COCIR
Brussels, Belgium

Additional RoHS substances

Review of impact of potential new RoHS substance restrictions on the medical sector

Report No. 2019-0749 - September 2019

Project No. REG0364001

Rev.	1
Description	FINAL
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Date	19/09/2019

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Rev.	Description	Prepared by	Controlled by	Approved by	Date
0	DRAFT	Paul Goodman			11/07/2019
1	Final	Paul Goodman	Emily Tyrwhitt Jones	Chris Robertson	19/09/2019

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1 INTRODUCTION

The European Commission has responsibility for amending Annex II of the RoHS Directive to add substances that are believed to cause harm to human health or the environment or to negatively impact the management of waste from Electrical and Electronic Equipment (EEE). There is an emphasis on end-of-life of electrical equipment, as other legislation, such as the REACH Regulation, is intended to protect human health and the environment from chemical and production processes.

Currently, the Oeko Institut is assessing seven types of substances on behalf of the European Commission. COCIR 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 developed by COCIR to estimate the time required for substitution to provide evidence of the minimum transitional period (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.

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

2 USES OF THE SEVEN PROPOSED SUBSTANCE TYPES IN MEDICAL DEVICES

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

2.1 Diantimony trioxide

Diantimony trioxide is very widely used in electrical equipment. Its main use is as a flame retardant synergist where it is added to plastics and polymeric materials, such as paints, adhesives, coatings and resins, and is usually used with halogenated compounds. Over 70 different halogenated flame retardants are used in electrical equipment and most are not classified as hazardous in the EU. The few that are hazardous are restricted either by RoHS or REACH (such as the PBDEs and PBBs). Halogenated flame retardants can sometimes be used on their own without diantimony trioxide, but much higher concentrations are needed and they can be much less effective as flame retardants without diantimony trioxide.

Diantimony trioxide is also added to flexible polyvinyl chloride (PVC) as a flame retardant. Rigid PVC is not flammable and so does not require the addition of flame retardants, but flexible PVC contains plasticisers which are flammable substances and so diantimony trioxide is required to give flame retardancy.

Most manufacturers of electrical equipment, including medical equipment manufacturers, do not know which electronic components or materials that they use contain this substance because it is not a REACH SVHC so there is currently no requirement for suppliers to provide this data. However, information submitted to the stakeholder consultation by the American Equipment Manufacturers (AEM) Association included data from manufacturers in the automotive sector who have access to the IMDS (International Materials Data System) database, which includes data on diantimony trioxide. This showed that a very large number of electronic components contain diantimony trioxide. Effective flame retardancy is essential in electronic components, circuit board laminates and enclosures to prevent fires in the event of a fault.

Diantimony trioxide is also used as a catalyst to manufacture polyethylene terephthalate (PET) and other similar polymers, such as polybutylene terephthalate (PBT), which is used to make electrical connectors and electronic components. The polymer will typically contain about 0.015 – 0.02% of diantimony trioxide.

Diantimony trioxide has other uses as a process chemical where it does not occur in the finished product. This includes in the manufacture of glass and other antimony chemicals, but these should not be affected by a RoHS restriction of diantimony trioxide.

To summarise, the main uses of diantimony trioxide in medical devices are:

- Printed circuit board epoxy laminates,
- Electrical component mounting epoxy resins,
- Cable insulation,
- Electronic component insulation and encapsulation, such as diodes, connectors, voltage suppressors and regulators, transformers, displays, Integrated circuits, transistors, inductors, capacitors, resistors, inverters, temperature and other sensors, transducers, switches, relays, etc.

- Plastic housings, enclosures and other parts that require fire retardancy,
- Rubber components such as grommets and drive belts, and
- PET and PBT components, such as connectors.

2.2 Medium Chain Chlorinated Paraffin (MCCP)

MCCP is primarily used as a combined flame retardant and plasticiser and its main use is in flexible PVC wire insulation, tubing, hoses and sheet. It 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. It may also occur in many types of rubbers that are used for hoses, sheet, cable covers, etc. As it is used in paints, coatings and adhesives, it may occur in many types of parts and subassemblies used in medical devices. MCCP was proposed for restriction by KEMI, the Swedish Chemical Agency which is the government authority of the Swedish Ministry of the Environment, which submitted a 109 page dossier in support of this proposal.

2.3 Tetrabromobisphenol A (TBBP-A)

TBBP-A is mainly used as a reactive flame retardant to manufacturer flame retarded epoxy resins, which are used for printed circuit board laminates as well as adhesives and as an encapsulant of electronic components. It is also used to manufacture flame retarded polymers such as polycarbonate. As a reactive component of polymer production, only trace residues of TBBP-A remain in the finished product. One publication reports only 0.7ppm is present in cured resin[1].

Only small amounts of TBBP-A are used as an additive flame retardant mainly in Acrylonitrile Butadiene Styrene (ABS) used in mouldings, enclosures, etc., although according to the stakeholder consultation contribution from ZVEI, TBBP-A is not used as an additive in Europe[2].

2.4 Beryllium and its compounds

Beryllium is used in medical devices in up to three different forms:

- As elemental beryllium metal as transparent windows for allowing the transmission of X-radiation and other types of ionising radiation. X-ray windows are essential in X-ray Imaging equipment.
- As beryllium alloys, especially as copper beryllium which is used for its low electrical resistivity and its superior stress relaxation resistance. This combination of properties make it ideal for electrical connector and switch applications with high reliability and a long lifetime. Nickel beryllium alloys may also be used. Uses of copper beryllium include:
    - Sprung clips, contact springs, switch contacts and terminals in connectors and in switches, relays and circuit breakers,
    - Electric motor brushes,
    - Bearings and bushes, and
    - Low resistivity EMC seals used to ensure permanent electrical connections between enclosure parts that may need to be periodically separated for maintenance.

      Beryllium alloys are used in applications where very long reliable lifetime of components is essential. Copper beryllium alloys also have very low electrical resistivity so are ideal for making electrical connections (e.g. switches and connectors) that are required to have long lifetimes. All metals suffer from a process called “creep” when under stress and this results in springy materials relaxing so that contact forces decrease to a level where it is insufficient for making a good electrical connection. Beryllium copper has an especially good resistance to stress relaxation so that it maintains contact force for much longer than other lower cost alloys such as phosphor bronze (commonly used in cheaper connectors that do not require long lifetimes).

      Beryllium alloys are also non-magnetic so are suitable for use in MRI, unlike some alternative connector alloys.

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[1] https://www.epa.gov/sites/production/files/2015-08/documents/pcb_ch5.pdf

[2] ZVEI submission to the proposed additional substances stakeholder consultation.

- The only beryllium compound used in electrical equipment is beryllium oxide. Its main use is as an electrically insulating thermal conductor which is used inside high speed power semiconductor devices. It is used in high-performance, high-power microwave integrated circuits, high-frequency electronic transistors and high-circuit density multichip components. It is used because it has a very low dielectric constant and high thermal conductivity. It is also reported to be used in some types of microwave devices, vacuum tubes, magnetrons, and gas lasers and medical excimer lasers used for surgery.

2.5 Indium phosphide

Indium phosphide's main use in electrical equipment is as a semiconductor, where it is mainly used for high frequency optical communications. It is used in laser diodes and detectors that operate at 1310 and 1550 nm. These components are mainly used by the telecom sector, but these are also used in medical devices to transmit large amounts of data via Ethernet. MRI, CT, PET, etc., all generate large amounts of data which needs to be rapidly transmitted to specialists at other locations.

