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Impact of the RoHS Directive – Scope and Additional Substance Evaluation

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EXECUTIVE SUMMARY

MedTech Europe has asked RINA to review the past and potential future impact of the RoHS Directive on medical devices and healthcare provision in the EU.

Issue 1.1 of this report was submitted as part of the previous Stakeholder Consultation. The version (with minor amendments) of issue 1.1 is now marked as **Part 1**, which describes results of a survey of MedTech Europe's members. Concerning the costs of compliance, these were reported to vary between a one-off cost of compliance between 0.1 to 10% of revenue/turnover and additional yearly on-going cost of compliance. The impact on the environment due to the inclusion of medical devices in the RoHS Directive was calculated as contributing a reduction of between 8.6×10^{-7} to 2.8×10^{-12} % of total EU emissions of specific metals, with the values dependent on the substance and their respective reductions.

The reduction of RoHS substances in medical devices has been due to significant effort undertaken by the medical device industry, with some substance uses being reduced significantly and others still requiring the use of exemptions, notably lead. However, the RoHS Directive has negatively influenced innovation of medical devices and therefore healthcare provision within the EU due to factors such as increased product prices, delays in development of new products with superior capability and withdrawal of products. There is limited evidence that reliability of devices has been affected, likely due to the extensive testing required and lengthy qualification periods for medical devices, with timeframes of 2-8 years, which, due to limited data, may be an underestimate. Full details of the results and their impacts are described in this report.

Part 2 is concerned with the three potential additional RoHS substance restrictions that are the subject of the current consultation. Of these, any restriction on diantimony trioxide is likely to have the largest effect on MedTech Europe members. The Öko Institut has reported that the risk of harm to consumers and to the environment are "low". However, as shown in this report, such a restriction could have a very large negative impact on healthcare provision in the EU. The recommendations from Öko for restrictions of Tetrabromobisphenol A and Medium Chain Chlorinated Paraffins are discussed in detail in this report, and, in particular, whether RoHS is the most appropriate mechanism to manage these substances given that in some cases the main uses are outside the scope of products covered by RoHS.

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1 INTRODUCTION

The EU RoHS Directive has restricted six substances in electrical and electronic equipment (EEE) since 2006, with a further four restricted by the amendment to RoHS by Directive 2015/863. The EU RoHS Directive has had a very significant impact on the design of medical devices, including *in vitro* diagnostic (IVD) medical devices, as changes to materials and designs have had to be made to comply with substance restrictions. A decrease in use of hazardous substances would appear to be beneficial to health and the environment; however, the RoHS Directive restrictions were adopted on the basis of the precautionary principle. Hence, harm from RoHS substances has not necessarily been proven in all instances, even though harm from some substances is known to have been caused in the past, such as from unsafe recycling of illegally exported circuit board scrap in developing countries causing lead poisoning.

Benefits may arise from reduced mining, refining and production of raw materials and components if reuse or longer lifetimes were encouraged by legislation. Benefits may potentially arise from processing waste electrical and electronic equipment (WEEE) at end-of-life, although it is unclear whether WEEE that contain hazardous substances is any more difficult to recycle than WEEE not containing these substances. Increased reuse of parts and equipment would also be beneficial if this is encouraged and permitted by legislation. Emissions of lead into the air can occur during end-of-life recycling processes with the quantities emitted depending on how the waste equipment is recycled or landfilled.

The RoHS Directive permits the European Commission (EC) to amend Annex II of the directive, which is a list of the restricted substances, in order to protect health and the environment. The EC has asked the Öko Institut to assess seven types of substance for possible addition to Annex II. Öko has concluded in its reports that four of these should not be restricted.

This report comprises the previously submitted report (Part 1) with minor amendments, and Part 2 covering the additional substances.

1.1 OBJECTIVES

The results in this report can be used by MedTech Europe to help ensure that any future restrictions are proportionate, reasonable and to minimise the negative impacts on healthcare provision in the EU.

1.1.1 Part 1: RoHS Impact Analysis

Medical devices have been in scope of the original six RoHS substance restrictions from 22 July 2014 for medical devices and 22 July 2016 for IVD medical devices, and will need to comply with the additional four phthalates restrictions from 21st July 2021. In the future further restrictions may be adopted by the EU. MedTech Europe has asked RINA to review that past and potential environmental and health costs and benefits of the RoHS Directive.

An impact analysis has been carried out by RINA to determine the costs and benefits of RoHS on MedTech Europe members' products. A questionnaire was prepared and sent to MedTech Europe members with questions around the following topics:

- RoHS substance use and impact of RoHS on these amounts;
- Impact of RoHS exemptions;
- Financial impact of RoHS on medical devices;
- RoHS implementation timeframe;
- Reliability impact from RoHS;
- Refurbishment; and
- Disposal at end-of-life.

Fourteen companies responded to the questionnaire, representing over a quarter of the market share of medical device companies[1], with some companies detailing business unit specific answers, resulting in 20 responses with respondents from Europe, North America and Asia.

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[1] Calculation based on figures from https://www.medicaldevice-network.com/features/top-medical-device-companies/ and https://www.statista.com/statistics/329035/global-medtech-market-share-of-top-20-companies/

Further clarification questions and detailed discussions were undertaken with specific members where additional information was able to be provided. The data collected from members of MedTech Europe was supplemented by publicly available information sourced by RINA to aid comparative studies and benchmarking.

1.1.2 Part 2: Additional Substance Evaluation

Currently, the Öko Institut is assessing seven types of substances on behalf of the European Commission. MedTech Europe has asked RINA to carry out an assessment of the potential impact on medical devices if any of these are restricted by the RoHS Directive, and to apply a methodology to estimate the time required for substitution to provide evidence of the minimum transitional period (from date of adoption of legislation to being able to sell approved compliant products) required by the medical device sector. The assessment will analyse current uses, whether substitutes are available, sources of data on exposure to the proposed substances, and likely timescales required by the medical sector if restrictions are adopted.

2 CHARACTERISTICS OF MEDICAL EQUIPMENT

Medical equipment has significant differences to electrical products in the other RoHS Directive Categories. The following are some of the key differences:

- Products are often safety critical, with improvements to medical products helping to save lives or improve the quality of life of EU citizens;
- Number of produced items is relatively small when compared with consumer products;
- Medical devices have a long product lifecycle with long lifetimes and development timeframes. Consequently products require long-term reliability of supply of parts to support long product lifetimes;
- Availability of skilled engineering and leadership within the market is limited owing to the complexity of the products. This limits the ability of manufacturers to develop new innovative products if their engineers have instead to work on substitution of substances;
- Cost of compliance to RoHS and other legislation can be extremely high; and
- Components used in medical devices often require bespoke parts to be developed and qualified; therefore, the redesign and testing requirements for each company can be very significant.

Consequently, the RoHS Directive can have a more significant and potentially negative impact on medical devices than on other products in scope.

The medical technology market is expected to grow by a compound annual growth rate of around 7%, reaching a volume of €380 billion[2] by some accounts and €458 billion[3] by others, and the electrical medical technology sector is a significant part of these totals. The EU impact assessment of inclusion of categories 8 and 9 carried out in 2008 estimated the electrical medical market in the EU to be €95 billion in 2005 (€287 billion globally)[4].

3 MEDTECH EUROPE AND ITS MEMBERS

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Its members manufacture a wide variety of medical devices as well as *in vitro* diagnostic (IVD) medical devices. Many of MedTech Europe's members produce non-electrical products that are outside of the scope of RoHS, but many manufacture electrical medical equipment that fully complies with the EU RoHS Directive and have done so since medical devices and IVD medical devices were brought into scope by Directive 2011/65/EU. MedTech Europe's members assert that they aim to design and manufacture new medical devices that have superior capability to save lives and to improve diagnosis and treatment.

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[2] Refurbishment of medical equipment, Report on promising KETs based product nr. 4, Key enabling technologies observatory, 2015.

[3] The digital era in the MedTech Industry, Deloitte.

[4] Study to support the impact assessment of the RoHS Review, Bio Intelligence Service, 2006. https://ec.europa.eu/environment/waste/weee/pdf/ia_report.pdf

As with all manufacturers of electrical equipment, medical device manufacturers must comply with all applicable legislation, ensure the safety of their employees and maintain production. However, any increase in compliance or production costs will inevitably reduce funds and the time of suitably trained and experienced engineers available for new product development. As new medical devices can give superior health outcomes, the cost of compliance with RoHS compared to the benefits of RoHS is explored by this study.

PART 1 - IMPACT OF THE ROHS DIRECTIVE

4 ROHS IMPACT RESULTS

The responses from MedTech Europe members show a reasonable amount of variance, which is to be expected due to differences in company size, the make/buy ratio, the types of products sold, the type of technology of the equipment and company specific design cycles. Therefore, where data has been provided the minimum and maximum values are stated, with an average quoted where this is helpful adds value.

4.1 QUANTITIES OF ROHS SUBSTANCES

4.1.1 MedTech Europe Quantity Information

MedTech Europe conducted a survey of its members in November 2019. A key finding of this survey was that the only uses of RoHS substances was in exempt (i.e. permitted) forms but MedTech Europe members do not have information on quantities of the substances as their suppliers are not obliged to provide this information.

The MedTech Europe survey results, as outlined in Table 1, summarises the responses from the survey.

Table 1 RoHS Substance Quantities from MedTech Europe Members (including exempt uses)*

Substance	Amount pre-RoHS (% of parts)	Current % of parts
Lead	Average of 13% of parts, with most MedTech Europe members no longer having this data. One respondent stating up to 800 parts were affected	Most reported to be used at up to 23% of parts with an average proportion significantly less**
Mercury	One respondent stated 0.07%, with more than 50 parts identified by another	Still used in backlights by a few respondents
Cadmium	Four respondents averaging as 0.5% of parts	0% for most respondents. Three companies responded stating use with a max of 0.45%
Hexavalent chromium	Three respondents averaging as 5% of parts	0% reported
Polybrominated biphenyls (PBB)	None identified	0% reported
Polybrominated diphenyl ethers (PBDE)	Not determined until substitution programme began	0% reported
Bis(2-thylhexyl)phthalate (DEHP)	One company stated 4% of parts, the majority not determined until obligation began	2.7% from the same company, reported present. Other MedTech Europe members reported 14 as the average number of parts
Butyl benzyl phthalate (BBP)	Not determined until substitution programme began	0% reported
Dibutyl phthalate (DBP)	Not determined until substitution programme began	0% reported
Diisobutyl phthalate (DIBP)	Not determined until substitution programme began	0% reported

*Due to the short timeframes to gather the data on RoHS substances use, some MedTech Europe members were unable to collate their data in support of the questionnaire

** The data would suggest an increase in lead use post-RoHS which is clearly not the case but is due to pre-RoHS data reported at a low level due to a lack of time to collate data

It is clear from the MedTech Europe survey that MedTech Europe's members have made very significant efforts to remove restricted substances from their products and to only use RoHS restricted substances where no alternatives exist and are permitted by exemptions justified according to the criteria allowed by RoHS Article 5.1. These exemptions are time limited with some being required for many years and some may never be possible to remove for fundamental technical reasons. However, there are many cases where RoHS substances have been substituted, with many respondents completely eliminating cadmium and mercury and all eliminating hexavalent chromium, BBP, DBP and DIBP.

The survey of MedTech Europe members has shown that lead is still widely used in exempt forms. As non-exempt forms of restricted substances are not permitted, there will have been significant reductions in its use such as in solders used on printed circuit boards. One MedTech Europe member reports that replacement of lead solders by lead-free in one type of relatively large product has prevented about 1 kg of lead entering the EU market, whereas with another product, only a very small quantity of lead has been prevented.

It is understood that MedTech Europe members will comply with the phthalate substance restrictions from July 2021 and are currently working to substitute these substances and are therefore currently determining where these substances occur.

In support of information provided by MedTech Europe, RINA has gathered publicly available information, as well as information RINA has access to including historic uses of RoHS substances used in Section 4.1.2, the legislative impact on RoHS substance use in Section 4.1.3 and current levels of use in Section 4.1.4.

4.1.2 Reduction in RoHS Substances prior to RoHS requirement

In 2006, a study was carried out by ERA Technology for the European Commission to determine whether it was possible to include Category 8 in scope of the RoHS Directive[5]. This study estimated the amounts of the original six RoHS substances used by the medical technology sector in electrical products sold in the EU at that time, i.e. before substitution of the original six substances. It included data produced by the three main medical technology trade associations (COCIR, EDMA and EUCOMED[6]) which at the time was considered reliable, although there was significant uncertainty over the amounts of hexavalent chromium and PBDEs.

When Category 8 applications were included in scope, it was necessary to grant exemptions for some of the RoHS substances for uses where no alternatives could be identified. Therefore, the quantities of lead, cadmium and mercury in medical devices has not decreased to zero.

ERA's 2006 data[4] is shown in Table 2. The ERA study obtained data for the entire medical technology sector and also specifically for imaging equipment such as MRI, X-ray, CT, ultrasound, etc. The imaging sector uses unusually large amounts of some of the RoHS substances but these uses have no alternatives and so exemptions have been granted (e.g. lead in radiation shielding and cadmium in X-ray detectors). Therefore, in Table 2, quantities of RoHS substances are quoted (data from the ERA study) for:

- The entire medical technology sector; and
- The medical technology sector excluding imaging.

RINA has also estimated the current quantities used of the original six RoHS substances assuming that these are used only in exempt forms. These quantities are listed in the right hand column of Table 2. The data is from various sources:

- From the ERA study where this provided quantities for specific uses such as radiation shielding;
- From COCIR; and
- RINA's estimates where no other data is available (e.g. mercury in lamps and cadmium in filter glass and contacts).

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[5] Review of Directive 2002/95/EC (RoHS) categories 8 and 9, ERA technology, 2006. https://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf

[6] COCIR - European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry, EDMA - European Diagnostic Manufacturers Association, EUCOMED - European Confederation of Medical Suppliers Association. EDMA and EUCOMED together formed MedTech Europe.

Table 2. Estimated Quantities of the Original RoHS Substances in Medical Devices Placed on the EU Market and Current Estimated Amounts Permitted by RoHS Exemptions

Substance	All Cat 8 – pre-RoHS (from ERA study)	Cat 8 – pre-RoHS excluding imaging (COCIR) from ERA study	Cat 8 – Current Use
Lead	Ca. 1,300 tonnes	< 80 tonnes	758 tonnes shielding 6 tonnes superconductor bonds 3 tonnes in alloys <1 tonne other exempt uses Total = 768 tonnes
Cadmium	Ca. 1,700 kg	<10 kg	Now used only in exempt applications: 13b filter glass and 8b contacts (quantities not known, probably <1 kg) Annex IV ex 1 CdZnTe detectors (600 kg from COCIR)
Mercury	4 – 12 kg	Only slightly less than 4 – 12 kg (used in electrodes an backlights)	Not known, probably only a few kg
Hexavalent Chromium	2 kg (uncertain, may have been 100 – 400 kg)	1 kg, but uncertain	0
PBB	0 (no known uses)	0	0
PBDE	<8000 tonnes in Cat 8 & 9 (~4000 tonnes is more realistic for Cat 8 & 9 so ~ 2000 tonnes in Cat 8 seems more realistic)	Not known	0

Despite extensive study, RINA has not been able to confirm that PBB has ever been used in the types of electrical equipment in scope of the RoHS Directive. Many manufacturers have analysed plastics to determine compliance during the last 14+ years, but none has reported finding PBB.

