Department for Environment Food & Rural Affairs (Defra)

Review of the inclusion of Phthalates in The RoHS Regulations in medical devices and monitoring and control instruments

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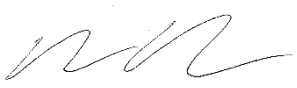

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Executive summary

Background and Objectives

When Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS 2) (1) entered into force on 21 July 2011 only six substances[1] were restricted from use in electrical and electronic equipment (EEE) and included in Annex II. Article 6 of this Directive, however, provides the ability for the substances in Annex II to be reviewed and amended. The first such review was mandated to be no later than 22nd July 2014. Accordingly, during late 2012 and into 2013, 56 substances were reviewed for potential inclusion in Annex II. This led to a delegated Directive ((EU) 2015/863) being adopted on 31st March 2015 to expand the list of restricted substances. The revised Annex II included four phthalates (Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP)) with deferred effective dates for their use in medical devices (category 8) and monitoring and control instruments (category 9) until 22nd July 2021.

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 "The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012" (The RoHS Regulations) (2) has been updated to reflect the rules for placing such equipment on the market in Great Britain and in Northern Ireland (3) (4). However, The RoHS Regulations have yet to be updated with respect to the restrictions pertaining to the four phthalates used in medical devices and monitoring and control instruments.

Anthesis (UK) Limited (Anthesis) has been contracted by Defra through award of contract No. 59661 to review the appropriateness for The RoHS Regulations to be updated to include phthalates such as they pertain to medical devices and monitoring and control instrumentation.

Key Findings

The inclusion of Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) in Annex II of The RoHS regulation is recommended. Their inclusion in RoHS 2 has triggered four exemption requests to the European Commission for medical devices (category 8) and monitoring and control instruments including industrial monitoring and control instruments (category 9). The

[1] lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers

number is small, as expected, because of the transition times afforded by the long lead times for regulatory change brought through (EU)2015/863 and concerns around the use of phthalates more generally. REACH is able to regulate substances of concern via Authorisation and Restriction but these processes have their limitations, thus extending the restriction of phthalates in EEE ensures imported articles are considered. Furthermore, their inclusion in The RoHS Regulations is anticipated to bring about additional worker protection, particularly for waste operators, and to reduce emissions to the environment. Industry has been working on finding alternatives to phthalates for several years and the exemptions requested in the EU should be seen as “bridging” requests, whilst the alternatives are validated. The financial impact to include phthalates in categories 8 and 9 is anticipated to be less than ±£5 million annual net direct cost to business (EANDCB).

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1 Introduction

1.1 Legislative context

Annex II of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS 2) (1) governs those substances restricted for use within electrical and electronic equipment. Article 6 of the Directive provides the ability for further substances to be added to Annex II and was specific that a review and amendment of Annex II should be considered by the Commission no later than the 22nd July 2014. This review was undertaken in period November 2012 – May 2014 and resulted in the adoption of the Delegated Directive (EU) 2015/863 on 31st March 2015 to expand the list of substances in Annex II. The revised Annex II included four phthalates (Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP)) with deferred effective dates for their use in medical devices (category 8) and monitoring and control instruments including industrial monitoring and control instruments (category 9) until 22nd July 2021.

The RoHS Regulations (2) have been amended several times following various European Directives amending Directive 2011/65/EU and have been preserved in Great Britain through the EU Withdrawal Act 2018 with subsequent Statutory Instruments to correct deficiencies arising from the UK leaving the EU. The amending regulations, Regulation 3, (4) repatriate powers to the Secretary of State to consider amending the list of restricted substances and their maximum concentrations to be permitted in homogeneous materials which may be contained in EEE. Such amendments must consider UK REACH, the potential impact of exposures to workers involved in waste EEE management and processing, environmental exposures and releases, as well as the availability of substitutes or alternative technologies. This scenario is thus applicable to the inclusion phthalates as they pertain to categories 8 and 9 as restricted substances and to align with the EU.

1.2 Project scope and methodology

Anthesis' review has focused on understanding the European Commission's rationale to include the four phthalates in Annex II of RoHS 2 in 2015. This review has been complimented with an analysis of regulatory developments for these substances both within the scope of REACH ((EU) 1907/2006) and exemption requests under RoHS 2. Informal outreach to sector trade associations was made to assess industry's response to the restriction of phthalates in medical devices and control and monitoring instruments, as well as a review of UK REACH (5) with respect to the substances.