Indium phosphide is also used as a quantum dot display material. These may be used for monitors or for displaying X-ray, MRI and other images to aid diagnosis and treatment.

2.6 Nickel sulphamate and sulphate

These nickel compounds are both used as process chemicals to manufacture nickel metal coatings by electroplating or electroless plating. They are also used to manufacture other nickel compounds. As process chemicals, they will not occur in medical devices.

2.7 Cobalt chloride and sulphate

Cobalt chloride and cobalt sulphate are used mainly as process chemicals for:

- Electroplating cobalt metal and its alloys,
- To manufacture other cobalt compounds such as pigments and driers (added to inks and paints), and
- As an additive in trivalent chromium passivation processes. It is unlikely that cobalt sulphate will be detectable (although unidentified cobalt compounds may occur) in the passivation coating.

Cobalt chloride and sulphate will not occur in medical devices. However, ECHA has proposed to impose restrictions on several cobalt compounds including the chloride and sulphate under Annex XVII of the REACH Regulation[3]. REACH restriction of cobalt compounds would negate the need for a RoHS restriction although is likely to cause technical difficulties for medical device manufacturers who manufacture in the EU.

2.8 Summary of mains uses

The main uses are as follows:

Substance	Main uses in medical devices
Diantimony trioxide	Flame retardant synergist in plastics, resins, laminates, coatings, cable insulation, electronic components, etc. Catalyst for PET and PBT
MCCP	Combined flame retardant and plasticiser in flexible PVC wire insulation, coatings, adhesives and sealants
TBBP-A	Additive flame retardant in ABS. Used reactively in epoxy resins, PET, etc, but will not occur in finished products

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[3] https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/21805/term

Substance	Main uses in medical devices
Beryllium metal and beryllium oxide	Alloys used for connectors, switches, springs, clips, etc. Beryllium oxide is used in integrated circuits where its high thermal conductivity and low dielectric constant are essential. Beryllium is also used for X-ray windows
Indium phosphide	High speed Ethernet communications and quantum dot displays
Nickel sulphamate and sulphate	Process chemicals, will not occur in finished products
Cobalt chloride and sulphate	Process chemicals, will not occur in finished products

3 POTENTIAL FOR SUBSTITUTION AND NEED FOR EXEMPTIONS

3.1 Diantimony trioxide

3.1.1 Fire retardant synergist

Diantimony trioxide will be very difficult to replace in medical devices (and in other types of electrical equipment) as there are no drop-in replacements that can achieve the same level of fire retardancy in the same types of polymeric material and without detrimentally affecting the physical properties. Diantimony trioxide is used to achieve at least UL94V0 fire retardancy which is required by most safety standards, but has only a small impact on colour, flexibility, impact strength, etc. unlike many other types of flame retardant.

Some manufacturers of consumer products make so-called “halogen-free” products. These tend also to be diantimony trioxide-free as this substance is usually used with halogens. Consumer products however have much shorter lifetimes, reliability is less important and only limited numbers of halogen-free laminates and components are available.

Replacement of diantimony trioxide in electronic components and in mouldings (such as housings) will be a huge task. This will usually require complete reformulation of resins, some polymers will have to be substituted and, inevitably, many components that are made in smaller numbers will become obsolete if the cost of substitution outweighs future income. Until research is carried out, the numbers of exemptions needed is not known, but it is likely that many exemptions will be needed - for example where the only alternative flame retardants do not achieve the same level of fire retardancy.

Flexible PVC must contain diantimony trioxide; there are no alternatives to achieve UL94V0. Therefore, if diantimony trioxide cannot be used, this is in effect also a ban of flexible PVC. Alternatives to diantimony trioxide in PVC tend to make this material much less flexible or cannot achieve UL94VO. The difficulties of substitution of PVC by alternative polymer materials for wire and cable are described in section 3.2

3.1.2 PET/PBT catalyst

Alternative catalysts have been developed and are used in limited amounts (95% of catalysts used for PET are diantimony trioxide). A review from 2001 showed that substitute materials give polymers with different properties and most are not satisfactory[4]. A more recent article states that although titanium and germanium catalysts are used for some applications, they cannot be used to replace diantimony trioxide[5].

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[4] https://www.polyester-technology.com/index.php?id=14&tx_news_pi1%5Bnews%5D=7&tx_news_pi1%5Bcontroller%5D=News&tx_news_pi1%5Baction%5D=detail&cHash=868f149788f9d01dfbb3ec3b19c4231f

[5] https://chemicalwatch.com/68491/european-pet-group-to-join-antimony-data-gathering-effort

3.2 Medium Chain Chlorinated Paraffin (MCCP)

The cable association Europacable stated in their response to the stakeholder consultation that substitution may not be possible when the cables are used under certain environmental conditions. They stated that various substitutes are being evaluated, although not all PVC insulated cables contain MCCP.

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 UL94V0. 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.

Another option is to replace PVC with alternative types of polymer. Several types are already widely used for wire and cable apart from PVC, but all have different properties and performance. Most alternative polymers are less flexible than PVC which is a severe limitation when complex wiring harnesses are needed and these are often required in medical imaging equipment. Many medical devices have moving parts so that cable need to move and be flexible without imposing stresses on other components such as connectors. Imposing cyclic stresses on connectors can cause failures due to a process called fretting where the surface coating of terminals is rubbed away and insulating oxide build up. Fluoropolymers and silicone insulation are flexible, but both have other limitations. Fluoropolymers emit extremely toxic and dangerous fluoro-compounds in fires and silicone insulation is porous to moisture so can break down causing electrical failure.

The following table compares the advantages and disadvantages of wire insulation materials.

Insulation Material	Advantages	Disadvantages
PVC	Durable, excellent moisture resistance. Can be recycled	Max operating temp. 70 - 105˚C (not usually a problem). High dielectric loss (only an issue with high frequencies)
Polyethylene (PE)	Low dielectric loss and high initial dielectric strength	Relatively stiff and inflexible. Moisture sensitive causing water treeing under high voltage and breaks down at high temperature
Cross-linked Polyethylene (XLPE)	XLPE has low dielectric loss but higher than PE. Max operating temp. 90 - 110˚C and has better ageing characteristics. Good resistance to cracking	Relatively stiff and inflexible. Medium resistance to water treeing
EPR (ethylene propylene rubber)	More flexible than PE and XLPE and lower thermal expansion	Medium to high dielectric loss. Poor tear resistance and easily damaged due to its softness
Polyurethane	Tough and flexible, even at low temperature. Good water and chemical resistance	Poor electrical properties so suitable only for outer cable jackets
EPDM	-55 to +150˚C range, good dielectric strength	Poor resistance to some chemicals
Fluoropolymers	Several types available. Very flexible, thermally stable and chemical resistant	FEP has poor cut through resistance, Susceptible to cold flow when stressed (bent) over tight radius or when laced too tightly, emits very toxic and corrosive gases in fires
Silicone	Wide temperature capability and will not burn	Poor cut through resistance, static electricity can build up, which is unacceptable with most types of electrical equipment

In addition to the above differences in materials, wire and cable used with medical devices may require properties such as resistance to chemical sterilisation (PVC is resistant) and bio-compatibility when contact with patient's skin occurs.