The reduction in the quantity of lead shown in Table 2 is mainly due to manufacturers now using lead-free solders and polyvinyl chloride (PVC) now being stabilised with alternative stabilisers. The reduction in use of cadmium is partly because cadmium phosphors are no longer used in image intensifiers, cadmium plating is no longer used, copper-cadmium flexible cables have been replaced and fewer cadmium contacts are used by the medical technology sector.

The above data may over-estimate the reduction in amounts used that were due to inclusion of medical devices in the scope of RoHS as other influences will have resulted in substitution even if Category 8 had not been included in scope. These factors included trends within the electronics industry to comply with RoHS since 2006, in particular the phase out of RoHS substances in components which will have resulted in significant reductions in lead in component termination coatings, lead and cadmium stabilisers in PVC, PBDE in plastics of electronic components and reductions were also achieved by voluntary substitution by medical equipment manufacturers.

MedTech Europe members are primarily users of electronic components and do not manufacture electronic components. Therefore trends within the electronics industry to, for example, replace lead in lower voltage ceramic capacitors (so that exemption 7c-III is no longer needed), develop new flip chip devices without lead solder bumps (so that exemption 15 can be replaced by 15a), etc. all result in less RoHS substances in medical devices, but have nothing to do with medical devices being included in RoHS.

4.1.3 Reduction due to Other Legislative Impacts

Due to the timescales of other legislation implementation, as well as the inclusion of Category 8 applications in RoHS, substances have been designed out prior to RoHS Implementation. One such example is the REACH Regulation (1907/2006) which applies to all substances, in mixtures or in articles, including substances in EEE. Consequently, the scope of RoHS and REACH partially overlap. The complexity of interacting legislation is

acknowledged in the REACH and RoHS review[7] undertaken by the EC which concluded that RoHS should be given priority over REACH for issues concerning the use of substances in EEE.

A large proportion of EEE is imported into the EU, which means it is not subject to the authorisation requirement under REACH. It was decided, based on a Commission funded study that it was appropriate to include the four phthalates in RoHS in order to ensure they were not used in electrical products. However, DEHP, BBP, DBP and DIBP were added to REACH Annex XIV in February 2012 with a "sunset date" of 21st February 2015 meaning they could not be manufactured or used in the EU after this date (without authorisation). This had a significant impact in reducing the use of these substances before their inclusion in RoHS for Categories 8 and 9 equipment which is not until 21 July 2021. Previously, all four phthalates were included in the Candidate List as Substances of Very High concern (SVHC's) which resulted in many manufacturers globally substituting these substances in parts used by the electronics industry (see Section 4.1.4). One MedTech Europe member has reported that only 0.1% of 90,000 parts surveyed in July 2019 contained phthalates due to other legislative drivers.

In addition to REACH, mercury was restricted by many US States starting in the late 1990's, resulting in the discontinuation of mercury in switches, thermostats, etc. by many manufacturers. The result these US State restrictions was that only 4 – 12 kg was thought to be used in medical devices in the EU before these were brought into scope of RoHS and most of this mercury was in uses with no alternatives (such as in electrodes).

PBDE is a family of flame retardants that includes very harmful tetra-, penta-, hexa-, hepta- and octa- bromodiphenyl ethers. When RoHS was adopted, Deca-BDE was not classified as being hazardous nor was the commercially available material that contains a small proportion of nona-BDE. Of the PBDEs, only tetra-, penta- and octa- were made commercially available although these were impure and contained other isomers. Tetra-BDE production was discontinued globally in the 1980s. Penta- and octa-BDE were determined to be Persistent Organic Pollutants (POPs) and so were banned globally by the Stockholm Convention. The EU adopted a POPs ban for these substances in 2004, which pre-dates RoHS and so RoHS only affected commercial Deca-BDE when it entered force in 2006. It has since been discovered that Deca-BDE is hazardous and so is now banned by the EU REACH Regulation.

4.1.4 Current RoHS Substance Use

The quantity of the four restricted phthalates used in electrical equipment has not been determined by the electronics industry, but historic published studies with this data are available. The quantities of phthalates are from before 2010, so do not take into account the very significant influence of the REACH Regulation on the use of these substances. All four phthalates are REACH SVHC's, three since October 2008 and DIBP since January 2010. Although being an SVHC is not a restriction, it does encourage manufacturers to substitute and this has occurred to a significant extent with all four phthalates before they were restricted by RoHS. RINA has monitored their use since 2008 and has found:

- Google search results for safety data sheets of adhesives and paints with DBP (Dibutyl phthalate) or DEHP (Bis(2-ethylhexyl) phthalate):
    - 2014 – A large number of materials contained DBP or DEHP;
    - 2019 – Very difficult to find DEHP in any adhesives (a few for PVC tape) with most now using DiNP (Diisononyl phthalate), DiDP (Diisodecyl phthalate) or a non-phthalate alternative;
    - 2019 - DBP is still used in some paints, but is less common than in 2014;
- DEHP in cables – confidential information from a UK components distributor was that in 2010, most PVC wire insulation contained DEHP, whereas by 2012 none that they supplied contained DEHP; and
- Review of EU and US PVC insulated wire and cable manufacturers in 2015 showed that by this date, most EU and US manufacturers had stopped using DEHP as they had substituted DEHP since it had been added to the REACH Candidate List of SVHC's. There was no information on Asian manufacturers except for that from the UK distributor described above which indicated that they had also phased out DEHP.

The four phthalates are now also included in Annex XIV of REACH which will have also very significantly reduced their use as substances in the EU. There are strong indications that inclusion of DEHP, BBP, DBP and DIBP as restricted substances has had minimal impact with evidence compiled from both national and commercial article surveys.

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[7] REACH and Directive 2011/65/EU (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE), European Commission, 2014.

The estimated quantities of the four phthalates before they became REACH SVHC's is outlined in Table 3. The quantity data in the right hand column of Table 3 is estimated using data from various publications as referenced in the middle column. The quantity data given in the publications is not the amounts used in electrical medical devices but in all uses. Some data is only from EU manufacture of chemicals, so is of limited use, however it does show that use in electrical equipment is a fairly small proportion of all uses. Data for two of the phthalates in the German Federal Environment Agency Umweltbundesamt (UBA) studies, which were carried out for the European Commission as part of the last RoHS review, is for the amounts of the phthalates in electrical equipment used in the EU and is data extrapolated from a Danish study. It is not clear how accurate this is and UBA give quite large ranges of possible quantities. UBA could not give a figure for BBP and they did not consider DIBP.

Table 3. Estimated Amounts of the Four RoHS Phthalates Used in the EU before Addition to the Candidate List

Substance	Data source	Amount used per year
BBP	COWI A/S consulting group, 2009	EU use 2007 In formulations: ca. 2,800 tonnes (1,520 in sealants (double glaze windows), 540 in extrusions and 400 tonnes in adhesives) Processing: ca. 8,000 tonnes – decreased from 19,400 in 2004* (3840 in flooring plastisols, 800 coatings of leather and textiles, 640 tonnes in hard PVC). 54% used in flooring, 19% in sealants, 10% in coatings of fabrics, etc. i.e. electronics is <10% of uses. 10% of 2,800 is 280 tonnes.
	UBA	No quantity known. Most is used in PVC flooring, but an unknown amount in EEE
DEHP	Annex XV dossier	EU production 2004 was 247,000 tonnes, consumption was 221,000 tonnes. No data on % used in EEE. However flexible PVC was a very significant use. EU consumption has decreased from 476,000 tpa in 1997.
	UBA	12,400 to 37,200 tonnes p.a. in EEE in the EU
DBP	Annex XV report	20,000 to 40,000 EU consumption in 1997
	UBA	5000 tonnes used in EEE
DIBP	Annex XV report	10,000 to 50,000 tonnes produced in the EU
	Öko "RoHS Annex II Dossier for DIBP" (RoHS impact assessment)	Öko concluded that DIBP is not used in EEE (note however that KEMI has found non-compliant EEE that contains DIBP)

The transition from phthalates such as those impacted by RoHS started significantly before the inclusion as a restricted substance under RoHS. The amounts of each of the substances in EEE post-REACH inclusion is extremely hard to find as no comprehensive studies have been carried out. However it is recognised that since 2005 active efforts have been made to reduce the volumes of medical products containing phthalates[8]. Table 4 details RINA's estimates based on the anecdotal information described on page 7. In Table 4, the quantity used in medical devices (pre-RoHS) assumes that medical devices are 1% of the mass of all electrical equipment in scope of RoHS sold in the EU (based on EUROSTAT WEEE data). The post RoHS data includes uses of the RoHS substances for which the medical technology sector has requested exemptions as RINA assumes that MedTech Europe members will be fully compliant after 21 July 2021.

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[8] Phthalates which are toxic for reproduction and endocrine-disrupting – proposals for a phase-out in Sweden, KEMI, 2015.

Table 4. Changes in Quantities of Four Phthalates in Medical Devices due to REACH and RoHS

Phthalate	Quantity used in EEE per year in the EU (Cat 8 = 1%)		
	Pre-RoHS and pre-REACH in Cat 8	Pre-RoHS but post REACH	Post RoHS (after July 2021 in Cat 8
DEHP	1240 to 3720 tonnes	Very large reduction due to REACH SVHC classification and addition to Annex XIV. Likely to be at least 80 – 90% of uses in EEE replaced. Potentially down to at most 1,240 tonnes in all EEE so <12 tonnes in Cat 8.	A few kg in applications requested exempt
DBP	500 tonnes	Very large reduction due to REACH SVHC classification and addition to Annex XIV. >75% of uses in EEE replaced. Potentially down to 1,250 tonnes in all EEE, 1.2 tonnes in Cat 8.	Should be 0
DIBP	0 tonnes	Some use due to substitution of DBP, but amount still very small (potentially <1 tonne)	Should be 0
BBP	<2.8 tonnes	Large reduction due to REACH SVHC classification and addition to Annex XIV. Potentially down to 70 tonnes in all EEE, 0.7 tonnes in Cat 8.	Should be 0

The magnitude of the reductions as outlined in Table 4 may be under-estimated, as medical equipment manufacturers (surveyed MedTech Europe members) have estimated the quantities of RoHS restricted substances that are currently used as detailed in Table 1 which detail lower phthalate use.

4.2 HEALTH AND ENVIRONMENTAL BENEFIT FROM NOT USING ROHS SUBSTANCES

The reason for RoHS restrictions is to protect human health and the environment (Article 1). There is no doubt that there has been a reduction in the quantity of RoHS substances used including by the medical technology sector, but it is less clear whether the size of this reduction has resulted in a significant benefit to human health and the environment and so this is assessed here. Calculation of benefits is not straightforward as this depends on many factors. This report focuses on end-of-life processes because RoHS is mainly concerned with end-of-life. The main factor that affects emissions is the process used. Most medical devices are business-to-business (B2B) and metal-rich and so are highly likely to be recycled by competent recyclers in the EU, as discussed further in Section 4.7. EU recyclers are regulated by the EU Industrial Emissions Directive (IED), which grants permits to recyclers but imposes emission limits that are based on “Best Available Technology Reference Guidance” (BREF Guides). The following methodology was utilised for the calculation of emissions in Table 5:

Lead: The non-ferrous metals BREF Guide is especially useful for lead as it gives limits to lead emissions from metal scrap recycling (based on two types of process). The approach used in this report and included in Table 5 is to calculate the quantity of lead that would have been emitted by recyclers from the lead avoided by RoHS. The calculation used the values of mg of lead emitted per tonne of lead produced and assumed that this is equal to the amount of lead in scrap treated, as yields are very high. This calculation used the mg lead emitted to air and water /tonne lead produced data provided by the BREF Guide.

Cadmium and Mercury: As cadmium and mercury are likely to occur with copper, emissions of these metals from scrap copper recycling process can be used. However these are quoted as mg/m^3 and so are not directly comparable with the amounts of these metals present in waste streams.

Therefore, the following approach has been used: For cadmium, copper scrap would contain much more lead than cadmium so it is possible that a higher proportion of input cadmium will be emitted to air than lead, perhaps up to 5 times more cadmium is emitted than the equivalent amount of lead as a proportion on input metal. RINA has therefore used the factor of 5 with the lead emission figure in mg/tonne of lead produced to calculate emissions of cadmium. The same approach is used for mercury.

Hexavalent chromium: Hexavalent chromium will usually occur as paint or passivation coatings on steel or aluminium. During the metal smelting process, all hexavalent chromium will be reduced to chromium metal or trivalent chromium and so there are no hexavalent chromium emissions.

PBB: It is widely accepted that PBB has never been used so no emissions are possible.

DIBP: It is widely accepted that DIBP is not in use in EEE so no emissions are possible. DIBP's inclusion in RoHS was due to the connection with the possible restriction of the phthalates DEHP, BBP and DBP.

PBDE: Whether any emissions occur depends on the recycling process used. Scrap EEE is usually shredded and separated into various fractions. Any PBDE present in metals fractions should be destroyed along with any harmful by-products such as dioxins and furans by the very high temperatures that are necessary to melt the metals. Also, the IED requires that all metals recycling processes destroy the harmful by-products that will be emitted from all types of plastics when they are burned (polycyclic aromatic hydrocarbons). Most medical devices that reach end-of-life in the EU are recycled in the EU due to their high metals content and safe processes should be used as long as the legislation is effectively enforced. Plastics fractions can be sorted by various methods and plastics containing halogenated flame retardants, can in principle, be separated and reused, however this is rarely carried out as the value of and demand for separated plastics is very low. Reuse is discouraged by EU legislation especially if there is a risk that they will contain a POP. Reuse in new EEE is also discouraged as there is no exemption for deca-BDE is reused plastics. As a result, most plastics are either landfilled or incinerated and when this is in the EU, there are no emissions of PBDE from well-managed landfill sites and emissions from incinerators are strictly regulated so that no harmful emissions occur.