The full assessment reports on each phthalate were not available to Anthesis at the time of the review, except for DIBP, but Anthesis does not see this as critical in its assessment of whether The RoHS Regulations should be extended to include the restriction of phthalates in medical devices (category 8) and monitoring and control instruments including industrial monitoring and control instruments (category 9).

2 Background to Directive (EU) 2015/863

As mentioned in Section 1, Article 6 of RoHS 2 provides the ability for further substances to be added to Annex II and was specific that a review and amendment of Annex II should be considered by the Commission no later than the 22nd July 2014. Furthermore Recital 10 highlighted four

substances[2] which were to be given priority for review. They had not been included at the time of the recasting of RoHS as there was insufficient information available on the environmental, economic and social impacts as well as the potential substitutes (6). Accordingly, the Environment Agency Austria, Umweltbundesamt (AUBA) was contracted by the Commission, firstly to develop a methodology for identifying and assessing substances for restriction under RoHS 2, and secondly to apply that methodology to the identified substances including those called out in Recital 10. This work was undertaken between November 2012 and December 2013 and the final reported published by the Commission on 4th February 2014 (6). It included stakeholder consultations; the fourth of which was specific to those substances in Recital 10.

AUBA assessed the potential inclusion of 56 substances which included 11 elements (metals), phthalates, brominated flame retardants, chlorinated flame retardants and chloroalkanes. Four phthalates – Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) – were ranked as having the highest priority for further assessment together with 4 other substances. AUBA went on to assess DEHP, BBP and DBP in more detail and DIBP was assessed by the Öko-Institut (7).

Table 1 summarises the key conclusions for the four phthalates. AUBA's assessments were based on the conditions set out in RoHS 2 Article 5 (1)(a), i.e. to ensure there would be no weakening of environmental and health protection, specifically during EEE waste management operations and releases from disposal, the availability and reliability of substitutes and the socioeconomic impacts of a restriction.

It was noted by AUBA that there was a limited amount of information about the use of these phthalates in EEE. AUBA had relied on modelling of worker and environmental exposures owing to the lack of available monitoring data and true operating conditions, but where such data did exist for DEHP, exposures had exceeded the Derived No Effect Concentration (DNEC) advised by the Committee for Risk Assessment (RAC) (8). AUBA also noted that the release estimates were likely underestimates but were dependent on the actual quantities of phthalates used in EEE, lifespan and collection rates of the EEE. Taking account of the precautionary principle, the risks arising from similarly acting phthalates should also be considered. Finally, although there would be some negative impacts by restricting these phthalates from use in EEE the overall health and environmental benefits outweighed these. Therefore, inclusion of these substances within Annex II was seen as a measure to reduce the impact on the environment and human health by reducing the amount of hazardous waste and the amount available in the recycling loop.

Although DEHP, BBP and DBP were identified to be potentially used within EEE, no evidence was found for the use of DIBP in EEE. However, owing to its similar functional properties and hazard profile with respect to reproductive toxicity, the risk of DIBP being used as an alternative was foreseen and thus recommended to be included in Annex II at the same time.

Further justification for the inclusion of these phthalates in Annex II was to align with REACH Annex XVII, entry 51 specifically for toys to avoid double regulation (8).

At the time of the adoption and publication of (EU) 2015/863, REACH Annex XIV included these phthalates due to their reproductive effects. Applications for Authorisation were received for DEHP and DBP for uses in EEE. As no applications were received for either BBP and DIBP these

[2] Hexabromocyclododecane (HBCDD), Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP)

substances could not be placed as the substances themselves or in mixtures on the EU market for use or used for the production of articles in the EU after 21st February 2015 (so-called Sunset Date) as per (EU) No 143/2011 and (EU) No 125/2012.

The Commission also advised that the compliance date of 22nd July 2021 should apply to Annex I categories 8 and 9 to respect the higher reliability requirements and longer innovation cycles of products falling within these categories and avoid legal uncertainty. The extension of Annex II would not exclude the ability for operators to apply for exemptions as per Article 5(1).