3.3 Tetrabromobisphenol A (TBBP-A)

Substitution is unnecessary in applications where this does not occur in finished products, unless it is restricted as a process chemical by the REACH Regulation. A RoHS restriction would only affect additive uses, which appear to be very few although information about its use by Asian manufacturers is not available.

ABS flame retarded with TBBP-A also contains diantimony trioxide. Alternatives in ABS would include other brominated flame retardants. One publication suggests that red phosphorous could be used, although this is a hazardous material that has caused reliability issues with electrical equipment in the past. Triphenyl phosphate is also suggested as a halogen-free substitute[6] but is an aquatic acute and chronic category 1 toxin, so is potentially very harmful to the environment. No halogen-free flame retarded grades of ABS are available.

3.4 Beryllium and its compounds

The US Geological Survey has assessed substitutes for beryllium and its compounds and states:
"*Copper alloys containing nickel and silicon, tin, titanium, or other alloying elements or phosphor bronze alloys (copper-tin-phosphorus) may be substituted for beryllium-copper alloys, but these substitutions can result in substantially reduced performance*"[7].

Beryllium has also been assessed[8] for the REACH Regulation (by Germany). 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*".

Beryllium is relatively expensive and so most manufacturers will have already searched for lower priced substitutes and have substituted beryllium wherever this has been technically possible. The remaining uses of beryllium therefore are those where substitution is not technically possible and it is very unlikely that alternative materials or designs will ever be developed. The three main uses are discussed below.

3.4.1 Windows transparent to X-rays and other ionising radiation

Beryllium windows are required in locations where on one side is a vacuum and the other air, and so the material must be mechanically strong enough to withstand the pressure of air against a vacuum and able to be effectively sealed to prevent leaks. Transparency to ionising radiation requires a material with a low atomic number. In some applications such as image intensifiers, aluminium is used as the transparent material because, although it blocks a proportion of the radiation, sufficient radiation passes to obtain a clear image. In other applications where low energy or low intensity radiation is required to pass through the window, aluminium would block too large a proportion of the radiation and only much lighter elements are suitable. The lightest elements and their atomic numbers are:

1 and 2: Hydrogen and helium, atomic numbers 1 and 2 are both gases so are unsuitable.

3: Lithium is the lightest metal with atomic number 3. It is however a reactive metal rapidly forming a thick oxide coating when exposed to air. Oxidation will continue until all of the lithium metal is consumed and the oxide will disintegrate as a powder. Furthermore, oxygen has atomic number 8 so will block more radiation than beryllium.

4: Beryllium is relatively strong and forms only a very thin oxide passivation coating and so beryllium is the optimum choice.

5: Boron is not a metal and cannot form physically strong sheet materials.

6: Carbon is also not a metal and although sheets of carbon (graphite) can be produced, these are too weak to withstand a vacuum. Carbon will also block more low energy radiation than beryllium.

7 – 10: Element with atomic numbers 7 – 10 are all gases.

3.4.2 Alloys

Copper beryllium is used in applications where low electrical resistivity and an ability to maintain tensile properties for long periods are both required. Alternative alloys which have either low electrical resistivity or suitable tensile properties exist, but none have both properties. The submission to the Stakeholder consultation by the Beryllium Science and

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[6] https://www2.mst.dk/udgiv/Publications/1999/87-7909-416-3/html/helepubl_eng.htm#kap7.2.3

[7] https://prd-wret.s3-us-west-2.amazonaws.com/assets/palladium/production/s3fs-public/atoms/files/mcs-2019-beryl.pdf

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

Technology Association[9] includes a graph of electrical conductivity versus yield strength (detailed on page 4 of the report) which illustrates that this unique combination of these properties is achieved only by beryllium alloys.

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 only the more expensive beryllium alloys are suitable. One stakeholder suggested that a copper-titanium-iron alloy or copper-nickel-silicon[10] alloys could replace copper beryllium. These alloys are already used for connectors and other applications where their properties are suitable as they are lower cost than copper beryllium. However copper-titanium-iron has a higher electrical resistivity than copper beryllium and both potential substitutes are slightly magnetic (as they contain iron or nickel) so could not be used in MRI applications.

3.4.3 Beryllium oxide

Beryllium oxide is used where an electrical insulator and thermal conductor are required. Most ceramics are electrical insulators but poor thermal conductors. A few however have reasonable thermal conductivity and so are used inside integrated circuit packages to remove heat from the silicon die. The thermal conductivity must be good enough to prevent overheating which would damage the die's circuitry. Beryllium oxide has the highest thermal conductivity of ceramic materials but is the most expensive and so is only used if other materials are inadequate to prevent overheating. Most integrated circuit packages can and do use alternative materials but high frequency high power telecommunications integrated circuits need to use beryllium oxide. AEM's submission to the stakeholder consultation included a comparison of the thermal conductivity of ceramic materials:

Material	Thermal conductivity
Beryllium oxide	265 W/mK
Aluminium nitride	180 W/mK
Silicon carbide	70 W/mK
Boron nitride	60 W/mK
Aluminium oxide	25 W/mK

Aluminium nitride, for example is used in ICs where its thermal conductivity is "good enough" as it is cheaper than beryllium oxide. Aluminium oxide is cheaper than aluminium nitride so this is used in preference if its performance is good enough for the application.

3.5 Indium phosphide

Indium phosphide semiconductor is an expensive material as it is very difficult to fabricate. As a result of its high cost, it is only used where no alternatives with suitable performance exist. Several stakeholders who contributed to the consultation stated that for the applications where indium phosphide semiconductor lasers are used, no alternatives exist.

The other use in displays has one alternative which is cadmium compounds. However cadmium is already restricted by RoHS and so can be used only if exempted.

3.6 Nickel sulphamate and sulphate

No need for substitution as these substances do not occur in finished medical devices.

3.7 Cobalt chloride and sulphate

No need for substitution as these substances do not occur in finished medical devices.

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[9] https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_BeST_ESIA_Beryllium_RoHS-Pack15_20180615.pdf

[10] According to the Copper Development Association, CuBe alloy C17460 has a higher electrical conductivity (45%IACS compared to 41% IACS) and higher modulus of elasticity than CuNiSi C64728, so CuBe is overall slightly superior.

4 RECYCLABILITY OF MEDICAL WASTE

Waste Electrical and Electronic Equipment (WEEE) containing the proposed RoHS substances is currently safely recycled in the EU and can also be recycled safely in non-EU countries. The impacts of the seven proposed substances and potential substitutes on recycling of WEEE is summarised as follows:

4.1 Diantimony trioxide

WEEE recycling processes have to collect and recover antimony to comply with the EU Industrial Emissions Directive and so safe and efficient processes for antimony recovery are in place and are used. The recovered antimony can be converted into antimony metal or chemicals for reuse. Antimony is present in WEEE not only as diantimony trioxide but also as antimony metal as an alloying additive, as compounds in glass, as pigments and in sodium antimonate flame retardant. Therefore, although a restriction of diantimony trioxide would reduce the concentration of antimony present in WEEE, it will not decrease it to zero and so the currently used recycling processes will need to continue unchanged.