Table 5 Emission Reduction from Recycling per Year

Substance	Reduction in use by Cat 8 (including medical imaging devices)	Emissions from EU recycling avoided
Lead	532,000 kg	1.436 kg emitted to air (based on lead refinery) 160 g based on ISASMELT 46 g to water
Cadmium	1,100 kg	1,100kg x 5 x 0.00003% = 1.65 g emitted to air If the worse lead smelter emission figure is used: 1,100 kg x 5 x 0.00027% = 14.9 g
Mercury	Up to 12 kg	Emissions from copper smelting are the same as cadmium, so at worst 12 x 5 x 0.00027% = 0.16 mg
Hexavalent Chrome	2 kg (uncertain, may be higher)	0 (converted to Cr metal or trivalent chromium during smelting)
Phthalates	see Table 4	Should be zero when destroyed by thermal recycling. Emissions during production phase and during shredding of waste will however be reduced by this restriction (see Section 4.2.2)
PBB	0 kg	0 as not used
PBDE	Ca. 2,000,000 kg	Should be 0 kg as destroyed by thermal recycling and manufacture and use will be restricted by the REACH Regulation

4.2.1 Comparison with Total EU Emissions

The decrease in emissions of RoHS substances due to the inclusion of medical devices in scope of the RoHS Directive is relatively small as especially when compared with total published EU emissions (for 2016) of lead, cadmium and mercury, outlined in Table 6[9].

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[9] EU Emissions Inventory report downloaded from https://www.eea.europa.eu/publications/european-union-emissions-inventory-report-2017

Table 6 Reduction of Material use due to RoHS

Substance	Total EU emissions	Decrease due to inclusion of medical devices in scope of RoHS	% of total EU emissions
Lead	1,661 tonnes (29% from industrial processes)	1.436 kg	$8.6x10^{-7}$
Cadmium	71 tonnes (42% from energy generation and industrial energy use)	14.9 g	$2.1x10^{-7}$
Mercury	58 tonnes (59% from energy generation and industrial energy use)	0.16 mg	$2.8x10^{-12}$

As stated in Table 5, emissions from the other original RoHS substances should be zero.

4.2.2 Phthalates

All four RoHS-restricted phthalates readily decompose to safe by-products (mainly CO_2 and water) when heated in air during high temperature recycling processes and there will be no emissions of phthalates. The only possible sources of phthalate emissions are during manufacturing processes and when scrap EEE is shredded if plastic dust is generated. Comprehensive EU risk assessments have been carried out on DEHP, DBP and BBP which covered all life cycle phases from manufacture to end-of-life. As a result of these studies, restrictions in toys and children's products were adopted by the REACH Regulation and workplace exposure limits imposed. The RoHS restriction was not based on these studies, which did not recommend restrictions in products that are sold to adults. Further research on the hazard classifications (e.g. the four phthalates were recently classified as endocrine disruptors) of all four phthalates has been carried out since these studies were completed and any future REACH regulation will be based on the results of this research, and so should be proportionate. If research shows that any substance is potentially more harmful than previously thought based on studies of their properties this could affect future restrictions.

4.2.3 Regrettable Substitutions

An issue that arises whenever one substance is replaced by another is ensuring that the substitute has a smaller impact on health and the environment. When deciding whether to restrict a substance the EU should take into account whether safer alternatives exist, however, often the potential alternatives are relatively new substances, made in smaller quantities where much less research has been carried out on their health and environmental hazards than commonly used, large-tonnage substances that have been thoroughly studied. It would be unwise to encourage manufacturers to replace one substance where the only suitable substitutes may be equally harmful or worse. This issue is described in more detail in Section 6.4.

4.3 COST IMPACT

RoHS compliance costs have been and will continue to be incurred by all medical equipment manufacturers, with these costs potentially being passed on to customers as higher prices (or smaller price reductions) or at the expense of reduced investment in new products.

Typical compliance costs include, but are not limited to:

- Legislation tracking and implementation into company systems;
- Review of product impact for legislative requirements;
- Tracking and update of RoHS compliance in the supply chain and internally designed items;
- Investigation into alternative RoHS compliant alternatives;
- Research, trials and testing of prototypes;
- Clinical trials if changes are significant;
- Redesign and rewrite of software;
- New process equipment and procedures;
- Potentially higher component or material price for RoHS compliant version or processing costs;
- Global approvals; and
- Validation and approvals from Notified Body if the change is significant.

Healthcare providers in EU Member States (i.e. hospitals and clinics) all have limited budgets which would not be increased due to legislative requirements such as RoHS. Consequently, if prices were to increase less new equipment would be purchased and the health benefits from new technology would be delayed, resulting in less effective detection and diagnosis of disease and inferior treatment of patients leading to reduced quality of life and inferior outcomes including possibly earlier death. Where legislative costs impact innovation, as detailed in Section 4.4, a similar outcome could be expected due to a reduction in advancements in unique capability.

The results of the survey of MedTech Europe's members shows very large variation in the size of transition costs to convert products to comply and for on-going compliance. There are many reasons for this variation such as differences in accounting practices, how the cost is calculated, e.g. for the whole company, for a business unit or for a specific product type and some manufacturers produce both electrical and non-electrical products and compliance costs are incurred only by the electrical products. Of the 20 survey responses received, only a few were able to produce quantitative data on the cost of compliance, with the ranges of values and averages outlined in Table 7.

Table 7 Financial Cost of RoHS

	% of revenue/turnover	
	One off transition cost	**On-going annual compliance**
Medical Devices	0.7 to 10, average 8.4	0.01 and <1 (only two responses)
IVD Medical Devices	0.1 to 0.6, average 0.42	0.01 to 0.002, average 0.007

The range of transition costs for medical devices is quite large and the cost appears to have been larger than the industry averages published after the RoHS Directive took effect in 2006. These surveys estimate only 1% expenditure whereas two MedTech Europe members reported numbers considerably higher than 1%. It is clear, however, that the transition cost for IVD medical devices is less than for medical devices with an average of only 0.42% (average of data from five responses that provide % of revenue data). Based on responses to other questions, this lower cost may be partly due to IVD manufacturers relying on suppliers to transition to compliant products and supplier's costs are not included in the above figures.

In addition to the costs as outlined in Table 7 there are the costs which are incurred in the supply chain of the MedTech Europe members, which one member has stated as being 5 tiers. The costs incurred by suppliers are not always transparent, with parts not specifically designed for the electronic industry incurring significant amounts of additional cost and effort.

The Bio Intelligence Service impact assessment report[10] estimated that the overall compliance cost for medical equipment and Category 9 equipment to be in the range of €400-1600 million, and the cost per product to modify it to comply with RoHS could be as high as 20% although most items will be less than this and in the range from 1-10%. This appears fairly consistent with the figures in Table 7 above.

Using the indicative costs from Bio Intelligence Service Impact assessment, the cost of achieving reduced emissions as outlined in Table 6 would be between €137,800 - €551,400 per gram of substance emission avoided in one year[11], calculated on the basis of Category 8 equipment equating to half of the costs of Category 8 and 9 compliance calculated by Bio Intelligence Service. Of course, these emissions are avoided in the future for many years, but even over an indicative 100-year period, the cost is €1,378 - €5,514 per gram of substance emission avoided.

Of the eight MedTech Europe members who responded to the question, "*have compliance costs been passed on to your customers*?" four responded "yes", i.e. 50% of respondents have increased their prices due to the cost of compliance with RoHS. Of those that responded that they had not increased prices, however, two said that they were able to rely on suppliers to convert components to compliant versions and one stated that the compliance costs were funded at the expense of new product development.

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[10] Study to support the impact assessment of the RoHS review, Bio Intelligence Service, 16th September 2008.

[11] These values are calculated by taking the cost of compliance (€400-1600 million) for both categories 8 and 9), dividing this by two to get the cost of category 8 compliance, as well as the cumulative reduction in RoHS substances due to category 8 (1,450.9 g from Table 6). This gives: 400,000,000/ (2*1450.9) = 137,845 or for 1,600,000,000/ (2*1450.9) = 551,382.

4.3.1 Typical Cost of Compliance

If substitution of materials or different designs to comply with RoHS results in very significant price increases, medical device manufacturers are likely instead to withdraw this product from the EU market. The percentage of turnover spent on new product development by medical technology companies is relatively high in comparison with other industries but funds are limited. It is a general principle that if the price of a product were to increase significantly, there would be a tendency by hospitals to delay purchase owing to budgetary constraints.

For a more detailed discussion on the impact on innovation, reference should be made to Section 4.4.

A 2019 survey undertaken by Emergo[12] surveying over 2,300 people worldwide shows Europe as the lowest scoring region for expected growth potential, with 77% of respondents citing the changing EU regulatory environment as the largest challenge faced by the business. In addition to this the EU was rated by 77% of respondents as more difficult to obtain regulatory approval including the EU CE mark. The survey demonstrates the significant impact legislation such as the RoHS Directive has on the medical industry and the impact it has on the growth of businesses.

4.4 INNOVATION

Medical technology is characterised by a constant flow of innovation, which is the result of a high level of research and development within the industry. Developments in medical equipment allow the better and earlier diagnosis, more effective and successful treatment and also completely new treatments; all of which are crucial innovations which protect and improve the health of EU citizens. Innovation is currently being impacted by the RoHS Directive for MedTech Europe members, as outlined below.

New products designs will not use RoHS restricted substances unless they provide a technical advantage that is unable to be achieved with any other substance. However, efforts to substitute RoHS restricted substances where they offer unique technical functionality are costly and time consuming, with resources diverted away from research and development.

Research and development is key to medical devices and is one of the highest sources of cost for medical technology companies, estimated to be between 6 and 7 percent of a company's revenues[13], as illustrated in Figure 1.

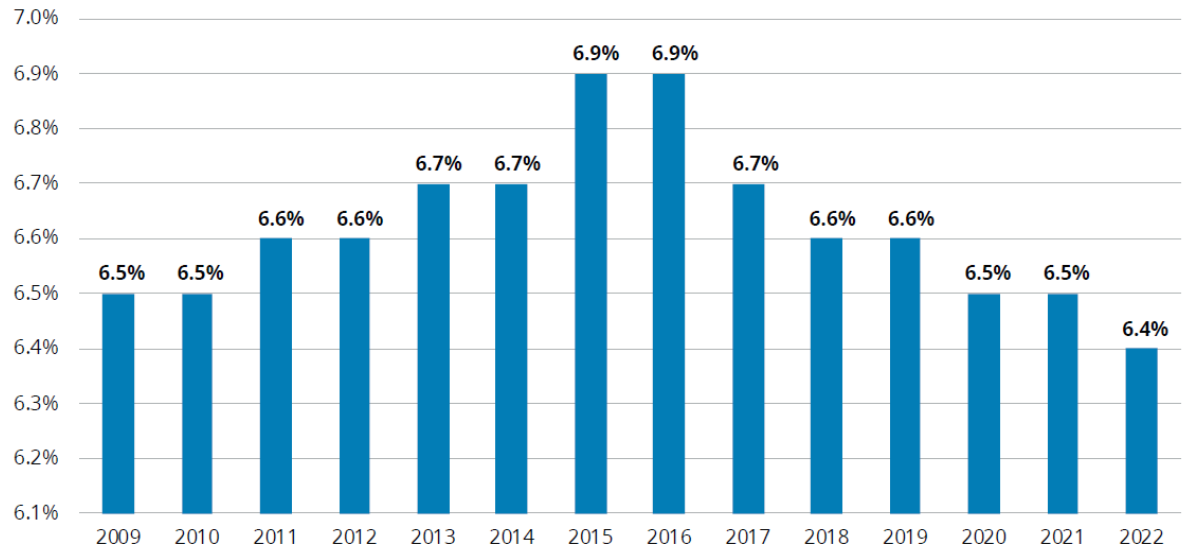

Figure 1 Research and Development Spending as a Percentage of Revenue

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[12] 2019 Outlook for the medical device industry, Emergo, 2019.

[13] The digital era in the MedTech Industry, Deloitte.

MedTech Europe members were asked in the survey if compliance with the RoHS Directive has affected innovation of new medical devices. The results are as follows:

In answer to the question "has *RoHS reduced innovation of new medical devices*?" 10 of 12 responded yes (one stated slightly). Most MedTech Europe members stated that they have had to reduce their efforts to develop new medical devices because design engineers are needed to work on substitution. MedTech Europe members have varying numbers of full time equivalent (FTE) engineers carrying out compliance work with numbers varying from 11 to 50 (with one example of 30 FTE for medical imaging devices and 20 FTE for IVD-devices) depending on company size. Of the two companies that answered no, this was because they were able to rely on suppliers for substitution.

Most MedTech Europe members could not provide data for their Research and Development (R&D) spending as a percentage of revenue but most who responded said that the cost of compliance was at the expense of new product development.

When asked if RoHS created innovation for new products with superior diagnosis or treatment, 95% of respondents stated RoHS has not created opportunities for innovation. The one MedTech Europe member which stated RoHS has created opportunities for innovation is reliant on suppliers to develop and recommend new materials, who then undertakes end product testing such as biocompatibility testing and performance testing.

4.4.1 Impact on Healthcare Provision in the EU

MedTech Europe members were asked questions relating to how RoHS may have affected healthcare provision in the EU. Potentially, healthcare may be affected in the following possible ways:

- By increased product prices. This is an issue for EU healthcare providers as their funds are always limited and have not been increased to pay for RoHS;
- Delays in the availability of new products having superior diagnosis or treatment capability;
- Products withdrawn from the EU market; and
- Inferior reliability of compliant versions (see Section 4.5).

Of the eight companies that responded, four had been forced to increase prices as a result of RoHS and this will have negatively affected EU healthcare providers. If 50% of all medical equipment manufacturers increase their prices, this would have a significant impact on EU hospitals and clinics ability to replace old defective equipment or buy new innovative products. This will have had a direct effect on the health of EU citizens that was not taken into account by the EU impact assessment of inclusion of medical devices in the scope of RoHS.

In addition to this negative impact on health, four responded that having to divert engineers away from new product development has delayed the launch of new products. When RoHS delays the availability of a new medical devices that give either superior diagnosis, such as an ability to detect health issues sooner or superior treatment, such as faster recovery, less side-effects, etc., the delay means that many patients will continue to be treated using methods that are inferior to the delayed new alternative.

Medical device manufacturers will convert an existing product to a compliant version only if this is economically viable, which can cost many millions of Euros. One MedTech Europe member reported that the cost of compliance for twenty circuit board redesigns, certification and validation and employee costs for RoHS compliance was $3M (~€2.7M).

A result of RoHS can be that some older products are withdrawn from the EU market and five MedTech Europe members reported that they had discontinued one or more products in the EU due to RoHS. One of the products withdrawn offered unique functionality, which is not only a loss to the EU healthcare system, but also erodes the innovation within the medical device industry. This can be an issue for EU hospitals and clinics if these products have unique performance characteristics that are ideally suited to a hospital or clinic's needs. Often medical devices and IVD medical devices do have unique ranges of capabilities that are not available with alternative products. This may mean that the hospital or clinic has to choose between the following options:

- Buy more than one product to obtain all of the performance characteristics;
- Settle for a capability that is not exactly what they require, with potentially a negative impact on health of EU citizens; or
- Buy a more expensive product that can provide the capability they need but which will affect their new equipment budget preventing the purchase of other life-saving equipment.