Substance	Sources of concern	Likely use areas	Availability of substitutes
Bis (2-ethylhexyl) phthalate (DEHP)	• Environmental releases during WEEE treatment notably to air (0.9 - 6.8 tonnes/annum) and wastewater (235 kg/annum). Releases could arise from landfill and incineration as well as shredding of PVC cables. • Potential for secondary poisoning. • Potential exposure of workers above the DNEC advised by RAC during mechanical treatment of WEEE and in plastics recycling. • Negative impacts on waste management due to reduced recycling possibilities (due to REACH) & collection of hazardous waste. • Concerns of endocrine disruption properties without threshold for safe use.	• In PVC as a plasticiser. • Not considered essential within EEE but niche applications could not be excluded.	• DINP (Di-isononyl phthalate) & DIDP (Diisodecyl phthalate) • DINCH (Di-isononyl cyclohexane-1,2-dicarboxylate) and ASE (Alkylsulfonic phenyl ester) identified to be available and technically feasible and have lower toxicity profiles and are reported to be used already. • Safe alternatives within the medical sector unknown.
Butyl benzyl phthalate (BBP)	• Environmental releases during WEEE treatment notably to air (0.06 – 0.56 tonnes/annum). Releases could arise from landfill and incineration as well as shredding of PVC cables. • Potential risk to workers in shredder plants. • Concerns of endocrine disruption properties without threshold for safe use.	• In PVC as a plasticiser. • Not as widely used in EEE as DEHP but niche applications could not be excluded.	As for DEHP plus DGD (Dipropylene glycol di-benzoate) and GTA (Glycerol triacetate).
Dibutyl phthalate (DBP)	• Environmental releases during WEEE treatment notably to air (0.15 - 1.4 tonnes/annum). Releases could arise from landfill and incineration as well as shredding of PVC cables. • Risk to workers of systemic toxicity due to repeated dermal exposure arising from aerosol forming activities & local effects to the respiratory tract due to repeated inhalation exposure. • Concerns of endocrine disruption properties without threshold for safe use.	• Not as widely used in EEE as DEHP but niche applications could not be excluded.	As for DEHP.
Diisobutyl phthalate (DIBP)	Exposure to the environment and human health were not assesses in the context of EEE due to its limited or non-use.	Understood to not be used in EEE but cannot be excluded from the scope of RoHS 2.	DBP

Table 1: Overview of the Commission's Assessment to include phthalates in Annex II of RoHS 2.

3 Developments within the EU since 2015

In the last six years there have been a number of regulatory developments with respect to the four phthalates included in RoHS 2 Annex II. The timeline of the developments within RoHS 2 and REACH are shown in the schematic in Figure 1 and are discussed in the following paragraphs as these are seen to be relevant within the context of this review.