4.2 Medium chain chlorinated paraffin

The most commonly used recycling process for electrical cables is smelting to recover the copper. The polymer coating is not recovered and so is used to generate energy. Copper wire smelting processes must be operated at a high temperature to destroy harmful combustion by-products that are formed when all types of plastics are burned. It is necessary to burn MCCP at high temperature to prevent the formation of dioxins and furans, and modern smelters are able to do this very efficiently. In the EU, harmful emissions are regulated by the Industrial Emissions Directive which imposes very strict limits on the emission of all harmful by-products. Alternative cable materials are likely to be PVC-based, although other polymers may be selected. However all of these polymers will also emit harmful substances if the smelting temperature is not sufficiently high, including the halogen-free polymers which will generate polycyclic aromatic hydrocarbons, which are carcinogens. Therefore restricting MCCP will not affect how WEEE needs to be recycled.

A ban of MCCP will have only a small impact on unsafe potentially illegal recycling that is carried out in some developing countries. Firstly, EU WEEE should not be exported to these countries. Also, unsafe recycling is banned in many countries including China. The problem with these unsafe processes is that the polymer coated is burned off the copper wire at too low a temperature. All polymers generate polycyclic aromatic hydrocarbons and the quantity of these harmful substances depends on the combustion temperature; hence all flame retardants increase these emissions as they function by lowering combustion temperature. Flame retardants are essential to prevent fires which cause many more deaths globally than can be attributed to polycyclic aromatic hydrocarbon emissions from illegal recycling.

4.3 Tetrabromobisphenol A

TBBP-A is mainly used as a reactant so is not present in WEEE. It will occur in small quantities if used additively in ABS. The same issues as described above for MCCP exist with recycling of all polymers and so restriction of TBBP-A would not change how WEEE is recycled.

Mixed recovered plastic are currently not recyclable as facilities in the EU are very limited and China no longer permits import of WEEE. Changing from one type of plastic formulation to another will not resolve this issue.

4.4 Beryllium and its compounds

Beryllium is an expensive metal and so beryllium X-ray windows are very likely to be collected for recycling of the metal. There are no alternatives to beryllium for windows. Medical device manufacturers publish WEEE Recycling Passports for their products and these specify that beryllium windows should be recovered for recycling and provide instructions to recover the windows.

Beryllium alloys are used in medical devices but in only small quantities (due to its high cost) and so the amounts of beryllium that will occur in WEEE are extremely low. The concentration of beryllium in WEEE is so low that it is not possible to recover it and levels of emissions are too low to be detected. A published study[11] found 6ppm of beryllium in one fraction (fine shredder waste), but it was undetectable in other fractions. Air emissions were also measured but beryllium was not detectable. Beryllium therefore does not inhibit recycling of WEEE.

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[11] http://beryllium.eu/wp-content/uploads/2016/07/Beryllium-Exposure-Assessment-during-WEEE-Recycling-23-Jan-14.pdf

4.5 Indium phosphide

Indium is a very scarce element so that its concentration in WEEE is too low for it to be economically recovered. Most indium in WEEE is as indium tin oxide (ITO), a transparent electrically conducting coatings on displays. The quantity of indium phosphide in WEEE will be much less than the amount of ITO so that it has no effect on WEEE processes and is not recoverable.

4.6 Nickel sulphamate and sulphate

Not present in WEEE so no impact.

4.7 Cobalt chloride and sulphate

Not present in WEEE so no impact.

5 EVIDENCE OF HARM FROM SUBSTANCES AND SUBSTITUTES

Article 1 of the RoHS Directive requires the European Commission to adopt measures to prevent harm to human health and the environment. Therefore, a RoHS restriction is justified if there is evidence that harm may be caused by use of a substance in electrical equipment, especially if due to end-of-life processes. One aim of the assessment by the Oeko Institut is to determine whether any evidence of harm is caused although the Commission needs to take into account the Precautionary Principle. In any case, if alternatives could be equally harmful or worse, then restriction would not be justifiable, thus being in conflict with the principle of proportionality. Therefore availability and identity of substitutes does need to be taken into account and is considered above in section 3. To determine whether harm is caused, data on a) exposure levels and also b) the minimum amount that causes harm is needed. Published sources of this data are described below.

5.1 Published impact assessments

5.1.1 Diantimony trioxide

A risk assessment by the US EPA (published in 2014) concluded that antimony oxide poses a minimal risk to the environment[12] and does not pose a significant health risk to the general population or to workers.

An earlier EU risk assessment published in 2008 gave similar conclusions; the environmental risk assessment for all impacts (air, water, terrestrial, sediments, etc.) was:
"There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already."

The human health impact conclusions were slightly different to the more recent US study. For workers, the assessment concluded that further risk reduction measures are necessary, although for patients or user of medical devices in hospital environment, no risk reduction measures are necessary. This conclusion includes exposure via the environment and the assessment considered exposure to consumers at locations where high levels of antimony occur which could include poorly controlled WEEE recycling plant. Protection of workers does not require restriction by RoHS as other measures can be and are being used such as worker safety legislation, national occupational exposure limits and the use of suitable personal protective equipment.

A CORAP assessment of diantimony trioxide is currently underway[13].

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[12] https://www.epa.gov/sites/production/files/2015-09/documents/ato_ra_8-28-14_final.pdf

[13] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180b91312

5.1.2 Beryllium

The German competent authority carried out a REACH substance evaluation of beryllium and its compounds which was published in 2014[14]. This study concluded: "*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*".

It also recommended:

- That the substance should be a REACH SVHC, and
- There is no need for restriction or other EU-wide measures (i.e. such as RoHS).

A risk assessment carried out by the World Health Organisation[15] concludes that the general population is exposed to beryllium mainly via food and drinking water (96% of this is beryllium emitted into the atmosphere from oil or coal combustion for electric power generation) and only workers who carry out processes with beryllium are exposed mainly from industrial sources. Therefore, protection of workers is needed to prevent harm but measures to protect consumers, patients or users of medical devices do not appear to be needed. In fact, restriction of oil and coal combustion globally would seem to be the only effective means of reducing consumer and environmental exposure to beryllium.

5.1.3 TBBP-A

A comprehensive EU human health risk assessment was carried by the UK in 2006 for TBBP-A[16], which concluded that there were no human health effects of concern. As a result, no restrictions were adopted at that time. An EU environmental risk assessment[17] was also published in 2008 which identified some concerns, but no restrictions were subsequently adopted, presumably as these were deemed to be unnecessary.

The United States Environmental Protection Agency (US EPA) carried out a comparative life cycle assessment on circuit board laminates made with TBBP-A and alternative flame retarded laminates[18]. This showed that alternatives are not benign as they have different impacts to TBBP-A laminates.

5.1.4 MCCP

Sweden (KEMI) has carried out an extensive study of MCCP and the report concluded that a RoHS restriction is justified. MCCP is clearly one of the most hazardous of the seven proposed types of substance and according to the Swedish study is used in relatively large quantities in the EU, although many of its uses are not in electrical equipment. The KEMI report does not state the proportion used in electrical equipment, but based on data in a report from the Danish Environment Agency, RINA estimates that this is less than 50% of the total amount used and is probably significantly less than 50%.

An EU environmental risk assessment of MCCP was carried out and published in 2005 which concluded that measures were needed to protect the environment. The corresponding human health risk assessment (2008) concluded that a risk to workers may exist and so MCCP needs to be controlled, but there was no risk to consumers[19]. No legislation has been adopted since 2005 to protect the environment or workers (apart from workplace exposure limits) and so RoHS would go some way to providing partial protection, but if MCCP is harmful, then a wider REACH restriction would be necessary to include non-electrical applications that appear to be the majority of uses.