4.4.2 Impact of the RoHS Exemption Process on Innovation

Under the present system, where a product is within the scope of RoHS and offers innovative properties but requires the use of a restricted substance, this could be used only if an exemption were to be granted. Moreover, it must be possible to prove that such technology would be superior to alternative existing ones for an exemption to be granted, and unfortunately, this is usually unknown when this work is being planned. This therefore discourages the use of RoHS substances in new designs, even if they are likely to give significant health benefits and so this is another limitation on innovation due to the RoHS Directive.

Manufacturers' recent experience with applying for exemptions is that this process takes more than two years. The timeframe under which research is carried out is not aligned with this as they are often delivered under short-term contracts of 1 to 3 years. In addition to this, the administrative burden of applying for an exemption and uncertainty that the exemption would be approved does not support researchers or companies investing in developments reliant on restricted substances. Even if an exemption does exist, the risk that the exemption may be removed will also push the direction of research away from the use of restricted substances even if this is the only technology that is able to meet the demand.

Where there are technical alternatives available that do not utilise restricted substances there is less negative impact on innovation. Unfortunately, this is not the case for all uses, as the unique properties offered by restricted substances cannot always be achieved with other substances or designs.

4.5 RELIABILITY

The main reason why medical devices were originally omitted from the scope of the RoHS Directive is believed to be due to concerns over the reliability of certain substitute materials, in particular the long-term performance of lead-free solders. High reliability is of key importance to medical devices and is essential for healthcare consumer safety. All electrical medical devices that are in scope of the RoHS directive (therefore not including Active Implantable Medical Devices (AIMD)) on the EU market are now made using lead-free solders. AIMDs are the most safety critical of all medical devices and represent a relatively small quantity of lead.

However, although the most complex and advanced products are believed to be very reliable, they cannot yet be produced with a very high degree of confidence over their long-term reliability that is essential for medical devices because, according to at least one MedTech Europe survey response, insufficient field data is available. Medical devices can have requirements for low temperature, expected lifetimes of well over 10 years as well as demanding shock and vibration tolerances; all of which create a technically demanding operational window in which solder joints have to demonstrate high reliability. Despite extensive research, no lead free solder has been found which has the same properties as tin/lead solder and so uncertainty will exist until many more years of field data has been collected.

The total number of recalls of defective medical devices relating to all incident types doubled from 2003 to 2012 with non-routine quality events such as major observations or recalls reported to have cost the global medical device industry an average of €2.25 - 4.5 billion per year, with a major recall costing as high as €540 million[14]. In addition to the financial cost the reputational damage can impact the company share price as much as a 10 percent drop. Due to the nature of medical products the impact of failures is much more severe than other industries where product failures are usually a mere inconvenience and readily forgotten by customers.

4.5.1 Failures

As discussed in Section 4.3 medical device manufacturers have invested a significant amount of time and money to qualify RoHS substance-free equipment wherever there is a technical alternative. As a consequence of this and the rigorous requirements for the validation and qualification of medical devices and IVD medical devices there is only one instance where this MedTech Europe survey identified an in-service failure, which was a RoHS compliant PCB.

The survey demonstrated that failures are uncommon as significant effort has been undertaken by medical equipment manufacturers to comply with RoHS and ensure that products are reliable. The failure mechanisms of lead-free solder in comparison with leaded solder are extremely complex, which is discussed in literature in depth. The use of lead solder is well understood and reliability can be predicted with reasonable certainty. To change from well understood technology to technology with which one has less understanding can only be undertaken on a risk

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[14] MTS Blog: The big, bad, and ugly costs of medical device recalls, Medical Tracking Solutions (website), 2017. http://medicaltracking.com/about/news-updates/the-big-bad-and-ugly-costs-of-medical-device-recalls

analysis based on adequate data. The product lifecycle and testing of alternatives as discussed in Section 4.6.2 details the timeframes of testing which are designed to ensure that the probability of failure is minimised.

Of particular importance is the long-term field behaviour of medical devices due to the long lifetimes of the products and the risk to patients' health if unexpected failures occur, also discussed in Section 4.6.2. Long-term reliability is unknown for designs using many RoHS alternative substances due to the limited maturity of alternatives and the associated in-service data, as well as the use of exemptions where required. Accelerated testing is unable in many instances to bridge this gap due to aspects such as non-linear failure probabilities. Failures in medical equipment can pose a serious problem with a direct impact on patients.

4.6 PRODUCT LIFECYCLE AND EXEMPTION TIMESCALES

The timescales for development of medical devices are lengthy due to the demanding applications they fulfil. Exemption applications are by necessity time consuming and require a depth of information which MedTech Europe members are often unable to provide as they are reliant on their supply chain; potentially reducing medical care offered by the EU if critical items are not considered.

MedTech Europe members state that current exemption timescales are too short to fully support the replacement of RoHS affected substances in medical devices with a burden placed on medical device manufacturers to apply for multiple exemptions due to long development timescales of their products. A further consequence is the reduction in refurbishment and spare part availability due to the inability to demonstrate RoHS compliance, undermining circular economy principles.

4.6.1 Supply Chain Availability

As discussed previously, medical device manufacturers generally do not manufacture electrical components and only specify components which meet their demanding technical requirements. To be able to assess if a component requires the use of an exemption detailed knowledge of the component manufacture is required, to which medical device manufacturers often do not have access. Therefore, medical equipment manufacturers often lack the information needed to support exemption requests, as it is only when the end use of the component is determined to be in a critical application that the component supplier is able to determine if an exemption request is required. Of the respondents to the questionnaire, eight MedTech Europe members stated that they were not involved in requesting exemptions either due to a lack of knowledge or reliance on their supply chain for this information. Some component manufacturers are involved in preparing exemption renewal requests however, most do not contribute for a variety of reasons, which vary from cost to a lack of knowledge. The impact on medical devices that rely on the technical function of the components that require exemptions could reduce the medical care available in the EU.

4.6.2 Product Development and Qualification

The MedTech Europe survey asked about the timescales required to undertake R&D, reliability testing, and obtain approvals for medical devices. Research to identify a substitute will usually take a significant period of time. For medical equipment there is the additional obligation to carry out reliability testing and sometimes also validation testing (essential for IVD medical devices) and clinical trials in order to obtain approvals for new equipment designs.

For the medical technology industry to implement RoHS without a negative impact on future healthcare the following timing impacts need to be considered. Medical device manufacturers prefer to design new products without RoHS substances so that the new product replaces an existing model at a time when its lifespan has reached the end. Substitution of substances in existing designs (legacy products) is undesirable because the high compliance cost may not be recouped by future sales, substitution does not give any health benefits and design engineers are prevented from working on new products (see Section 4.4). This means that the longer the period of time before new restrictions take effect or exemptions expire, the more likely that older models will be replaced by newer compliant models without having to redesign existing products. For designs that are not at an appropriate point in the lifecycle, the manufacturer has a choice of redesign or withdrawal from the EU market. Exemptions can be requested and granted only if they meet one of the criteria of Article 5.1 and it is usually not possible to justify an exemption just to obtain more time.

Due to the complexity of the exemption request process and for the technical complexity of medical equipment, the review of the request and subsequent EU procedures takes a substantial amount of time, with manufacturers currently experiencing timescales of 3 to 5 years for a decision on an exemption request. Consequently, there is

legal uncertainty, which is reflected in the Feedback provided by the Test and measurement Coalition to the RoHS Evaluation Roadmap[15].

Medical equipment manufacturers have reported timeframes as outlined in Table 8 for the qualification of RoHS substance free products.

Table 8 Range of Timeframes Reported for the Qualification of RoHS Substance Free Products

Qualification stage	Range of Timescales (maximum and minimum only)		
	Medical Devices	More Complex Medical Imaging Devices	IVD Medical Devices
Review of product impact	1 month – 2 months		3 months - 1 year
Testing of alternative of materials / components	2 months – 3 months		2 months - 3 years
Software rewrite			Specific items can require 6 months
Reliability testing	Up to 2 months		Up to 3 months
Redesign of product for alternative solution	Up to 18 months		Up to 6 months
Verification/Validation	2 months - Up to 18 months		3 months - 1 year
Clinical trials	Up to 2 years		Up to 1 year
Approval by a Notified Body for the Medical Devices Regulation or the IVD Regulation	Up to 1 year		Up to 6 months in the EU
Global approvals	8 months - 2 years		Up to 4 years
Cumulative Time (Upper and lower limits from responses)	**2 years - 6 years With an average of over 3 years**	**8 years-10 years**	**2 years - 8 years***

*From three sets of timeframes provided, which therefore may underestimate the amount of time to qualify an alternative solution

The timeframe to qualify a RoHS substance free product varies significantly dependant on the type of device undergoing qualification. For complex medical imaging devices, such as MRI, qualification timeframes to ensure reliability can be a long as 25 years to understand the impact of tin pest (occurs to tin when at low temperature), with the majority of qualification timeframes around 8 to 10 years. With the trend of medical devices becoming more complex, with a larger number of parts to allow functionality such as automatization the qualification timeframes of medical devices are likely to transition towards those of medical imaging devices, so that qualification timescales are getting longer.

Although there is a large variation in timeframes, this is sufficient to show that they are significantly longer than those for consumer products. This is well known and is due to the nature of the products and the legal requirement for approvals. Therefore, the time periods for exemptions, where required, and also in the future for additional substances if they are restricted, need to take into account these longer timescales required for the adaptation of medical products, with their longer design cycles and lifespans. This is necessary to ensure the availability in the EU of life-saving products.

The typical lifespan of products surveyed by the questionnaire, from launch to phase out is between 8 and over 30 years, with an average lifespan of about 15 years. With the qualification of RoHS substance-free products in the worst-case (see Table 8) being double that of the product lifetime, as well as exemption timeframes (a maximum validity of seven years) being as little as a quarter of the timescale in Table 8, this highlights the challenges faced by medical equipment manufacture when designing RoHS substance free products. Two MedTech Europe

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[15] Test and Measurement Coalition, Feedback to the EU Commission consultation on RoHS evaluation Roadmap, 12th October 2018.

members stated that the maximum validity period of exemptions was too short and this negatively affects their business. Moreover, the majority of respondents track the progress/status of current exemptions with concern owing to the possibility that these might no longer available if they expire or are not renewed. Despite the current impact, 75% of respondents stated that they would see the benefit of a longer maximum exemption period with suggestions varying from permanent exemptions, if it is possible to demonstrate there are no technical alternatives based on scientific understanding, to exemptions based on product lifetime of between 10 to15 years.

4.6.3 Spare Parts

The RoHS Directive excludes spare parts for the repair or refurbishment of medical equipment placed on the EU market for the first time before 21st July 2014 (or 2016 for IVD medical devices). The European Commission has stated in its Frequently Asked Questions that this extends to spare parts for upgrading equipment because one of the aims of the WEEE and RoHS Directives is to extend the life of products for a long as possible and avoid waste.

Due to the long lifetime of medical equipment, the availability of spare parts is critical to ensure the continued operation of equipment and the avoidance of additional waste and it is quite common for manufacturers to recover used parts for reuse. RoHS also allows the reuse of parts recovered from medical devices placed on the EU market after 21st July 2014 or IVD medical devices after 21st July 2016. This allowance does not however extend to parts recovered from equipment sold outside of the EU, except that temporary exemption 31a has been granted to allow the use of non EU spare parts. It appears that some manufactures do not rely on exemption 31a and are disposing of spare parts as they are not able to differentiate parts from EU and non-EU markets, causing additional waste, which is noted as an unintended consequence in some member state post implementation reviews[16].

Although RoHS exemption 31a does give greater flexibility to manufacturers and is used by MedTech Europe members, some MedTech Europe members still report difficulties over the use of spare parts and report an increase in waste due to the RoHS Directive.

4.6.4 Refurbishment

Refurbishment of medical equipment contributes to important societal challenges and is encouraged by the RoHS and WEEE Directives as well as by the Circular Economy. Medical devices are often refurbished and resold at around half of their expected lifetime. Refurbishment is a form of reuse, which allows:

- The reduction of waste, with reports such as the one released by DITTA[17] estimating that around 30 MWh can be saved for each tonne of refurbished medical devices;
- Conserving resources by saving energy in the production of new equipment, reducing material consumption and related mining requirements;
- Increasing access to healthcare in markets with increasing healthcare cost pressures;
- Offering economic benefits from extending the lifecycle value of manufactured equipment; and
- Creation of new jobs, growth and investment within the EU.

A global outlook is required to be able to achieve the required economies of scale when refurbishing medical devices and this requires that all used parts sourced globally can be used in any location globally.

In 2015, refurbished diagnostic imaging equipment accounted for 75.5% of the global demand for refurbished medical devices. By 2020, the global refurbished medical devices market alone is estimated to be worth €8 billion with a market growth rate of 8.31%[18]. With free movement, some equipment originally placed on markets outside the EU will be refurbished for use in the EU. As from July 2014 this has not been possible anymore for non-RoHS compliant devices, therefore only pre-2014 devices originally used in the EU are refurbished for reuse in the EU. This is reducing the supply to a level that is smaller than current demand which is preventing some EU hospitals from buying refurbished equipment (as their new equipment budgets will be fixed). This will have a knock-on impact on healthcare in the EU.

One company has reported that 1,000 kg of parts had been scrapped due to RoHS (they could not be used in new compliant products) where they could have been used for spare or reused parts due to issues with the ability to

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16 Restriction of the use of Certain Hazardous Substances in Electrical and Electronic Equipment Post Implementation Review, Defra UK, 17th May 2018.

17 http://globalditta.org/

18 Refurbishment of medical equipment, Report on promising KETs based product nr 4, Key enabling technologies observatory, 2015.

track RoHS compliance in the repair process. Instead defective but repairable parts are scrapped and new parts delivered, undermining circular economy principles as well as significantly increasing the health and environmental impact due to the processing of the waste and manufacture of new parts. This can also increase the repair costs incurred by EU hospitals if replacement parts have to be made specially. Findings, such as the interviews of stakeholders undertaken by Key Enabling Technologies Observatory, support this conclusion. The latter source mentions a 30% decline in medical device refurbishment in the EU market once RoHS was implemented.

Hospitals in the EU often want to buy refurbished medical devices, either to have a diagnosis technology that was not previously available or to replace an old device. However, all hospital's budgets are limited and they often cannot afford to buy new equipment, whereas refurbished ones are more affordable and can provide the diagnosis capability that they require. If fewer refurbished devices are available because of RoHS, this would prevent hospitals replacing old equipment and/or from having additional diagnosis capability and both would be harmful to the healthcare that hospitals are able to provide. The impact on patients is longer waiting times (if fewer older equipment are available that are less reliable) and later diagnosis with associated health risks if older technology has to be used.