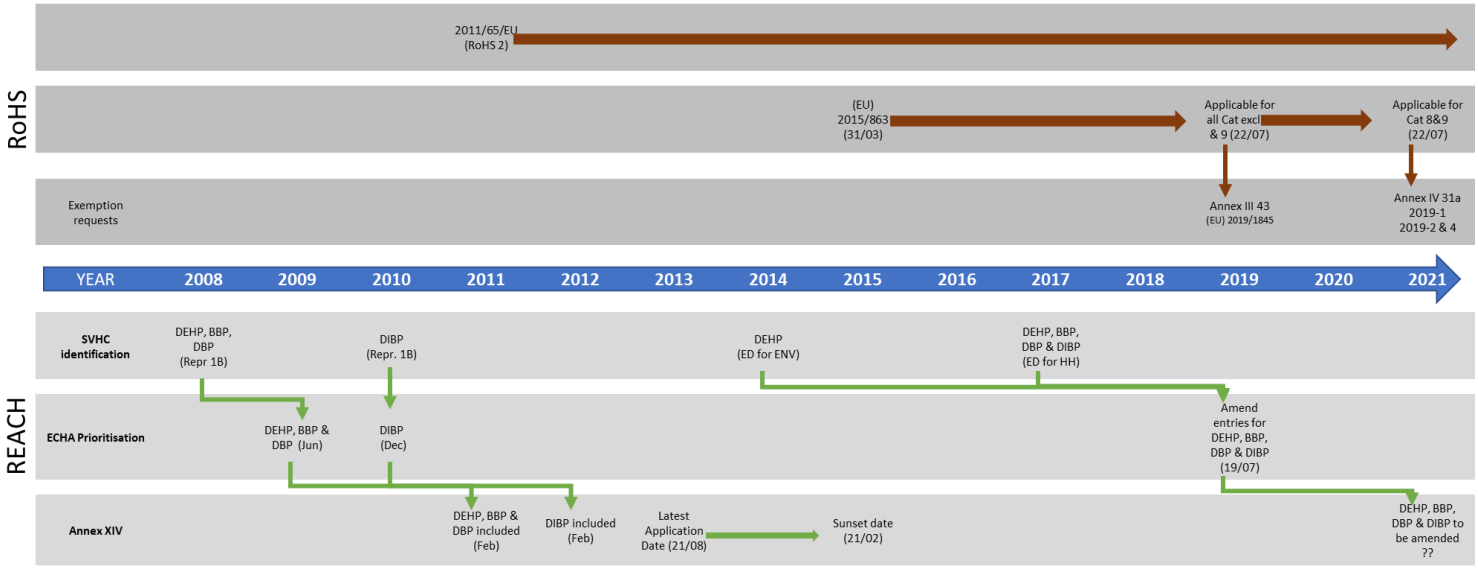

Figure 1: Overview of regulatory activities on phthalates (DEHP, BBP, DBP and DIBP) within REACH and RoHS 2.

3.1 EU REACH Authorisation

As remarked in Section 2, applications for Authorisation had been made for DEHP and DBP concerning EEE ahead of the Latest Application Date (LAD) of 21st August 2013. Anthesis' own analysis shows that applications included the use of DEHP or DBP as a plasticiser for PVC to be formed into articles as well as one use of DEHP to assist in the production of capacitors and lambda sensor elements which have been identified for use within the manufacture of computer, electronic and optical products, as well as wider electrical equipment (9). In this latter use, though, the applicant states that DEHP is not detectable in the final product as it is thermically decomposed during the production process of the ceramic article (11).

None of the authorisation applications considers 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 an authorisation for uses within medical devices when the intrinsic properties of the substance identified has hazards only affecting human health. Furthermore Article 62(6) states 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 identify phthalates and assesses the risk of those uses.

In late 2014, though, DEHP was identified as an SVHC for its equivalent level of concern based on its potential for endocrine disruption properties for the environment and 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

comitology process is already underway. Anthesis has confirmed that the WTO TBT was consulted (November 2020 – January 2021) (10) and the REACH Committee took a written vote on 5th March 2021 and approved the amendments with 26 Member States in favour and 1 abstention (11). The draft regulation must next be submitted to the European Parliament and Council for scrutiny and adoption before publication in the Official Journal. MedTech Europe anticipate that adoption will be in Q3 2021 which would mean the Latest Application Date would be in Q1 2023 based on an 18-month transition and the sunset date a further 18 months thereafter (12).

According to MedTech Europe, DEHP is used as a plasticiser in blood bags and intravenous bags, tubing, respiratory masks, nutrition pockets, catheters and disposable gloves (12).

If these medical device items are imported as finished articles into the EU then they would be exempt from needing an authorisation, as indeed would other imported articles containing phthalates. Authorisation only controls the use of the substance or the substance in a mixture and not the article itself unless that article is produced within Europe. 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 (13). Entry 51 was updated to its present form in December 2018 via the Commission Regulation (EU) 2018/2005.

3.2 Exemption requests under Article 5 of RoHS 2

The purpose of RoHS 2 is to restrict "the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE" (Art. 1). Article 5 permits exemptions to be sought where the amount of the restricted substance exceeds the concentration specified in Annex II and inclusion would not weaken the provisions set out within REACH and where any substitute is scientifically or technically impracticable, the reliability of the substitute is in question and socioeconomic benefits can be justified. New and renewal exemptions are granted or extended at the discretion of the Commission.