6 Published data on exposure

Emissions at and in the vicinity of WEEE recycling plant must be measured to comply with the EU Industrial Emissions Directive (IED) and this data is provided to Member State competent authorities that enforce the IED. This is the most reliable and accurate data available for exposure levels close to EU recycling plant. However other data is available that could be used for assessment of possible restrictions.

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

[15] https://www.who.int/ipcs/publications/cicad/en/cicad32.pdf?ua=1

[16] https://echa.europa.eu/documents/10162/32b000fe-b4fe-4828-b3d3-93c24c1cdd51

[17] https://echa.europa.eu/documents/10162/17c7379e-f47b-4a76-aa43-060da5830c07

[18] https://www.epa.gov/sites/production/files/2015-08/documents/pcb_final_report.pdf

[19] https://echa.europa.eu/documents/10162/13630/trd_rar_uk_mccp_en.pdf

6.1 Diantimony trioxide

The EU risk assessment of antimony oxide carried out by Sweden and published (as a draft) in 2008 (as described in section 5.1.1) includes extensive emissions data for all life cycle phases and this data was used to reach its conclusions that no additional measures are necessary to protect consumers or the environment[20]. The risk assessment based its conclusion on worker exposure levels and so recommended a requirement to protect workers (such as via workplace exposure limits) but these were based on production plant emissions, not from recycling plant.

RoHS is mainly concerned with end-of-life. When diantimony trioxide is used in electronic components and when waste plastic is disposed of by incineration (the most commonly used method), diantimony trioxide is oxidised to the less hazardous diantimony pentoxide and this is the main reason why at end-of-life, diantimony trioxide recycling causes no harm. Shredding and recycling plastics may emit small amounts of dust, but these emissions are included in the 2008 EU risk assessment as shredded plastics are used as a feedstock for plastics production.

The more recent US EPA risk assessment concluded from more recent data (collected during the 3 years before the 2014 report) that measured antimony concentrations from environmental monitoring samples showed that exposure levels do not exceed levels hazardous to the environment[21]. This study also points out that the consumers are exposed to antimony mainly via food and water and that these will contain mainly the less hazardous pentavalent form (e.g. diantimony pentoxide) and significant health risks do not occur. There is evidence that trivalent antimony is converted to the pentavalent form under aerobic conditions and that release of diantimony trioxide from consumer products is minimal. The USA EPA study reports that a 0.5mg/m^3 exposure limit is sufficient to protect workers (the same limit as used in the EU).

6.2 Beryllium

The WHO has published a detailed risk assessment concerning beryllium. Interestingly, this shows that over 99% of air emissions of beryllium globally are from coal crushing and combustion for power generation[22]. Air concentrations and human and worker exposure data are described. However, some of the data used is not recent and exposure levels will have declined in industrialised countries where mandatory control measures are imposed.

The UK Health and Safety Executive (HSE), who enforce worker safety in the UK, has published extensive guidance and also states that ill health has been caused in the past to workers who produce beryllium and beryllium oxide ceramics[23], although the data is pre-2000. Risk assessments are required in workplaces in the EU where beryllium is used and workers' health monitoring may be necessary to ensure that no harm is caused. The UK and most other countries have an 8 hour time weighted average workplace exposure limit of 2 µg/m^3, but the US recently adopted a 0.2 µg/m^3 8 hour average limit.

The International Agency for Research on Cancer (IARC) has published some data on levels of exposure to beryllium[24], including in factories where beryllium oxide and beryllium alloys are processed. Levels of exposure to beryllium by consumers from food, water and air is also published in the IARC Monograph.

The Beryllium Science and Technology Institute (BeST) lists on its website[25] potentially useful publications include one on beryllium emissions at a UK WEEE recycling plant. This plant recycles all types of WEEE including domestic appliances, IT, consumer products, etc. Beryllium-containing parts are not separated before shredding, etc. Airborne beryllium was measured but was in all cases below the detection limit of 0.0069 µg/sample and so would be below an occupational exposure limit of 0.2 µg/m^3. Beryllium was present in the WEEE being treated, but unsurprisingly, concentrations were very low at concentrations up to 6.1 ppm. Smelting of metallic fractions was not carried out at this site.

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[20] https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=11&ved=2ahUKEwiouN7qh9rkAhXdRxUIHdKLAgwQFjAKegQIARAC&url=https%3A%2F%2Fecha.europa.eu%2Fdocuments%2F10162%2F13630%2Ftrd_rar_sweden_diantimony_trioxide_en.rtf&usg=AOvVaw0baWtYadodv0NQAbIQxwgi

[21] https://www.epa.gov/sites/production/files/2015-09/documents/ato_ra_8-28-14_final.pdf

[22] https://www.who.int/ipcs/publications/cicad/en/cicad32.pdf?ua=1

[23] https://www.hse.gov.uk/research/rrpdf/rr873.pdf

[24] https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100C-7.pdf

[25] http://beryllium.eu/resources-2/

Clearly there is potential for emissions during beryllium production and processing, although effective control measures are available. However, due to the very low beryllium content of WEEE, emissions of beryllium are likely to be undetectable, unless beryllium-containing components are separated for separate recycling.

6.3 TBBP-A

Measured data is as follows from the EU environmental impact assessment published in 2008[26].

Measured emissions from TBBP-A production plant:

Dust (measured 1998) 0.031 g/hour

EU emissions from production plant in 1993

To air 0.07 kg (particulates)/tonne TBBP-A produced

To water <0.5 kg/tonne + 0.045 to <0.45 kg/tonne

Use phase:

Reactive uses From 6 sites, there were no emissions to air and water from 3 sites.

The remaining 3 sites: To water <0.075 kg/day, 25 kg/year and 0.72 kg/day

To air – local emissions 0.027 kg/day

Additive uses To air; local release of 0.25 kg/day

To water; local release of 0.25 kg/day (over 33 days/year only)

Emissions from recycling materials that contain additive TBBP-A are included in the impact assessment. Incinerator emissions are given as 0.013 to 0.018 mg/hour. However, analysis of TBBP-A in bottom ash of a Finnish incinerator used for circuit board scrap found that TBBP-A was not detectable.

Where plastic is recycled by remoulding, emissions to air were 0.13 mg/hour. At a newer Japanese recycling plant with similar materials, emissions were 50 ng/m^3.

However, most applicable to WEEE recycling is the following result on release of free TBBP-A during recycling and disposal which is are described in section 3.1.0.3.4 of the EU impact assessment. This states that "*The potential for emissions of tetrabromobisphenol-A from the collection, separation and regrinding of printed circuit boards (or other plastic articles that contain tetrabromobisphenol-A reacted into the polymer backbone) would appear to be limited owing to the relatively low residual or free tetrabromobisphenol-A content of the polymer (less than 200 ppm (<0.02%) based on the mass of resin*". No TBBP-A emissions were measured.

6.4 Indium phosphide

IARC has published a monograph on indium phosphide that includes some data for workers' exposure to indium phosphide in the semiconductor industry, but no data exists for exposure from indium phosphide to the environment[27]. Exposure data for indium to consumers and the environment exists but there are many natural and anthropogenic sources of indium so these give no information on exposure to indium phosphide.