4.7 ENVIRONMENTAL IMPACT – END-OF-LIFE

As the use phase of medical devices is heavily regulated by the Medical Device Directive and the In Vitro Diagnostic Medical Devices Directive (which will be replaced by the Medical Device Regulation and the In Vitro Diagnostic Medical Device Regulation) to ensure safety for patients and users, the manufacturing processes and end-of-life disposal/recycling are usually the only life phases where exposure to humans or environment could potentially occur. According to the medical device industry, recycling is already the common practice to treat Category 8 products, at the end-of-life. The European healthcare industry states that over 90% of the medical imaging devices are collected, reused or recycled and thus do not end up in the environment[19]. The remaining up to 10% is disposed of safely in strict compliance with EU waste legislation. Although Eurostat WEEE data for 2016 show 12% medical devices are recycled, this does not capture all of the industry take back schemes, most of which are not reported to WEEE schemes.

In the EU, manufacturing and recycling are strictly regulated (e.g. by the Industrial Emissions Directive and worker safety legislation), so that no harm should be caused to workers or the environment. Uncontrollable risk for such activities in the EEE sector has become extremely uncommon because of this legislation.

A further unintended consequence of RoHS is part scrapping, as discussed in Section 4.6.4, where they could have been used for spare or reused parts previously, with 55% of survey respondents reporting instances where this has had to occur. Manufacturers make every effort to ensure that products are able to be reused, with one respondent stating that around a tonne of parts is recovered annually in the EU. However, this is not always possible due to issues around the ability and cost to track RoHS compliance in the repair process. A way that this is managed, as reported by one company, is to maintain separate stocks of RoHS and non-RoHS spare parts however, this adds to the complexity and cost of repair, leading to older systems being scrapped rather than repaired undermining the circular economy goals.

5 SUMMARY OF ROHS IMPACT FINDINGS

The public consultation on the RoHS Directive closed on the 6th December 2019 through the submission of a questionnaire located on the European Commission website[20]. The following discussions were aimed at the support of submission of the questionnaire, with identification of applicable questions for each section. The report will not support all questions as some by their nature are company specific and focuses on the section for stakeholders and individuals with special knowledge.

5.1 ROHS SUBSTANCE USE IN MEDICAL DEVICES

MedTech Europe's members have made very significant efforts to remove restricted substances from their products and only use RoHS restricted substances where no alternatives exist and are permitted by exemptions. There are many cases where RoHS substances have been substituted, with many respondents completely eliminating the

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[19] COCIR, 2007.

[20] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-3106007/public-consultation_en

small quantities of cadmium and mercury and all eliminating hexavalent chromium, BBP, DBP and DIBP. Lead is still widely used in exempt forms, however there has still been significant reductions in its use in applications such as in solders used on printed circuit boards. Many MedTech Europe members are experiencing reductions in RoHS restricted substances before the implementation of the RoHS Directive for Category 8 equipment due to other legislative impacts.

In support of Question 1:

All MedTech Europe members which took part in the survey have reported undertaking efforts to remove RoHS substances from their products, with only exempt forms currently included in their designs. Consequently, it is reasonable to assume that RoHS has reduced the use of hazardous substances produced and sold in the EU, as well as produced and sold outside the EU.

The extent to which there have been reductions in RoHS substances varies dependant on the technical capability of the product in question but can be largely attributed to a limited reduction for lead, cadmium, mercury (used in backlights) and DEHP, and a large reduction (i.e. a high proportion of the original amount used) in use for hexavalent chromium and PBDE. For the remaining phthalates (BBP, DBP and DIBP), there is limited data from MedTech Europe members, but discussions outlined in Section 4.1.4 would indicate that there would be limited impact for these substances.

As medical devices were included in scope of RoHS after most other types of products and because of the reductions in substance use by other legislative drivers as described in Section 4.1.3, the reported decrease in amounts of RoHS substances solely due to inclusion of Category 8 in scope of RoHS is relatively small. Furthermore, it is reported that the decrease in amounts of phthalates is mainly due to the EU REACH Regulation. This highlights the overlap in legislation posed in **Question 40**, although most MedTech Europe members reported either no phthalates or that they have not determined how much was used previously.

Consequently **Questions 1 and 9** concern whether RoHS has reduced the use of hazardous substances in EEE. The data in this report supports the assessment of a “limited” decreases in lead, mercury, cadmium, chromium, PBDE, DEHP, BBP, DBP and DIBP but no decrease in PBB (i.e. no effect).

The presence of RoHS substances does not hinder recycling of WEEE and the quantities of RoHS substances emitted at end-of-life are relatively small, as supported by the data in Table 5 and Table 6. Therefore, “the way that electronic waste is recycled” in **Question 7** does reduce the risk to the environment. Furthermore, the reported avoidance of lead in solders may have avoided harm to small-scale recyclers in developing countries and avoiding manufacture of DEHP may be beneficial, so RoHS has reduced the risk to human health.

Conversely, **Question 8** which asks if hazardous substances hinder the treatment of waste, can be demonstrated to certainly not to be the case.

In support of Question 2-3:

As a consequence of the small quantities of RoHS substances reported to be withdrawn in Category 8 products due to RoHS it can be suggested that there is a limited positive impact on the protection of human health and the environment.

The reported decrease of RoHS substance use due to inclusion of medical devices and IVD medical devices in scope of RoHS equates to an extremely limited decrease in emissions of RoHS substances when compared with total published EU emissions as discussed in Section 4.2.1. The benefits of the directive, as posed by **Question 21** offers ‘Avoided emissions’ as a potential benefit which although this would be correct, the magnitude of the reduction of these emissions due to medical devices when compared to total EU emissions of these substances would be so minimal as to have an extremely limited impact.

5.2 IMPACT ON WASTE

In support of Question 5 & 10:

Results of the MedTech Europe survey indicate that inclusion of medical devices and IVD medical devices in the scope of RoHS has resulted in an increase in the quantity of waste. Due to both:

- Unused parts; and
- A few early failures.

One of the original arguments given for the RoHS Directive was that elimination of hazardous substances aids recycling. There is no evidence reported from MedTech Europe members that RoHS has had any beneficial impact

on WEEE recycling and it is known from literature that some potential substitutes for lead actually make recycling more difficult. For example, a potential alternative to lead in brass is bismuth but bismuth severely hinders copper recycling. A possible substitute for lead in aluminium is tin and this also hinders recycling. Recycling of WEEE to recover valuable materials relies on very large-scale processes which are versatile so that a wide variety of feedstocks can be used. In the EU, for example, Umicore recover a wide variety of metals from many different materials, not only electrical scrap, and so they must be able to recover lead, cadmium, mercury and other hazardous substances safely and according to their IED permits[21]. To date, therefore, the RoHS Directive has not altered the recycling processes that are used in the EU (for all types of WEEE including medical devices), although RoHS may have benefited the health of small-scale, but inefficient recyclers in developing countries that recycle EU IT and consumer products (often illegally) that are now lead-free.

In support of Question 18 & 19:

Due to the long lifetime of medical equipment, the availability of spare parts is critical to ensure the continued operation of equipment and the avoidance of additional waste. Although the reuse of parts is permitted, this allowance does not however extend to parts recovered from equipment sold outside of the EU and most manufacturers are not able to differentiate parts from EU and non-EU markets resulting in trade limitations. Some MedTech Europe members reported that there were less refurbished products sold in the EU as a result of RoHS.

The EU was rated by 77% of respondents to the 2019 survey undertaken by Emergo as more difficult than other regulatory areas to obtain regulatory approvals in the EU, including the EU CE mark, demonstrating the significant impact legislation such as the RoHS Directive has on the medical technology industry and the impact it has on the growth of businesses.

5.3 IMPACT ON INNOVATION

In support of Question 14 & 15:

MedTech Europe members have reported that compliance with RoHS has required that some of their design engineers have been required to stop designing new products because their time was required for substitution work. It can therefore be extrapolated that this has a negative impact on EU health as new products are generally developed to provide benefits such as superior diagnosis or treatment compared to older products. With IVD products, newer models may reduce the cost of testing or allow faster testing both of which are significant benefits to EU hospitals which all have limited funds for treating patients. These benefits are not realised or are at best delayed if design engineers are forced to work on substance substitution instead of new product development. Therefore, to answer Question 14, responses from MedTech Europe members suggests that RoHS has negatively affected innovation and to answer Question 15, less is spent (negative effect) on R&D as funding is needed for substitution work.

5.4 BENEFITS VERSUS COSTS

The reported decrease in the amount of RoHS substances used in medical devices due to the inclusion in scope is a benefit, however as the decreases in quantities are small or very small, the benefits to health and the environment are limited, especially when compared with published EU emissions of these substances. Costs however are relatively high; with indicative costs based on the Bio Intelligence Service data and estimated emission from published data resulting in €137,800 - €551,400 per gram of substance emission avoided in one year. Of course, these emissions are avoided in the future for many years, but even over an indicative 100 year period, the cost is €1,378 - €5,514 per gram of substance emission avoided, see Section 4.3.

Results of the survey of MedTech Europe members showed that transition costs for medical devices was calculated as an average of 8.4% of revenue/turnover and IVD medical devices 0.42% of revenue/turnover. Similarly the on-going compliance costs was calculated as between 0.01 and less than 1% of revenue/turnover for medical devices and an average of 0.007% of revenue/turnover for IVD medical devices.

Furthermore, there are indirect costs resulting from medical device manufacturers having to divert design engineers from new product development to substance substitution, with 92% of respondents to the MedTech Europe

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[21] https://link.springer.com/content/pdf/10.1007%2FBF03214988.pdf

questionnaire stated RoHS has not created innovation for new products. The results of the MedTech Europe survey and the resultant indirect cost to EU healthcare are described in Section 4.3.

In support of Question 25:

The responses received from MedTech Europe members would indicate that the following are significant costs:

- Collecting and reviewing information;
- Management of information (legislation tracking and implementation into company systems);
- Technical documentation;
- Exemption procedures;
- Gathering supply chain information;
- Capital expenditure (new process equipment and procedures); and
- R&D (including trials, testing and prototypes) and operating expenditure.

There is also potentially higher component or material price for RoHS compliant version or processing costs.

Other costs not included in the EC questionnaire (so can be included in the “other” Section of Question 25):

- Review of product impact for legislative requirements;
- Redesign and rewrite of software; and
- Validation and approvals from Notified Body if the change is significant.

In support of Question 26:

One MedTech Europe member reported up to 28 FTE employees working on RoHS compliance per year and another 50 FTE, although others provided lower values. Although this metric varied considerably between responses there was agreement that a large amount of resources has been required by every company to manage RoHS compliance and so a response of >3 FTE is likely to cover most MedTech Europe members that make medical electrical equipment, although the “other” box could be checked and up to 50 FTE inserted.

In support of Question 27:

The initial investment by MedTech Europe members for products to be RoHS compliant for medical devices was between 0.7 to 10% of revenue/turnover, with an average of 8.4%. For IVD medical devices expenditure of revenue/turnover was between 0.1 to 0.6%, with an average of 0.42%. The costs of the supply chain compliance are in addition to this, with significant additional costs for items not designed specifically for the electronics industry.

In support of Question 28 & 29:

The on-going cost of compliance has increased the operational costs for MedTech Europe members with on-going annual compliance for medical devices being between 0.01 and 1% of revenue/turnover. For IVD medical devices, the on-going annual compliance cost was 0.01 to 0.002% of revenue/turnover with an average of 0.007%. Overall, it can be concluded that the perceived small benefits of the directive, taking into account only the very small benefits from the medical technology sector, would not justify the costs for the majority MedTech Europe members.

In support of Question 36:

The cost of compliance with RoHS has increased company costs with half of MedTech Europe members stating there has been no effect on customer prices, with expenditure taken from research and development costs and the other half increasing customer costs. Some however report that they have raised prices due to RoHS.

It is not clear whether this affects company competitiveness as all companies have to comply with RoHS to sell in the EU. In circumstances where a MedTech Europe member competes with companies that do not comply with RoHS and only sell in non-EU markets, they may be at a small competitive disadvantage when selling into these markets.

5.5 IMPACT OF EXEMPTIONS

In support of Question 31:

The majority of the issues outlined by the table in the questionnaire were not flagged by MedTech Europe members as items of particular concern (although most issues were not specifically included in the MedTech Europe survey). An issue which was deemed as significant by two MedTech Europe members, is the length of maximum exemption timeframes, which can be attributed to 'Other' field in the table. In support of the suggestion 75% of respondents stated that they would see the benefit of a longer maximum exemption period. Suggestions included permanent exemptions, if it is possible to demonstrate there are no technical alternatives based on scientific understanding, to exemptions based on product lifetime or between 10 to 15 years. Most MedTech Europe members are not actively involved in exemption renewals although this may be because they see the process as being too complex (as well as too slow).

In support of Question 39 & 35:

The exemption system is deemed by many medical device manufacturers as generating a large amount of administrative burden due to the long qualification timelines of medical devices in comparison with the maximum exemption validity period. The qualification of RoHS substance free products in the worst-case is double that of the product lifetime, as well as exemption validity timeframes being as little as a quarter of the qualification timescale. The exemption process is seen as being particularly inefficient.

In support of Question 46 & 47:

MedTech Europe members have undertaken a large amount of work to ensure that RoHS substances are designed out of their products. It is only where this is not possible that exemptions are utilised, therefore it is reasonable to assume that Annexes III and IV are up-to-date to with the most recent technical and scientific progress.

Conversely the fitness for purpose of the application and assessment process has been highlighted by MedTech Europe members as too lengthy for a decision to be made and there is general consensus, although not echoed by all MedTech Europe members, that the maximum exemption timeframe should be longer. Suggestions of a maximum exemption period have varied from permanent to 10-15 years. Due to the complexity of the exemption request process, the review of exemption requests and subsequent EU procedures takes a substantial amount of time, which creates significant legal uncertainty for manufacturers. Manufacturers are currently experiencing timescales of 3 to 5 years for a Commission Delegated Decision after an exemption request is submitted, which is too long.

MedTech Europe members report that they need many of the RoHS exemptions. Usually they are users of components that are made by suppliers and so they have no control over the use of RoHS exempt substances or substitution.

5.6 IMPACT ON EU HEALTHCARE

MedTech Europe members have reported that some of their products have been discontinued in the EU due to the RoHS Directive because substitution was impractical. Which could potentially be added in addition to company specific points in **Question 49**.