An exemption request was received and granted in 2019 for the use of DEHP in rubber parts in category 11 ((EU) 2019/1845) which was in line with the deadlines in (EU) 2015/863. The exemption was granted due to the uncertainty of the availability of alternatives beyond July 2019. At the time of the RoHS 2 application no application for authorisation had been received for the use of DEHP in rubber products and it was concluded based on the applicant's justification that the finished articles were imported and thus no authorisation was required and granting the exemption would not be in conflict with REACH Annex XVII.

(EU) 2015/863 provided a transition period for phthalates in EEE falling within categories 8 and 9 until 22nd July 2021. With this impending deadline four exemption requests have been received by the Commission and have been reviewed by the contractor Öko-Institut and their assessments and recommendations published in 2020 (14) (15). Table 2 provides an overview of the recommendations made by Öko-Institut, which were in principle to agree with the applicants' requests. In the case of the application submitted as an amendment to Annex IV number 31a the Öko-Institut foresaw two possible options for modifying the present exemption but did not suggest a preferred mechanism as this was considered out of scope. Referral by the European Commission to the WTO Committee on Technical Barriers to Trade (TBT) on 29th June 2021 has confirmed that the Commission has decided upon a new exemption (Annex IV, entry 47).

Publication of these three exemption requests in the Official Journal is expected imminently due to the 22nd July 2021 deadline in (EU) 2015/863 and much reduced commenting window by the WTO TBT of 15 days.

All three exemptions were discussed at the Member States Expert Group for RoHS on 23rd February 2021. The minutes from this meeting report that there was some discussion on spare parts as relevant to entry Annex IV, 31a but as the Directive does not allow for such a provision the proposal could not be accommodated (17). Reference to the SCIP database was also made but the minutes do not describe how this might impact the exemption request, if at all. Since 5th January 2021 article suppliers are required to notify articles containing SVHCs above 0.1 % (w/w) to the SCIP database to improve information in the value chain and specifically to assist waste operators (17), Anthesis therefore assumes this was mentioned during the meeting if only to record that information about WEEE would be better informed going forward about SVHCs therein.

Entry No.	Recommended exemption	Expiry Date (recommended)
Annex IV, 31a To be granted as Annex IV, 47 (text in bold)	Either as a new exemption: **Bis (ethylhexyl) phthalate, dibutyl phthalate, diisobutyl phthalate and benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.**	**7 years – 21 July 2029**
	Or as an amendment to the existing entry: Bis (ethylhexyl) phthalate, dibutyl phthalate, diisobutyl phthalate, benzyl butyl phthalate, lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.	Various due to the current exemption
2019-1	Bis (ethylhexyl) phthalate (DEHP) in ion selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids.	7 years
2019-2 merged with 2019-4	Bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils.	1 January 2024

Table 2: Overview of exemption requests received for phthalates for use in categories 8 and 9.

4 Impact of adopting (EU) 2015/863 in Great Britain

4.1 Links to UK REACH

On 1st January 2021 UK REACH (5) 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 allow for continuity of supply, transitionary measures have been put into place enabling prior supply chains to initially notify the substance(s) concerned followed by full registration within 2 to 6 years depending on the volume and/or hazards associated with the substance(s). These notifications can be made until 27th October 2021 and as a consequence there is currently no equivalent publicly available database of those substances registered in Great Britain.

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.

4.1.1 Annex 14 (Authorisation)

Substances included on 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 thus 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 awaited 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 (16) but is out of scope of this report.

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. Similarly, as only one application for authorisation for electrical equipment was identified and described in Section 3.2 it is more likely that phthalates will be contained in imported articles, if at all, and would thus be governed by Annex 17.

The Candidate List (the list of substances of very high concern (SVHCs)) is the precursor for including substances on Annex 14 and at the time of writing it is not known when the UK will move forward with updating Annex 14 and whether it will consider previous ECHA recommendations. The Candidate List was transposed on 1st January 2021 to UK REACH and includes those substances added up to and including June 2020 (19): thus, the phthalates are included for their endocrine disrupting properties for human health and the environment. If the Secretary of State's decision agrees with ECHA's recommendation (17) to amend the Annex 14 entries, then medical devices will be in scope of Authorisation.