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[26] https://echa.europa.eu/documents/10162/17c7379e-f47b-4a76-aa43-060da5830c07

[27] https://monographs.iarc.fr/wp-content/uploads/2018/06/mono86-9.pdf

6.5 MCCP

Only very limited published exposure level data is available. The KEMI proposal for a RoHS restriction of MCCP[28] includes some data. This states that emissions from incinerators are negligible as MCCP is destroyed, as are the potential by-products dioxins and furans which are also destroyed at the required high temperature. Some data for concentrations of MCCP in water, sediment, landfill, human milk and in biota (animal material) was included, but often this data does not differentiate between SCCP, MCCP and LCCP. Also, most data is from China which will not be representative of the EU as in the past environmental standards were lower than the EU, although these are believed to have improved in recent years. Also, China no longer accepts EU WEEE so most EU WEEE should be recycled in the EU where high safety standards are expected to be applied.

7 REQUIRED TIMESCALES IF RESTRICTIONS ARE ADOPTED

The time required to substitute a RoHS substance in all medical devices sold in the EU will depend on many variables. These include:

- The substance; for example diantimony trioxide substitution is likely to require much longer timeframe to qualify alternatives than MCCP as diantimony trioxide is used in a very large number of components and materials, with different technical requirements,
- How many components, parts, etc., contain this substance that need to be replaced. The availability of suitably qualified engineers who can complete this work is limited so the more changes needed, the longer this will take,
- Whether substitutes already exist that have as good performance and reliability. If not, research will be needed and possibly exemptions requested and granted (the time between submission and granting exemptions can take 3 – 5 years), and
- Whether design changes to medical devices are required. If redesign is needed, more extensive testing, possibly clinical trials and re-approval by an EU Notified Body (and equivalents globally) will be required.

As described in section 3, no alternatives exist for some of the proposed substances and it may never be possible to replace them. Exemptions are therefore not a good solution as these are temporary and effort is required by industry and the Commission to renew them. A much longer transition period for category 8 or exclusion of category 8 may therefore be more appropriate options.

Medical device manufacturers have determined the timescales if any of these substances were to be restricted and these are described here.

A typical process for substitution is shown below:

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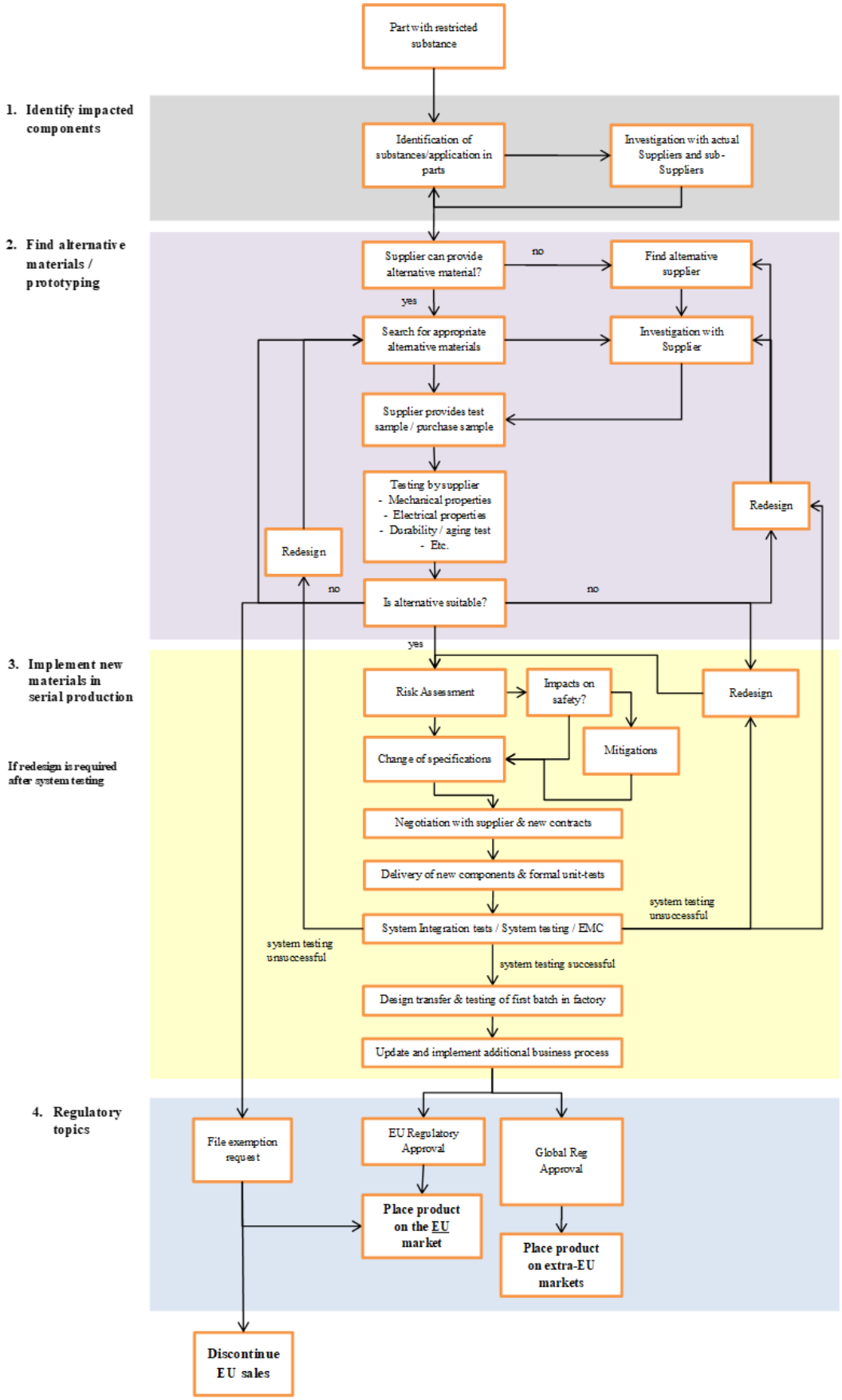
[28] https://www.kemi.se/global/rapporter/2018/report-4-18-rohs-annex-ii-dossier-mccp.pdf



The total elapsed time for substitution required will depend on the substance, for the reasons listed above as well as the type of medical device as some are much more complex and have more uses of these substances than others.

Considering the substance- time dependency first:

- Diantimony trioxide - A relatively long time would be needed as this is used in thousands of types of electronic components, mouldings, flexible PVC and in other parts. Also, substitution will not be straightforward and in many uses, substitution may not be possible, so exemptions would be needed,
- Medium chain chlorinated paraffin (MCCP) - Has fewer uses than diantimony trioxide and substitutes exist for many of these, although these may rely on using diantimony trioxide. A shorter timescale than is needed for diantimony trioxide would be required although this will be longer if diantimony trioxide were to also be restricted,
- Tetrabromobisphenol A (TBBP-A) – as reactive uses can be excluded, only additive uses such as in ABS need be considered. ABS is mainly used for mouldings (enclosures, etc.) and so as long as a suitable alternative flame retardant can be used that is not restricted and will not be restricted at least for the medium term (>10 years), then substitution is fairly straightforward. However, if manufacturers are forced to use different polymers, then longer timescales will be required,
- Beryllium and its compounds – The main contribution to timescale for beryllium is the preparation, submission, review and granting of exemptions as for all current uses no alternatives exist. Recent experience by COCIR of the time needed to prepare multiple exemption requests and the time taken by the Commission to grant exemptions, indicates that a total timescale of 5 years is needed[29],
    - Writing multiple exemption requests to cover all uses 1 – 2 years,
    - Time for review by the Commission's consultants – typically 1 year, but some have taken longer (ca. 18 months), and
    - Commission review, proposals, approval and publication – recently this has taken up to 3 years when many exemption requests are being considered.
- Indium phosphide – same as for beryllium as no substitutes exist,
- Nickel sulphamate and sulphate – Do not occur in electrical medical devices, and
- Cobalt chloride and sulphate – Do not occur in electrical medical devices.

