for refurbishment as allowed by the exemption.

For avoiding disruption, the Commission decided that the Directive should enter into force as a matter of urgency and should apply with retroactive effect from 21st July 2021 when the restriction of the substances entered into force.

Whilst COCIR selected both category 8 (Medical devices) and category 9 (Monitoring and control instruments including industrial monitoring and control instruments) in their application, the information provided (incl. the stakeholder consultation) was not considered sufficient by the Öko-Institut to support exemption in category 9.

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

Regulation 5 of The RoHS Regulations[ii] 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[vi] 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[xv]. 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 [xvi]. 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).

Out of the four phthalates in question, only DIBP is listed. This means at least one company manufactures or imports DIBP in greater than 1 tonne per annum, however, no information is available to confirm whether it is used in medical devices.

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, these include DEHP, BBP, DBP and DIBP due to their 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[xvii], 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 these phthalates for their 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[xviii]: thus, the phthalates are included for their 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 (as the spare parts already exist), whilst the scope of Authorisation is to use substances own 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 the four phthalates, as they focused on ECHA's 10th and 9th recommendations, whilst amending the Annex XIV entries for the four phthalates was included in the 8th recommendation[xix]. Therefore, at the time of writing the report, it is not known when the UK will move forward with updating Annex 14.

Moreover, as only one application for Authorisation for electrical equipment was identified in the EU, it is more likely that phthalates will be contained in imported articles, if at all, and would thus be governed by Annex 17.[v]

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[xx]. Thus DEHP, BBP, DBP and DIBP are 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[xxi], and has since created a Registry of restriction intentions[xxii]. 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 any of the four phthalates.

3.1.3. SCIP Database

In November 2020 the Defra confirmed that it will not transpose the SCIP provisions[xxiii], 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[xxiv]. The Agency for UK REACH Work Programme 2021/2022 does not mention SCIP[xxv].

This means, that whilst the SCIP notification might create a barrier for the reuse of spare parts containing phthalates as the Applicant states there is no way of knowing if the parts contain any phthalates and at what concentration level. In the UK, no such requirements are foreseen (for the time being). It will therefore be easier to circulate spare parts on the UK market, introducing the environmental and health impacts of using parts that may contain phthalates, whilst improving the socioeconomic benefits, such as lower refurbishment costs for hospitals and shorter downtime for patients.

3.1.4. Medical Device Regulations

The Medical Device Regulations (UK MDR 2002)[xxvi] require any materials presenting a hazard to be replaced as soon as alternatives with a more positive risk-to-benefit balance are available. The Medicines & Healthcare products Regulatory Agency (MHRA) provided guidance on the use of DEHP phthalates in medical devices in January 2021[xxvii]. The update was in response to potential concerns about the possibility of DEHP leaching from the PVC into solutions and the intrinsic reproductive effects, but concluded that the DEHP may be essential in some medical devices in critical circumstances. The medical devices cited were not EEE and as such would not fall within the scope of RoHS 2. However, in accordance with the objectives of UK MDR 2002, the guidance does encourage operators to find alternatives to DEHP.

3.2. Scientific and technical practicability of substitution

As the restriction of the four phthalates for categories 8 and 9 is not a new concept, many manufacturers have already switched to the use of alternative parts that do not use these four phthalates in new part production. As such, the substitution is scientifically and technically practicable. However, the purpose of this exemption is to enable the reuse of parts potentially containing phthalates, due to the costs and environmental impacts of manufacturing new parts shown in Life Cycle Assessments.

3.3. Environmental and socio-economic considerations

The Applicant confirmed that the collection and refurbishment take place in the required closed-loop business-to-business return systems, thus exposure is minimised. They estimated that an

additional 2,200 tonnes of new parts would need to be produced if the exemption was not granted. At the time of the application the UK would have been included in these figures. As discussed above, granting the exemption would only extend the lifetime of parts potentially contain DEHP, BBP, DBP and DIBP, not manufacturing new equipment or parts containing these, therefore, the environmental benefit of keeping these in circulation compared to producing new parts expected to overweigh the risks.

Anthesis believes that adopting the exemption in the UK would not lead to the loss of innovation or pushing alternatives out of the market during the period of the exemption (i.e., until 2028), due to the high market barrier to the medical device market (given the high reliability requirements) and the long innovation period associated with it. As the Applicant pointed out "all substitutes must provide the same or better performance as the old part in order to obtain Notified Body approval of medical devices as required by the Medical Devices Regulation". MedTech Europe stated in their submission to the stakeholder consultation, that it takes 3 to 7 years (up to 10 years for IVD) to bring a new MD to the market [xiv]. Furthermore, the Applicant highlighted that new parts are made by the same manufacturers that make the medical devices, until the production of the individual designs cease, although sufficient stocks for warranty periods of 2-5 years are available.

Anthesis has identified several UK trade bodies supporting the medical devices industry and control instrumentation. A brief description of these is given below [v].

- AXREM is UK trade association representing the interests of suppliers of diagnostic medical imaging, radiotherapy, healthcare IT and care equipment in the UK. Members supply most diagnostic medical imaging and radiotherapy equipment installed in UK hospitals. They are an associate member of COCIR.
- Association of British HealthTech Industries (ABHI) and British In Vitro Diagnostics Association (BIVDA) are both UK national association members of MedTech Europe.
- British Healthcare Trade Association (BHTA) represents the healthcare and assistive technology industry.
- PAGB, the consumer healthcare association represents manufacturers of branded OTC medicines, self-care medical devices and food supplements in the UK.
- GAMBICA is the UK trade association for instrumentation, control, automation and laboratory technology.

Based on earlier engagement with BHTA and PAGB, neither are concerned with the phthalate restriction at all. As AXREM is an associate member of COCIR, whilst both BIVDA and ABHI are members of MedTech Europe, their members should be aligned with the exemption request. These statistics may have changed due to Brexit, but historically, approximately one-third of GAMBICA's members' products are exported to the EU, so compliance with RoHS 2 is required.[xxviii]. Thus, they probably support harmonisation between jurisdictions as this means members have greater ability to supply single products globally without considering regulatory nuances between jurisdictions; MedTech Europe pointed out the same.

Adopting the exemption should help the members to maintain their continuous refurbishment and repair services without delays post the 2021 restriction. That in turn helps to extend the lifetime of the medical equipment that is both environmentally and economically beneficial, not to mention the benefits for the healthcare system by being able refurbish existing equipment with existing spare parts. Anthesis estimates that the economic impact of the exemption is likely to be low, i.e., less than ±£5 million annual net direct cost to business (EANDCB) not least as the exemption request is for less than the 10 years required to be considered with an Impact Assessment[xxix] .

3.4. Exemption duration

Seven years, the maximum exemption duration permitted for EEE in category 8 (Regulation 5(7)(b)) seems reasonable for the exemption application and should start retroactively from the EIF date of the restriction, i.e., 22nd July 2021, to avoid legal uncertainty.

4. Recommendation

It is recommended to extend the exemption, Annex IV, entry 47 granted under RoHS 2 in EU-27 to Great Britain. As the EIF of the restriction of DEHP, BBP, DBP and DIBP 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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