4.1.2 Annex 17 (Restrictions)

REACH Annex XVII as of 31st December 2020 was transposed to UK REACH and included all EU restrictions that had entered into force which included any in their transitional period (18). 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. To date there have been no proposals from the UK Government to revise the present restriction for these phthalates.

4.2 Medical Device Regulations

The Medical Device Regulations (UK MDR 2002 (19)) 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 (20). 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.

4.3 Expected response by industry

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. COCIR was the applicant for the current exemption requests in the EU (see Table 2). The inclusion of the phthalates in Annex XIV owing to their endocrine properties to the environment will impact its Members' suppliers rather than the Members themselves, as the Members purchase components containing DEHP. However, the membership has been working to substitute phthalates from the components and the exemptions have been sought under RoHS 2 to bridge the gap between Annex II restrictions applying to categories 8 and 9 and replacement components being approved (e.g. in MRI coils) or better technologies with greater sensitivities for in vitro diagnostic devices being available to the market. COCIR's present concern is that the formal adoption and publication in the Official Journal will not be achieved by 22nd July 2021 for the new exemption requests (2019-1 and 2019-2/4), therefore they are working with the Commission to avoid having to stop selling such devices until the decision is in force (21).

Anthesis has identified a number of UK trade bodies supporting the medical devices industry and control instrumentation. A brief description of these is given below.

- 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 the majority of 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. MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health.
- 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.

Anthesis was able to engaged in some informal discussions with each. Neither BHTA's nor PAGB's members are concerned by phthalates and their inclusion in The RoHS Regulations. BHTA clarified

that in vitro and monitoring and control instruments are not within their scope and PAGB's website would suggest that the nature of the self-care medical devices is not of the type to be covered by The RoHS Regulations.

GAMBICA had evaluated the impact of the inclusion of phthalates prior to 2015 to their sectors. Their members had been proactive in asking their component suppliers to ensure that the restricted substances, including phthalates were not contained in their products. They also contributed to the drafting of the RoHS harmonised standard, EN IEC 63000:2018 which defines the tasks expected of a manufacturer to comply with the restriction of hazardous substances.

Even though some of GAMBICA's action pre-dated the UK's referendum to leave the EU, approximately one-third of GAMBICA's members' products are exported to the EU, so compliance with RoHS 2 is still required. The industry has had six years to remove phthalates from the supply chain and many supply chains adjusted before 2019 when the phthalates restriction in the other RoHS 2 categories came into effect (26).

The length of the implementation timeframe, and thus the fact compliance should not be a surprise for anyone was echoed by MedTech Europe. The representative also indicated that their members support harmonisation between jurisdictions as this means members have greater ability to supply single products globally without considering regulatory nuances between jurisdictions. Even COCIR who have supported the pending exemption requests, have members who have been reformulating or sourcing alternative products where possible. Furthermore, Great Britain's own guidance is worded to imply that medical devices and monitoring and control instruments will be in scope after the 22nd July 2021 (27).

Anthesis estimates that the economic impact of including the restriction of phthalates in categories 8 and 9 is likely to be low, i.e. less than ±£5 million annual net direct cost to business (EANDCB) not least as the exemption requests are less than the 10 years required to be considered with an Impact Assessment (27). In fact, through the informal discussions with the trade associations, Anthesis learned that a greater financial impact would be incurred if The RoHS Regulations did not follow those of RoHS 2 in the EU.

5 Recommendation

The decision to extend the scope of RoHS 2 Annex II and include phthalates in EEE is not new. Since the publication of RoHS 2 in 2011 these substances have always been a target for further review and with the developments under REACH to include them in Annex XIV industry has been aware of the growing concern about the safe use of these substances. Evidence suggests that industry has already moved away from their use in EEE, given the few exemption requests received by the European Commission for the use of phthalates above 0.1% (w/w) in medical devices (Category 8) and monitoring and control instruments including industrial monitoring and control instruments (Category 9).

The modification to accommodate the whole of scope of (EU)2015/863 in The RoHS Regulation is anticipated to have little negative impact on operators or society, but rather, as anticipated by the EU, a positive impact protecting human health and the environment. It is therefore recommended to include the restriction of phthalates in medical devices (Category 8) and monitoring and control instruments including industrial monitoring and control instruments (Category 9) in The RoHS Regulations.

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