Timescales for different types of medical device:

- MRI – timescales will be long as these are very complex, typically containing 100,000+ components. An additional complication is that any parts used within 1 metre of the centre of the electromagnet must be non-magnetic (even commercial purity copper is unsuitable). Some circuits are used at low temperatures and some parts suffer from severe vibration which is an additional reliability concern for alternative materials and components. MRI probably will require one of the longest timescales for substitution,
- CT – Also very complex (same as MRI) having very many electronic and other components,
- X-ray imaging – Have fewer components than CT or MRI, but as with all medical devices must be proven to be reliable and the performance must not be inferior to previous designs. The wide range of designs and medical applications, sometimes for niche examinations, make substitution very time consuming,
- PET / SPECT – Very complex, which contain even more components than CT. These use extremely sensitive detectors and so selection of materials is very important to ensure that performance and reliability are not compromised. Likely to require a timescale at least as long as CT and potentially longer,
- Ultrasound imaging – These contain fewer components that MRI, CT, PET or SPECT, but image quality is very susceptible to any stresses imposed on the transducer material and so substitution of substances in cables is especially complex requiring extensive testing,

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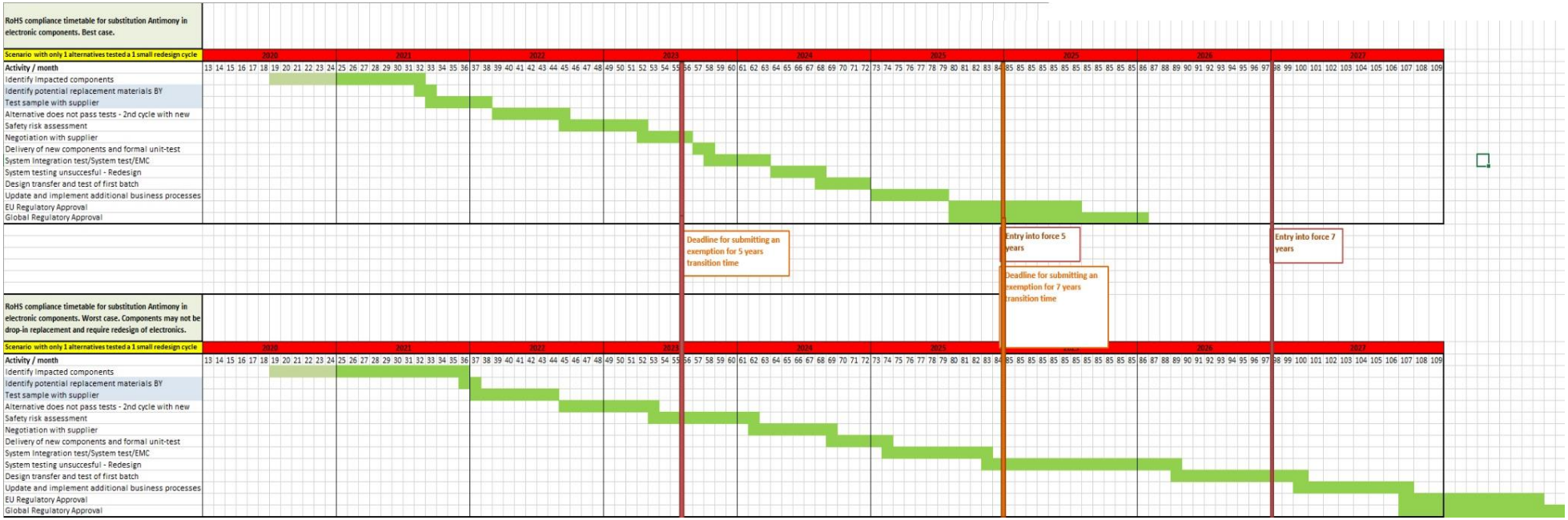
[29] Annex III exemption renewals (Pack 9) were submitted January 2015, Oeko's review was published June 2016 and the last batch of exemptions were published February 2019, however some exemption renewal requests are still outstanding with decisions awaited.

- Portable emergency defibrillators – As any defects can result in death of a patient, very high reliability is essential. Redesign is usually impractical as this introduces reliability concerns and this also diverts engineers away from developing new superior medical products. As a result, it is preferable to allow sufficient time for current models to be replaced with new models, which typically occurs over a 15 year cycle or longer, and
- Patient monitors – These are examples of simpler products than those described above and so a shorter timescale may be possible. However, as with all medical devices, there needs to be sufficient time for redesign, testing, clinical trials and approvals. For one product, this can be 6 – 8 years, but to change an entire product range can potentially take much longer at over 15 years.

COCIR has estimated the timescale for substitution as shown in the diagram below for some applications, in both the best- and worst-case scenarios. Usually, the medical device manufacturer will need to first determine where newly restricted substances occur and search for suitable substitutes and then a worst-case timescale for one type of medical device could be 15 years or longer. However, as most of the proposed RoHS substances will be used in many types of medical device (diantimony trioxide is used in all products), the timescale will be much longer as there will be insufficient engineers to work on all products simultaneously. Therefore, even longer timescales would be needed. If restrictions take effect too soon and exemptions do not apply, manufacturers only option will be to stop sales in the EU and, as all manufacturers would be affected in the same way, EU hospitals and clinics will not be able to obtain many or most new medical devices affected.

Antimony trioxide in electronic components: best- and worst-case scenarios.

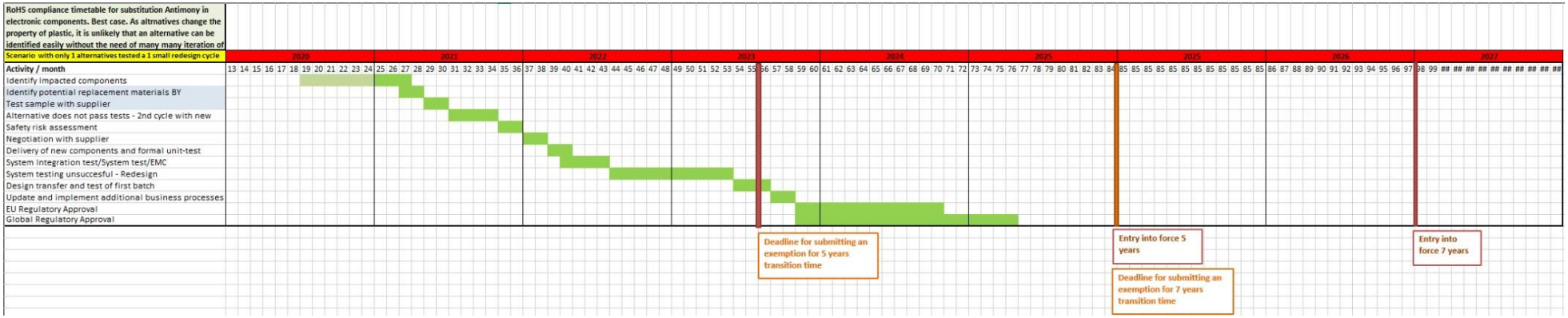
Even in the best-case scenario, a 5 years transition time could not be enough. In particular, there is a high risk that by the time exemptions need to be submitted, industry will not yet have enough knowledge to prepare a dossier. That would mean reaching the date of entry into force of the restriction with applications for which alternatives are not technically feasible or be known to be reliable and without published and adopted exemptions. As stated previously, the very high number of applications of antimony and the risk of non-drop-in components would significantly increase the time required for substitution. It should be noted that medical device manufacturers do not develop electronic components and they do not purchase sufficient numbers of components to drive changes in the design. Therefore, limited options will be available for medical devices manufacturers in case of non-drop-in components, namely by redesigning devices. While this may be possible for new models, all legacy models will not be allowed to be sold anymore, with the subsequent impact on industry and healthcare providers.