PART 2 – ASSESSMENT OF ADDITIONAL SUBSTANCES

6 ADDITIONAL SUBSTANCES UNDER ASSESSMENT

Currently, the Öko Institut is assessing seven types of substances on behalf of the European Commission. The seven substances and groups of substances are:

- Diantimony trioxide;
- Tetrabromobisphenol A (TBBP-A);
- Indium phosphide;
- Medium chain chlorinated paraffins (MCCPs);
- Beryllium and its compounds;
- Nickel sulphate and nickel sulfamate; and
- Cobalt dichloride and cobalt sulphate.

Öko has also produced an inventory of 43 substances that may in the future be considered for addition to Annex II.

6.1 USES OF THESE SUBSTANCES AND POTENTIAL FOR SUBSTITUTION

The seven types of substances proposed for potential restriction and their main uses in medical devices are discussed below.

6.1.1 Diantimony trioxide

Diantimony trioxide is widely used as a flame retardant (FR) synergist in polymers, elastomers, rubbers, paints adhesives, potting, sealants, etc. It is usually used in flexible PVC and in polymers that contain halogenated flame retardants. Diantimony trioxide is very commonly used with halogenated compounds in plastic parts which have flame retardancy ratings of UL94 V0 or better because, in many polymers, there are few other types of suitable flame retardants. Effective flame retardancy is essential in electronic components, circuit board laminates and enclosures to prevent fires in the event of a fault. Most electronic components that contain plastic encapsulation contain diantimony trioxide including connectors, resistors, capacitors, integrated circuit packages, etc.

A study published by the Danish government showed that several widely used polymers can be flame retarded to acceptable UL94 V0 flame retardancy levels only by use of halogenated flame retardants and this will usually require the use of diantimony trioxide[22].

There are many published examples of consumer products that are claimed to be halogen-free and therefore could be diantimony trioxide-free. These claims can however be misleading, as “halogen-free” does not always mean zero halogen as manufacturers allow the presence of halogens up to certain amounts in so-called halogen-free products[23]. Also, many manufacturers “green-procurement” policies allow halogens for certain uses that they cannot avoid, such as in components. Similarly, an example of an ecolabel that is followed by many manufacturers is the Nordic Swan Ecolabel which allows the use of halogenated flame-retardants under specified circumstances (including TBBP-A in PCB and in small parts; i.e. most electronic components) in products such as televisions and projectors[24]. In addition, the lifetimes of the types of product which are claiming halogen-free status tend to be much shorter, as well as having lower reliability than that required by medical devices.

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[22] Downloaded from https://www2.mst.dk/udgiv/publications/2007/978-87-7052-349-3/pdf/978-87-7052-350-9.pdf

[23] Typical Green Procurement policies allows up to 900ppm of bromine in laminates and 0.1% in certain other products, and also state “This is except in cases where doing so would negatively affect product quality or cause technical problems”. For example: https://www.sony.net/SonyInfo/procurementinfo/ss00259/ss_00259e_General_use_17E.pdf

[24] http://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=071

Flexible PVC requires the use of diantimony trioxide to provide the required UL94 V0 rating. The combination of halogens and diantimony trioxide is required by many different types of electronic components in MedTech Europe member products, as well as in enclosures and in wires and cables.

The replacement of diantimony trioxide would often require substitution with other polymers that may not have the same mechanical properties (e.g. flexibility) or may emit very toxic fumes in the event of a fire (e.g. when fluoro-compounds are used). Resins will have to be reformulated and, if the required flame retardancy properties are able to be achieved, requalification would have to be undertaken and, if not, exemptions would have to be requested.

Another function of diantimony trioxide is as a polymerisation catalyst for manufacture of polyethylene terephthalate (PET), but is present at a relatively low concentration - typically containing about 0.015 - 0.02% of diantimony trioxide.

6.1.2 Tetrabromobisphenol A

TBBP-A is used mostly (>90%) as a reactive flame retardant[25] in FR4 laminates and some flame retarded polymers, so is not present in electrical and electronic equipment. Substitution is unnecessary in applications where this substance does not occur in finished products (unless it were to be restricted as a process chemical by the REACH Regulation).

In addition to reactive uses, small quantities of TBBP-A are used as an additive flame retardant in acrylonitrile butadiene styrene (ABS), which is used for plastic mouldings, enclosures, etc. which a RoHS restriction would affect. According to a Danish report[26] only brominated flame retardants would offer an alternative for ABS, which would require testing to ensure the technical performance of the alternative is suitable as well as qualification activities.

6.1.3 Indium phosphide

Indium phosphide's main use is in high power and high frequency electronics, laser diodes and photodetectors, especially for telecommunications applications such as to connect equipment (including medical devices) to digital networks. It is also used as a substitute for cadmium selenide quantum dots in displays.

Indium phosphide semiconductor is an expensive material that is difficult to use and so is used only if no alternatives exist.

6.1.4 Medium chain chlorinated paraffins

MCCP is primarily used as a combined flame retardant and plasticiser with its main use in flexible PVC in applications such as wire insulation, tubing, etc., but may also be used in other polymers or rubbers. MCCP has the advantage that it is both a plasticiser and a flame retardant and so additional flame retardant is not needed. A significant proportion of PVC wire and cable insulation that is used in the EU is MCCP-free as it contains a plasticiser, which is usually a phthalate, and diantimony trioxide as the flame retardant. Phthalates are combustible and so diantimony trioxide is essential to achieve UL94 V0. Therefore, if diantimony trioxide is also banned, it will be much more difficult (and potentially impossible for some uses) to find an alternative to MCCP in PVC cable insulation.

MCCP is also used in adhesives and sealants (polyurethane, polysulphide, acrylic and butyl rubber) and in PVC-based coatings and paints based on chlorinated rubbers and polymers.

6.1.5 Beryllium and its compounds

Beryllium can be used in medical devices in up to three forms:

1. Beryllium oxide (the only compound used) is used as a heat sink for power semiconductor components;
2. Beryllium metal is used in X-ray windows; and

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[25] When TBBP-A is used as an additive flame retardant it is present as this compound in a simple mixture of substances including the polymer and other additives such as pigments and fillers. TBBP-A is more frequently used however as a reactive flame retardant where the TBBP-A molecule reacts chemically with other monomeric substances to form a flame retarded polymeric material that does not contain free unreacted TBBP-A.

[26] "Deca-BDE and Alternatives in Electrical and Electronic Equipment", published by the Danish Ministry of the Environment, prepared by COWI AS, Öko-Recherche GmbH and Concorde East/West Sprl, 2006.

3. Beryllium alloys, such as beryllium copper, nickel beryllium and aluminium beryllium. Copper-beryllium is used for connectors, springs, thermostats, EMC gaskets, etc. due to its low electrical resistivity and its stress relaxation resistance.

Beryllium is relatively expensive so manufacturers use it only if lower cost substitutes are unsuitable and have already replaced beryllium where this has been technically possible. In applications where high reliability or long lifetimes are less important, alternative, cheaper beryllium-free alloys such as phosphor bronze are used in connectors and switches, but medical devices must maintain high reliability for long periods and so often only the more expensive beryllium alloys are suitable. Beryllium has also been assessed for the REACH Regulation (by Germany[27]). This assessment concluded that '*Since substitution of Beryllium might be impossible in most cases (including the problematic cases), a general restriction does not seem to be the best option*'.

Therefore substitution of current uses will have already been extensively researched over the past decades and is impossible for most applications where beryllium is used.

6.1.6 Nickel sulphate and nickel sulfamate

These nickel compounds are used only as process chemicals (e.g. electroplating of nickel metal) and so these substances will not occur in electrical equipment[28].

6.1.7 Cobalt dichloride and cobalt sulphate

Cobalt chloride is used as a very uncommon ink drier. Otherwise, both substances are used only as process chemicals and as such will not occur in medical devices. Cobalt compounds are additives in trivalent chromium passivation coatings although it is unclear whether these substances are present in these forms in the coating or whether they could be detected by any analysis method.

6.1.8 Inventory

Öko originally published a list of about 850 substances in an inventory, although some of these are already restricted and others have already been assessed for RoHS restrictions. This list included 57 high priority substances and the current stakeholder consultation concerns 43 of these. Of these 43, only five are not REACH SVHC's. The main uses, whether they are likely to occur in electrical equipment such as in MedTech Europe's members electrical products and whether they are SVHC's, are listed in the Appendix of this document.

6.2 ÖKO REPORT RECOMMENDATIONS

Öko have undertaken a detailed assessment carried out in line with the updated methodology to create a substance dossier for each of the seven substances considered for the amendment of the RoHS Annex II list of restricted substances. The following are MedTech Europe's comments on the dossiers. Öko's assessments are able to be accessed via the Öko website[29].

6.2.1 Diantimony trioxide

Öko's study has considered exposure to workers in recycling plant and found a report that:

> "*The measured data are way below the estimates and also below the national occupational exposure limit (OEL) of 0.5mg/m^3*".

This implies that workers are not exposed to unsafe levels of this substance, although Öko notes that Germany recently diverged from all other Member States by adopting a much lower OEL of 0.006mg/m^3 (compared with 0.5mg/m^3) and so they say that it is difficult to draw conclusions from this. They also report that the risk of harm to consumers and to the environment are "low". Despite these results, Öko is still deliberating over its recommendation to restrict or not. Öko states that this is because they found that a likely substitute for diantimony trioxide would significantly increase the concentration of halogenated flame-retardants. Most halogenated flame-retardants that

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[27] https://echa.europa.eu/documents/10162/f76365ec-ce93-4422-bdf6-519517cc68be

[28] Previous MedTech Europe statement relating to flow cytometers use of nickel sulphate, after further investigation, has been found that the substance is not provided as part of the electrical equipment.

[29] https://rohs.exemptions.oeko.info/index.php?id=349

are not already restricted by RoHS or REACH are not classified as being hazardous and so it would appear that this should not be a concern. However, halogenated flame-retardants (and PVC) have been targets for restrictions by several Non-Government Organisations (NGOs) for many years although these demands are not based on strong scientific evidence. As a group of substances, they are not classified in the EU as hazardous substances.

However, the concern with halogenated organic compounds is that when the plastics are burned (e.g. at end-of-life), if combustion is carried out at too low a temperature, very hazardous by-product substances are emitted. Although this will occur, all types of plastics including halogen-free polymers emit very dangerous by-products when burned at too low a combustion temperature and so substitution of halogen-based compounds with halogen-free will not prevent emissions of all toxic by-products. The best solution to this issue may be to use the REACH Regulation to restrict individual substances that cause harm (as already occurs) and strictly enforce the restriction of export of waste electrical equipment to countries which do not recycle it safely. A ban on exports of all waste electrical equipment may be an even more effective option as it would benefit the EU if the valuable metals in WEEE were recovered and reused in the EU. This would also be consistent with the EU's Circular Economy policy.

Halogenated organic substances, as a group, are not included in the inventory proposed by Öko (see Section 6.3.5), but this would not prevent the Commission or a Member State from proposing such a restriction.

6.2.2 Tetrabromobisphenol A

Öko has recommended that TBBP-A be restricted by the RoHS Directive. This is based on a report by Öko themselves published in 2014 that found that about 10% of TBBP-A is used as an additive flame retardant and so may be emitted during shredding or grinding processes. However stakeholders indicated during the original consultation that very little TBBP-A is now used additively and so the Öko pre-2014 data may be out of date. The current impact of additive TBBP-A may be much less than previously and so much of Öko's conclusions may be based on out of date data.

Öko reported that TBBP-A is a hazardous substance as it may have endocrine disrupting properties on the basis that it is similar in structure to Bisphenol A. TBBP-A has an EU harmonised classification, as an acute and chronic aquatic toxin category 1 so is hazardous to the environment but it is not classified as hazardous to humans. Öko's statement that TBBP-A may be an endocrine disrupting substance is unproven and comparison with Bisphenol A is clearly not sufficient to give it such a classification.

Although TBBP-A is not classified as being hazardous to humans, this does not mean that it is completely harmless. Researchers have calculated "Derived No Effect Levels" (DNEL) for TBBP-A for inhalation, dermal and oral exposure. These levels are not especially low so that consumers would not be likely to be exposed to close to these levels. There is however research that under anaerobic conditions, TBBP-A decomposes to Bisphenol-A (BPA) which is a known human endocrine disruptor so may be harmful if the levels of exposure is sufficient. The DNEL values of BPA are much lower than for TBBP-A, for example (from Öko's report):

TBBP-A	Oral exposure general population (long term) is 2.5 mg/kg bw/day
BPA	Oral exposure general population (long term) is 4 µg/kg bw/day.

Oral exposure includes ingestion by consumption of food contaminated by these substances, which is often the main source of exposure to substances by consumers.

Öko found that TBBP-A has been detected in the serum (blood) of recycling workers and in-house dust which could pose a risk to children. The data on workers that are exposed to recycled electrical waste may be due to the larger amounts of TBBP-A which may have been used as an additive flame retardant[25] in the past in comparison with current levels (and so the level of exposure will decrease in the future). The presence of TBBP-A in house dust is more likely to be from the manufacture of TBBP-A and processes to manufacture products from TBBP-A, (as over 90% is used reactively).

Production processes would not be regulated by a RoHS restriction and so if TBBP-A poses a risk, as claimed by Öko, then a REACH restriction would be the only effective option to protect health. A RoHS restriction would prevent <10% of its EU uses. REACH restrictions have the advantage over RoHS in that they can cover all EU uses. REACH Annex XVII restrictions are imposed only if an uncontrollable risk of harm is proven after very thorough investigations being carried out. Therefore, it would seem to be reasonable that consideration be given to the benefits of REACH restriction before deciding whether to restrict the substance under RoHS.

6.2.3 Indium phosphide

Öko found that indium phosphide is widely used in electrical equipment in fairly small quantities. Öko's estimate is only 100kg used in the EU in types of products that are in scope of RoHS and currently available substitutes (suggested to be gallium arsenide for telecom applications or cadmium compounds in displays) are at least as

hazardous and a restriction would not give substantial benefits for the environment or health. Öko also concluded that a restriction would have very significant costs for the EU, which would negatively affect competitiveness. Öko concluded "*it currently cannot be recommended to pursue a restriction under the RoHS Directive of indium phosphide*".

6.2.4 Medium chain chlorinated paraffins

A RoHS restriction of MCCP had previously been proposed by the Swedish Chemical Agency (KEMI) who had carried out a comprehensive study. The quantity of MCCP used in electronic and electrical equipment (EEE) sold in the EU is unknown as most is likely to occur in equipment imported from outside of the EU. Öko did not find evidence that MCCP caused harm to workers, to the environment or to adult humans, but may harm children. However, despite these findings, they concluded that MCCP used in EEE does pose a risk of harm to workers and to the environment because it may be an endocrine disruptor, however this has not yet been proven. Öko recommends that MCCP be restricted by RoHS. Note that KEMI found that it is also used in large quantities in non-electrical products (such as PVC flooring), which a RoHS restriction would not prevent.