In practice, timescales will be even longer if the first redesign performs poorly or proves to be less reliable and a second redesign cycle is needed. Also, COCIR has assumed that an exemption will be granted and published within two years of submitting an exemption request. Recent experience has shown that this timescale may not be too optimistic as some exemptions have taken more than three years.

Antimony in plastic: best-case scenario with multiple uses

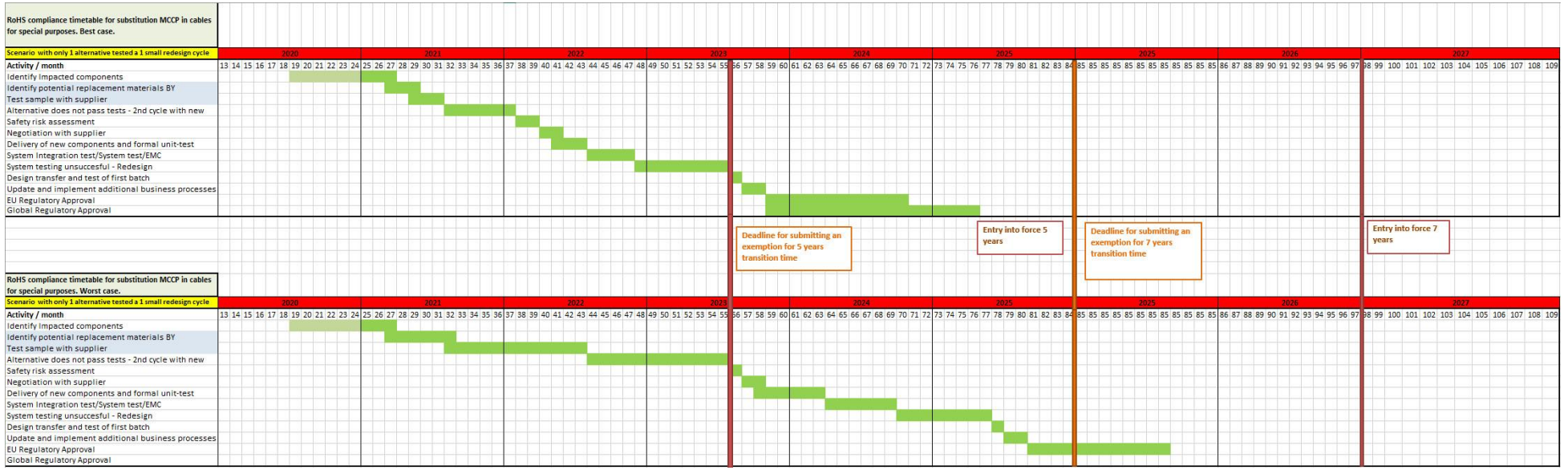
The best-case scenario shows that substitution could be possible in 5 years. As previously explained, the high number of applications and the fact that alternatives to antimony trioxide alter the mechanical and physical property of plastic may require far more iterations than the best-case scenario. Moreover, different applications may require different alternatives due to required mechanical and physical properties. It has to be noted that the deadline for submitting exemption is dangerously close to the point in time when industry may realize that alternatives are not available for some application. If industry is not able to prepare dossiers in time for exemption requests, the risk is entire medical modalities may not be available on the market.



MCCP in special purpose cables: best- and worst-case scenarios

As for previous cases, even the best-case scenario shows that a 5 years transition time could be extremely dangerous for medical imaging devices, in particular as it would be virtually impossible to submit exemption requests for applications that are found to be technically impossible to substitute.

The worst-case scenario, which is still based on the assumption that an alternative can be found at second iteration, including a short redesign cycle, shows that 5 years may not even be enough to achieve compliance. The issue of legacy devices (medical devices that were designed and were being sold before a restriction took effect) would impact companies and healthcare providers directly.



8 CONCLUSIONS

The main conclusions from this review are as follows:

- Some of the substances do not occur in electrical medical equipment (nickel and cobalt salts) or are only rarely used (additive TBBPA),
- Published risk assessments have been identified for many of the proposed substances. These conclude that the substances do not cause harm to consumers via environmental exposure, patients or user of medical devices and, although some may harm workers, occupational health and safety legislation offers the most effective and efficient way to tackle the problems. The risk assessments concluded that only MCCP and free-TBBP-A are harmful to the environment,
- The majority of emissions of two of the proposed substances - beryllium and MCCP - are not from manufacture, use or recycling of electrical equipment. Emissions to air of beryllium are mainly from coal and oil combustion, and >50% of MCCP used in the EU appears to be in non-electrical products. A restriction would bring limited benefits therefore it is reasonable to leave companies enough time to proceed with substitution while limiting costs and impacts on industry and healthcare providers,
- Substitution for all current uses of beryllium and indium phosphide is not possible in medical devices and exemptions will also be needed for most of the other proposed substances that occur in electrical equipment.

Substance	Is it present in medical devices?	Is substitution possible?	Is there evidence that it causes harm when used in medical devices?
Diantimony trioxide	Yes	Yes, but will be very difficult and exemptions will be needed	No
Beryllium and its compounds	Yes	No	Not at end-of-life of medical devices. 96% of emissions are from coal and oil combustion
TBBP-A	No except as additive in ABS	Probably	No (probably only small amounts are used as an additive)
MCCP	Yes	Yes for most uses although more difficult if diantimony trioxide can't be used	Some, but >50% of EU uses are non-electrical
Indium phosphide	Yes	No	No
Nickel sulphate and sulphamate	No	No	No
Cobalt sulphate and chloride	No	No	No

As shown by the timelines, it is expected that a full substitution in the medical devices sector would take from 10 to 15 years to be accomplished for all medical devices, both legacy (models being sold between now and the time compliance can be reached) and new devices that hopefully can achieve compliance before the end of the transition period.

A transition period of at least 10 years would be required for medical devices to substitute diantimony trioxide. While substitution can be achieved in a shorter period for one application as shown by the timelines, the huge number of possible applications would require more time,

Substitution of beryllium would require an even longer transition time as with the current state of the technology, no alternatives are known to exist for all uses.

Shorter timescales than the ones proposed, would create a critical situation:

- Due to the impossibility to test and approve so many different applications and alternatives, including redesign, it would not be possible to be compliant by the deadline and it would also not be possible to submit exemption requests if alternatives are available.
- The knowledge on alternatives and their suitability and reliability would not be sufficient by the deadline to submit exemptions. Dossier would not be corroborated by sufficient evidence.

It is also important to note that R&D programs in the medical device sector are normally longer than 5 or 7 years, therefore any shorter period than 7 years would also impact innovation as the investment risk would be too high (manufacturers will not invest if there is a risk that they cannot sell the products).

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