MCCP is classified as hazardous to humans and to the environment. A comprehensive EU risk assessment published in 2008 recommended that further controls are needed to protect workers, but no controls were needed to protect consumers or the environment. More research will have been done since this 2008 study but at present there does not appear to be any "proof" that MCCP causes harm (only "indications") although it is noted that the RoHS Directive can restrict substances based on the "Precautionary Principle" so a possibility that harm is caused is sufficient for the EU to be able to restrict a substance by the RoHS Directive. However, any potential negative impacts on health or the environment by substitutes should also be considered under the Precautionary Principle.

6.2.5 Beryllium and its compounds

Öko reports that beryllium has many uses in electrical and electronic equipment; however, it is also very widely used in applications outside of the scope of RoHS, such as in transport, aircraft, etc. Öko concluded that substitution is currently not possible and this is mainly from information from various documents generated in context of the REACH Regulation (such as the German impact assessment), which was "accepted with a high degree of confidence". Their main conclusion is "*inclusion of beryllium and BeO in ANNEX II of RoHS is currently not recommended*", however they suggest that a limited restriction in sliding contact brushes is an option.

Many industry stakeholders also provided information that substitution is not possible but this was implied by Öko to be accepted with less confidence than EU Member State recommendations.

6.2.6 Nickel sulphate and nickel sulfamate

Öko agrees that these two compounds are used only as process chemicals and will not occur in electrical equipment and so should not be restricted by the RoHS Directive. They pointed out that other compounds and nickel metal do occur in electrical equipment and may have a health or environmental impacts but these were outside of scope of the Öko study.

6.2.7 Cobalt dichloride and cobalt sulphate

Öko agrees that these two compounds are used only as process chemicals and will not occur in electrical equipment and so should not be restricted by the RoHS Directive.

6.3 POTENTIAL IMPACT ON THE MEDICAL SECTOR

The medical sector uses a very large variety of materials and components that may contain the substances that Öko has recommended for restriction (TBBP-A and MCCP) or for further investigation (diantimony trioxide). The main uses of all three substances are as flame-retardants. It is therefore worthwhile before proceeding further to consider why flame-retardants are used.

6.3.1 Risks arising from restricting flame retardants

Electrical equipment contains parts that can become hot, or faults can occur that generate electric arcs or high temperatures. The only practical form of electrical insulation in most electrical equipment is usually plastics. Many types of plastic have been developed but each has a unique combination of properties and performance so that it is often difficult to replace. Most types of plastic are combustible, which means that they will burn to some extent when exposed to flames or heat. Combustion tends to become self-sustaining as the thermal decomposition of

plastics can result in (depending on the polymer and its additives) heat and/or combustible gases that ignite as flames. These flames cause the fire to spread.

In the past fires were a serious problem with electrical equipment causing many deaths and injuries and so the EU as well as most other countries have developed safety standards that require that fires are inhibited by fire barriers or by flame retardants. Each standard specifies a flame retardancy level and this varies depending on the type of equipment. It is surprising that the required flame retardancy level required for household appliances is lower than that required for IT and telecom equipment given that both are used in similar contexts. Despite safety standards usually requiring the use of flame retardants, electrical fires are still common in the EU. The submission by Association of Equipment Manufacturers (AEM) to the first stakeholder consultation reported:

In the UK, for example [30], in the year 2016 / 2017, 261 people died in fires of which 231 were in homes and 4% of these were caused by faulty electrical appliances (other than cooking appliances) and 5% were due to faulty electrical distribution, which in total (9%) was equivalent to 21 deaths in the UK. Danish research showed a similar statistic with 4% of fatal fires being caused by technical faults to electrical equipment[31]. In the EU as a whole, there are many hundreds of deaths caused by faulty electrical equipment each year.

AEM quote UK data because it is readily available in detail, but there is no reason to suspect that the UK has an unusually bad fire record. There are no published statistics for fires due to faulty medical devices and it is likely that these are extremely rare, however restrictions of flame retardants, especially those that are difficult to replace, pose a risk that manufacturers of plastics, components and parts may use less effective flame retardants resulting in an increased fire risk. In the 1990s, televisions sold in Sweden stopped containing flame-retardants in the plastic housings and this was reported to increase the number of fires ten-fold[32]. As flame-retardants prevent fires and so prevent deaths and injuries[33], they should not be restricted if there is no evidence of harm. Electrical fires will cause many deaths and injuries in the EU annually and any measures that could increase the numbers of deaths and injuries would be contrary to the Precautionary Principle as well as not meeting the requirement of Article 1 of RoHS for the Commission to protect human health.

6.3.2 Diantimony trioxide

A restriction of this substance would have a very significant impact on MedTech Europe's members as it is very commonly used and is present in many 1000s of electronic components. If halogenated flame-retardants and diantimony trioxide as a group were to be restricted, the impact would be even bigger. It is likely that many exemptions would be needed due to the dispersive use of the substance and limited availability of technical alternatives.

Based on the findings from the Öko review, there is no obvious benefit of a restriction as no evidence of harm caused by diantimony trioxide was identified.

Exemptions that may be needed

Prediction of how many exemptions would be needed before manufacturers have carried out research into substitution is not possible. However based on current knowledge, there are likely to be very many needed if diantimony trioxide were to be restricted. At a minimum, the following would need detailed consideration and are likely to require exemptions.

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30 Detailed analysis of fires attended by fire and rescue services, England, April 2016 to March 2017, Statistical Bulletin 16/17, 12 October 2017, published by the UK Home Office ISBN: 978-1-78655-572-4.

31 Consumer fire safety: European statistics and potential fire safety measures, Version 431N8032/3.0, January 2009, published by Austrian Standards Institute. Accessed from https://www.ifv.nl/kennisplein/Documents/09-06-24_rapport_consumer_fire_safety_pdf1.pdf

32 Encyclopedia of Polymer Applications, 3 Volume Set, edited by Munmaya Mishra, CRC, 2018, page 1127. Downloaded from https://books.google.co.uk/books?id=buiCDwAAQBAJ&pg=PA1127&lpg=PA1127&dq=sweden+television+fires+flame+retardant&source=bl&ots=f4IJeVKqwh&sig=ACfU3U20Bwz6lMWcWmbS5ol6QoSdNI_04Q&hl=en&sa=X&ved=2ahUKEwj0i7H_ks7mAhWRO8AKHWIRBSEQ6AEwAHoECAUQAQ#v=onepage&q=sweden%20television%20fires%20flame%20retardant&f=false

33 Also by preventing fires, they prevent the emission of the very hazardous by-products that can be formed.

1. It is known that in applications where components operate at relatively high temperatures, a combination of diantimony trioxide and halogenated compounds are the only known flame retardant combination that can achieve UL94 V0[34].
2. Danish research published in 2006[22] concluded that several commonly used polymers can achieve UL94 V0 only with diantimony trioxide and halogenated compounds.
3. This Danish work also showed that for several other polymer types, organophosphate flame-retardants can be used but, as there are concerns over their toxicity, exemptions may also be needed for these uses.
4. The Joint Research Council (JRC) published a report for the EU to identify suitable flame-retardants for many types of polymers and to achieve UL94 V0[35]. This work also showed that, for many types of polymer, only a combination of diantimony trioxide and halogenated compounds is effective. Some polymers can be flame retarded with organophosphate compounds, but, as stated above, there is evidence that these may be equally or more harmful. Only a few types of polymer can be flame retarded without halogens or organophosphates and these plastics cannot be used for many end-uses in electrical equipment due to their unsuitable physical, electrical and chemical properties.
5. Diantimony trioxide is used in plastics, rubbers, paints, adhesives/sealants, potting compounds and plastic encapsulation and so separate exemptions may be needed for each type of use.

The above will not be an exhaustive list and manufacturers may discover many more uses of diantimony trioxide that cannot be substituted.

6.3.3 Medium chain chlorinated paraffins

The impact of a restriction would mainly be on suppliers of cables and components. Alternatives exist although substitution would be more difficult if diantimony trioxide were also banned. The medical sector would need sufficient time for substitution, reliability testing, approvals, etc. Based on the timeframes outlined in the questionnaire responses, a timeframe of up to 10 years for medical devices and 8 years for IVD medical devices would be required for this.

6.3.4 Tetrabromobisphenol A

A RoHS restriction of TBBP-A would have the least impact of the currently proposed substance restrictions as it is used mostly used as a process chemical. The major impact if this were to be restricted would be the management of compliance data so MedTech Europe's members will incur considerable compliance costs with extremely limited health or environmental benefit. The supply chain of many medical device manufactures is complex and can easily be five tiers or more deep; consequently the management of the compliance data is costly and time consuming to gather and administer.

It is understood that very little TBBP-A is used additively in ABS but there will be compliance costs incurred in determining if suppliers are using this substance, sourcing substitutes (if used), testing these and gaining re-approvals. This will also take up to ten years to complete.

6.3.5 Inventory

Öko was requested to propose an inventory of prioritised substances. The result is a list of 43 substances, of which only five are not REACH SVHC's. As SVHC's are already being assessed by the EU under the REACH Regulation the feedback to the Commission should be that there is no merit in duplicating this effort. As REACH is not limited only to EEE, the broader scope would be more appropriate as the context within which to review substances. For a more detailed analysis of each substance, reference should be made to the Appendix of this document.

Two of the substances which would particularly affect MedTech Europe members are:

- Nickel metal: this is very widely used by the electronic industry and for most uses it is probably impossible to replace. It is already restricted by REACH so should not cause harm to users of EEE.
- DiDP: this is one of the most commonly used substitutes for DEHP in cables, adhesives, paints, etc. and so, if restricted, will result in polymer manufacturers having to substitute again. Polymer manufacturers

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[34] Discussed at RoHS additional substances meeting organised by the European Commission in 2007.

[35] https://publications.jrc.ec.europa.eu/repository/bitstream/JRC36323/EUR%2022693.pdf

would have chosen DiDP as a safe substitute for DEHP because it is classified (by the EU and by most REACH Notifiers) as non-hazardous.

6.4 POTENTIAL NEGATIVE IMPACT OF SUBSTITUTION OF FLAME RETARDANTS

Whilst designing out RoHS substances from EEE is desirable, this is not always possible owing to key functionality that the substance provides.

Any alternative substance needs to be carefully considered and the currently known or potential deleterious effects considered. Where data is collected through the implementation of REACH, Classification, Labelling and Packaging (CLP) or Biocidal Products Regulations or there is information in support portals like SUBSPORT[36] this can assist in the assessment of hazard and risk of alternatives. However, as recently demonstrated by the concerns with organophosphate ester flame-retardants (OPFR) which are used as alternatives to PBDE[37], a lack of information on the health impacts of alternatives can lead to regrettable substitutions. Circumstances may arise where the Commission is encouraged to restrict a substance because alternatives exist and which appear to be less harmful, only for those alternatives subsequently to be found to be no safer than the substance that they replace and maybe worse.

The recently published technical paper found that OPFRs might not be an improvement on PBDEs as it states '*data from toxicity testing, epidemiological studies, and risk assessments all suggest that there are health concerns at current exposure levels for both halogenated and non-halogenated OPFRs'*. The positive impact of RoHS would therefore be eroded in instances such as this where manufacturers have undertaken substitutions to OPFR based alternatives on the assumption that these are less harmful while still incurring the costs of substitution.

The importance of there being genuinely safer alternative substances is particularly important where additional substance restrictions are being considered for RoHS, as discussed above. Although alternative product design which does not require the use of harmful substances is the preferred option, this is not always technically possible. Where a substitute substance that has hazards which have not been extensively studied is used, the lack of understanding of the impact of these alternative "regrettable substitutions" may have far reaching negative impacts.

7 ADDITIONAL SUBSTANCE RECOMMENDATIONS AND CONCLUSIONS

For the current stakeholder consultations closing on the 30th January 2020 concerning diantimony trioxide, TBBP-A and MCCP, the following issues are of importance to MedTech Europe's members.

7.1 DIANTIMONY TRIOXIDE

Öko reports that there is no evidence that diantimony trioxide cause's harm to consumers or the environment. It also found that levels of exposure are below EU Member State Occupational Exposure Levels. Germany has significantly reduced its national Occupational Exposure Levels and, assuming that manufacturers are able to comply, which should be technically possible, no harm would come to workers in the future. However, these findings are inconsistent with the recommendation made by Öko that this substance should be considered further as a group with halogenated flame-retardants. If there is no evidence that it causes harm, then it should not be restricted and no further investigations are needed.

A restriction of diantimony trioxide would have a huge negative impact on MedTech Europe's members (identified as EEE producers). A restriction of diantimony trioxide and halogenated flame-retardants would have an even larger impact. Most electronic components, PVC insulation and many plastic parts contain these substances and substitution would be difficult or impossible. Although substitution in electronic components would be the responsibility of suppliers to MedTech Europe's members, this huge task will inevitably result in many essential components becoming obsolete with a potentially damaging impact on the medical sector. Many products would

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[36] https://www.subsportplus.eu/

[37] Organophosphate Ester Flame Retardants: Are They a Regrettable Substitution for Polybrominated Diphenyl Ethers?, Arlene Blum, Mamta Behl, Linda S. Birnbaum, Miriam L. Diamond, Allison Phillips, Veena Singla, Nisha S. Sipes, Heather M. Stapleton, and Marta Venier, Environmental Science & Technology Letters 2019 6(11), pp.638-649.

need to be redesigned if essential components can no longer be obtained in the EU and so many medical devices would have to be withdrawn from the EU market detrimentally affecting EU healthcare. Based on the timeframes outlined in the questionnaire responses, up to 10 years for complex medical devices and 8 years of IVD medical devices would be required for the substitution time needed for redesign of a limited number of products. The total elapsed time needed to redesign, test and obtain approval of a large number of medical devices will require considerably longer as the availability of trained and experienced design engineers is limited.

7.2 TETRABROMOBISPHENOL A

Öko recommends restriction by RoHS despite clear evidence that at least 90% is used as a reactive flame retardant and so would be excluded from the scope of RoHS. If there is evidence that free-TBBP-A may cause harm, as claimed by Öko, then a restriction using the REACH Regulation should be considered as this legislation can regulate its use as a process chemical. An EU risk assessment of TBBP-A was carried out and reported in 2008[38]. This found that TBBP-A causes no harm to humans but further tests were needed to assess the impact on the environment. It may therefore be appropriate for the EU to reconsider this substance for restriction under REACH as a RoHS restriction is likely to have a minimal benefit, but at a significant cost to the EU medical industry, which would be passed on to hospitals and clinics.

The main impact of a RoHS restriction of TBBP-A on MedTech Europe's members would be that they would need to use ABS containing a different halogenated flame retardant (as only halogenated flame retardant can achieve UL94 V0 in ABS). Öko recommended that a maximum concentration limit of 0.1% be set, if the substance were to be restricted, so that FR4 epoxy resin PCB laminates made with TBBP-A would not be affected.

7.3 MEDIUM CHAIN CHLORINATED PARAFFINS

Öko's findings for MCCP appear inconclusive. Öko recommends that MCCP should be restricted in part because:

- It may contain Short-Chain Chlorinated Paraffins (SCCP) which is a POPs restricted substance; and
- It may contain congeners that are classified Very Persistent and Very Bioaccumulative (which increases the risk of harm).

Of the three flame-retardants being considered, MCCP is clearly the most hazardous and so most likely to be harmful, although there is no clear evidence from Öko's assessment that any harm is caused by this substance. It seems likely that most, if not all, MCCP in medical devices made by MedTech Europe's members is in the form of polymers, especially in cables and in components made in Asia. Therefore, the main impact if MCCP is restricted will be on suppliers who will be required to substitute MCCP for an alternative flame retardant / plasticiser. This should be technically possible (as long as diantimony trioxide and halogenated flame-retardants as a group are not also restricted) with minimal effect on technical properties and performance. MedTech Europe's members will however incur costs to complete:

- Compliance analysis;
- Supplier communications; and
- Testing and qualification of substitutes.

One possible impact that would have a more significant impact is if a component becomes obsolete. This can result in having to completely redesign products that use this component if a very similar one cannot be found. Redesign can be very costly and so all but the newest models are likely to be withdrawn from the EU market which would have a negative impact on EU hospitals and clinics who would not be able to obtain these medical devices.

Based on the timeframes outlined in the questionnaire responses, up to 10 years for complex medical devices and 8 years of IVD medical devices would be required for the substitution of MCCP. The transition costs estimated by MedTech Europe Members of 0.7-10% of revenue/turnover for medical devices and 0.1-0.6% for IVD medical devices are likely to be appropriate for MCCP substitution.

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[38] https://ec.europa.eu/environment/waste/weee/pdf/hazardous_substances_report.pdf

8 ANSWERS TO ÖKO QUESTIONNAIRES

In this section, the specific questions asked of stakeholders by Öko have been extracted and are shown *in italics*. Where it is possible to respond based on data provide by MedTech Europe members and publicly available sources this is provided. It should noted, however, that MedTech Europe's members, as users of components and parts, will understandably not be able to answer some of these questions.

8.1 TETRABROMOBISPHENOL A

Q1. Specific information is requested regarding the amount and the form (reacted / additive) of TBBP-A imported to the EU market as part of goods and commodities. The requested information should at least pinpoint the total amount of additive TBBP-A placed on the European market. The estimations should be detailed so that the numbers given can be followed. In particular, stakeholders are requested to also provide estimations on imported articles. It should further be specified how the proportions are distributed between the different types of application. Specific information is requested on the concentration of TBBP-A used in relevant applications, such as:

- *Thermoplastics for housings / enclosures;*
- *Resins for printed wiring boards; and*
- *Resins for other applications.*

Q2. Specific information – beside what is already referred to here – is requested to clarify the amount of unreacted TBBP-A in PWBs in percentage weight (%/w) at the homogenous material level of the epoxy resin, i.e. excluding copper, glass fibre etc.

Answer: Only one published concentration of TBBP-A in laminate material can be found which is 0.7ppm[39].

Q3. As the extrapolation of Fraunhofer ITEM and IPA is based on outdated numbers from 2004 (e.g. a tonnage of 32,000 t/a TBBP-A used as FR in the EU and several assumptions), stakeholders are requested to provide comprehensive data on the TBBP-A releases from WEEE in Europe [g TBBP-A/ t treated WEEE].

8.2 MEDIUM CHAIN CHLORINATED PARAFFINS

Q1. Please provide data on typical formulations for MCCPs as a secondary plasticiser or plasticiser (extender) in PVC in relation to the share of plasticisers and in relation to PVC mouldings in total, e.g. for cable and wire sheathing and insulation.

Answer: One publication[40] states that 15-30% of chlorinated paraffins is used in polysulphide materials (sealants and rubbers) but does not give a concentration in PVC.

Q2. To what extent does the content of MCCPs vary in PVC and to what extent do requirements on flame retardancy determine the use of MCCPs and the amount used?

Q3. Please provide evidence for the above-cited assumption that imports and exports of MCCPs in PVC and/or EEE are largely equivalent

Q4. Are there different assumptions on use of MCCPs in articles, which take into account the different levels of the supply chain, especially electronic components (including cables and encapsulated components), electronic assemblies, and electronic equipment?

Q5. Please provide information on the composition of flexible LED-strips, i.e. the presence and concentration of MCCPs in the polymeric insulation material

Q6. Please provide information contributing to the transparency of disposal routes including information on releases during treatment processes of any kind

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[39] From the stakeholder contribution by AEM at https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_AEM_TBBPA_20180615_RoHS.PDF

[40] Handbook of Plasticisers, chapter 11 "Plasticizers Use and Selection for Specific Polymers", by George Wypych, 2003.

8.3 DIANTIMONY TRIOXIDE

Q1A. Specific information is requested to the ratio of ATO to the flame retardant, e.g. weight or volume ratio and specification of the flame retardants. It should be further specified which halogenated flame retardant requires which concentration of ATO. Specific information is requested on the concentration of ATO used in most relevant applications which are:

- *Plastics for housings / enclosures;*
- *Cables; and*
- *Printing Wiring Boards.*

Specific information is requested on the amount of ATO in the above listed applications. The amounts should at least include estimations on the total amount placed on the European market. The estimations should be detailed so that the numbers given can be followed.

Answer: Reference 40 provides examples of flame retarded PVC formulations including the quantities of ATO, brominated flame retardant and plasticiser. The high performance grade suitable for cables contains 15 parts ATO per 100 parts PVC plus a total of 40 parts of halogenated flame retardants (all by weight). MedTech Europe members cannot provide data on the total amount placed on the European market.

Q1B. Can you confirm the conclusion that the most promising substitution routes for ATO are (a) substituting the halogenated flame retardant together with ATO as synergist ATO, and (b) alternative technologies?

Answer: No, MedTech Europe is not able to confirm this conclusion. MedTech Europe's members would usually be reliant on component and polymer suppliers to carry out substitution and achieve the required performance and properties. As this work has not yet been attempted for most components or materials, it is not possible to confirm this statement and may turn out to be untrue for some or many uses.

Q2. The outlined findings indicate that substitution of some components and parts of EEE might still be challenging. If this is the case, please provide evidence for which parts substitution is seen to be difficult. Please provide details on reasons.

Answer: Substitutes not only need to achieve the desired flame retardancy, but physical and chemical properties must be suitable and components must be manufacturable. Meeting all requirements is likely be extremely challenging because each type of polymer has different properties. Some types of polymer cannot achieve UL94 V0 without halogenated flame-retardants and diantimony trioxide[25]. Further details are given above in Section 6.3.2.Potential impact on the medical sector

Q3. Which technical criteria are relevant for substitution?

Answer: There are many required criteria but these are always use dependent. These will include:

- Flame retardancy specification;
- Flexibility;
- Hardness;
- Young's modulus;
- Elasticity;
- Tensile strength;
- Yield strength;
- Colour;
- Chemical resistance (sterilising chemicals, detergents, etc.);
- Resistance to stress cracking;
- Softening temperature;
- Etc. There are many others.

Q4. To what extent does line density affect substitution, especially regarding power cords, power adapters and display panels?

Q5. Please provide information on actually applied alternatives, especially on the application of inherent flame retardant materials

Q6. In order to understand the socio-economic impacts of a potential restriction of ATO in the various fields of applications as descried in Section 2 more in depth, stakeholders are requested to provide information on the costs and benefits that can be associated with such a restriction of this substance in electrical and electronic substances under RoHS. Within this context, please make available quantitative data wherever possible. However, also qualitative information is considered to be helpful for the assessment of the socio-economic impacts. Concerning the impacts, information should be distinguished and specified according to the following scheme as far as possible:

- *Impact on chemicals industry;*
- *Impact on EEE producers;*
- *Impact on EEE users;*
- *Impact on waste management; and*
- *Impact on administration.*

Answers:

Impact on EEE manufacturers. The results of MedTech Europe's survey of its members on the transition and on-going compliance costs of RoHS is estimated to be similar or possibly higher for diantimony trioxide:

- Transition costs for medical devices was between 0.7% and 10% of revenue/turnover, with an average of 8.4%. For IVD medical devices expenditure of revenue/turnover was between 0.1 and 0.6%, with an average of 0.42%; and
- On-going compliance costs was calculated as between 0.01% and less than 1% of revenue/turnover for medical devices and an average of 0.007% of revenue/turnover for IVD medical devices.

The cost may be higher because so many components contain this substance which are used in almost every medical electrical product.

Impact on EEE users – There would be many negative impacts as explained in this report. These include:

- Many medical device manufacturers report that they pass on compliance costs to their customers as higher prices;
- Work on substitution negatively impacts innovation so that development of new life saving medical devices is delayed. This is explained above in Section 5.3; and
- Some medical devices will have to be withdrawn from the EU market so that they are not available to EU hospitals and clinics. Patients would as a result have to be treated using less effective techniques (see Section 5.6).

APPENDIX – ANALYSIS OF THE PROPOSED INVENTORY OF 43 SUBSTANCES

This appendix comprises the proposed inventory of 43 substances, their main uses, whether they occur in electrical equipment and if they are REACH SVHC's.

It should be noted that there are no additional applications for the below substances which have not already been identified by Öko, unless otherwise highlighted in red in the below table. The quantities of substances and waste management practices of the substances are not items that can be commented upon by MedTech Europe's members due to the members' position in the supply chain.

Substance	Main uses	Will it occur in electrical equipment?	Is it a REACH SVHC?	Further comment worth noting
Boric acid	Mostly used as a process chemical	Unlikely	Yes	
1-bromopropane	Solvent (low boiling point)	No	Yes	Not contained within finished EEE
Bis(2-methoxyethyl) ether (Diglyme)	Solvent (rarely in lithium batteries, which are excluded from RoHS)	No	Yes	Not contained within finished EEE
Tris(2-chloroethyl)phosphate (TECP)	Flame retardant	Yes	Yes	Mostly used historically
Bis(2-methoxyethyl) phthalate	Plasticiser	Yes	Yes	
C,C'-azodi(formamide) = Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)	Bleaching agent for flour	No	Yes	Not contained within EEE
N,N-dimethylacetamide (DMAC)	Solvent	No	Yes	Not contained within finished EEE
Diarsenic pentaoxide; Arsenic pentoxide; Arsenic oxide	Process chemical	No	Yes	Not contained within finished EEE
Diboron trioxide	Process chemical	No	Yes	Not contained within finished EEE
Disodium tetraborate, anhydrous	Mainly as a process chemical. Also used as a flame retardant for cellulose insulation	Very unlikely	Yes	
Dipentyl phthalate (DPP)	Plasticiser	Yes	Yes	
Nickel monoxide	Pigment used mainly in glass, ceramics, porcelain enamels	Yes	No	
Zinc oxide	Process chemical	No	No	Not contained within finished EEE
Diarsenic trioxide; Arsenic trioxide	Process chemical	No	Yes	Not contained within finished EEE
Tris(2-chloro-1-methylethyl) phosphate (TCCP)	Flame retardant	Yes	No	
Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP)	Flame retardant	Yes	No	
Hexahydro-4-methylphthalic anhydride	Resin hardener	No	Yes	Not contained within finished EEE, except as an impurity
Henicosafluoroundecanoic acid	Surfactant	Very unlikely	Yes	Traces may remain in polymers due to manufacturing
Trixylyl phosphate (TXP)	Flame retardant	Yes	Yes	
Hexahydromethylphthalic anhydride	Resin hardener	No	Yes	Not contained within finished EEE, except as an impurity

Substance	Main uses	Will it occur in electrical equipment?	Is it a REACH SVHC?	Further comment worth noting
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	UV stabiliser used in plastics, paints, etc.	Yes	Yes	
Tricosafluorododecanoic acid	Surfactant	Very unlikely	Yes	Traces may remain in polymers due to manufacturing
Perfluorodecanoic acid (PFDA)	Waterproof coatings and as a process chemical	Very unlikely	Yes	Traces may remain in polymers due to manufacturing
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	UV stabiliser used in plastics, paints, etc.	Yes	Yes	
Perfluorononan-1-oic-acid (PFNA)	Manufacture of fluoropolymers. An additive in lubricating oils, in cleaning agents, for waterproofing and textile coatings and in liquid crystal displays	Possible but unlikely	Yes	Traces may remain in polymers due to manufacturing
Heptacosafluorotetradecanoic acid	Surfactant	Very unlikely	Yes	Traces may remain in polymers due to manufacturing
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV320)	UV stabiliser used in plastics, paints, etc.	Yes	Yes	
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	UV stabiliser used in plastics, paints, etc.	Yes	Yes	
Hexahydro-1-methylphthalic anhydride	Resin hardener	No	Yes	Not contained within finished EEE, except as an impurity
Formaldehyde	Process chemical used to make resins but can occur at low concentrations	Possibly but only at low concentrations	Yes	
[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride	Also called Crystal Violet. Dye for paper, blue/black inks in printer cartridges, textiles	Possible	Yes	
Hexahydro-3-methylphthalic anhydride	Resin hardener	No	Yes	Not contained within finished EEE, except as an impurity
N,N-dimethylformamide (DMF)	Solvent	No	Yes	Not contained within finished EEE. No evidence is used in electrolytic capacitors used by MedTech Europe's members.
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	Plasticiser used in PVC, rubber, adhesives	Yes	Yes	
1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich = Di-'isodecyl' phthalate (DiDP)	Plasticiser- Commonly used substitute for DEHP	Yes	No	Commonly used substitute for DEHP so if restricted will result in polymer manufacturers having to substitute again. Polymer manufacturers would have chosen DiDP as a safe substitute for DEHP because it is classified (by the EU or by most REACH Notifiers) as being not hazardous

Substance	Main uses	Will it occur in electrical equipment?	Is it a REACH SVHC?	Further comment worth noting
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	Plasticiser	Yes	Yes	
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters	Plasticiser in PVC, sealants, flexible adhesives and paints	Yes	Yes	
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich = Diisoheptyl phthalate (DIHP)	Plasticiser	Yes	Yes	
Perfluorotridecanoic acid	Surfactant	Unlikely	Yes	
Nickel (Ni)	Metal used in alloys and electroplated coatings	Yes (very common)	No	Very widely used by the electronic industry and for most uses it is probably impossible to replace. Already restricted by the REACH Regulation
Cyclohexane-1,2-dicarboxylic anhydride	Resin hardener	No	Yes	Not contained within finished EEE, except as an impurity
1-methyl-2-pyrrolidinone (NMP)	Solvent (rarely used in electrolytic capacitors)	No	Yes	Not contained within finished EEE
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	Heat stabiliser (mainly in PVC)	Yes	Yes	

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